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Contents

I *Legislative acts*

REGULATIONS

★ **Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC** [1] 1

★ **Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU** [1] 176

[1] Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Council Directive 90/385/EEC ([3]) and Council Directive 93/42/EEC ([4]) constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

(2) This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods.

([1]) Opinion of 14 February 2013 (OJ C 133, 9.5.2013, p. 52).
([2]) Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 7 March 2017 (not yet published in the Official Journal).
([3]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).
([4]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

(3) This Regulation does not seek to harmonise rules relating to the further making available on the market of medical devices after they have already been put into service such as in the context of second-hand sales.

(4) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, to improve health and safety.

(5) To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative, the International Medical Devices Regulators Forum (IMDRF), should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations.

(6) For historical reasons, active implantable medical devices, covered by Directive 90/385/EEC, and other medical devices, covered by Directive 93/42/EEC, were regulated in two separate legal instruments. In the interest of simplification, both directives, which have been amended several times, should be replaced by a single legislative act applicable to all medical devices other than *in vitro* diagnostic medical devices.

(7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as *in vitro* diagnostic medical devices, medicinal products, cosmetics and food. Therefore, Regulation (EC) No 178/2002 of the European Parliament and of the Council [1] should be amended to exclude medical devices from its scope.

(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. In order to ensure consistent qualification decisions in that regard across all Member States, particularly with regard to borderline cases, the Commission should be allowed to, on its own initiative or at the duly substantiated request of a Member State, having consulted the Medical Device Coordination Group ('MDCG'), decide on a case-by-case basis whether or not a specific product, category or group of products falls within the scope of this Regulation. When deliberating on the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products or food products, the Commission should ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency and the European Food Safety Authority, as relevant.

(9) Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility of taking a Union-wide decision regarding the regulatory status of a product should also be introduced in Regulation (EC) No 1223/2009 of the European Parliament and of the Council [2].

(10) Products which combine a medicinal product or substance and a medical device are regulated either under this Regulation or under Directive 2001/83/EC of the European Parliament and of the Council. [3] The two legislative acts should ensure appropriate interaction in terms of consultations during pre-market assessment, and of exchange of information in the context of vigilance activities involving such combination products. For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements laid down in this Regulation for the device part should be adequately assessed in the context of the marketing authorisation for such medicinal products. Directive 2001/83/EC should therefore be amended.

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[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

[2] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

[3] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(11) Union legislation, in particular Regulation (EC) No 1394/2007 of the European Parliament and of the Council ([1]) and Directive 2004/23/EC of the European Parliament and of the Council ([2]), is incomplete in respect of certain products manufactured utilising derivatives of tissues or cells of human origin that are non-viable or are rendered non-viable. Such products should come under the scope of this Regulation, provided they comply with the definition of a medical device or are covered by this Regulation.

(12) Certain groups of products for which a manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. In order for manufacturers to be able to demonstrate the conformity of such products, the Commission should adopt common specifications at least with regard to application of risk management and, where necessary, clinical evaluation regarding safety. Such common specifications should be developed specifically for a group of products without an intended medical purpose and should not be used for conformity assessment of the analogous devices with a medical purpose. Devices with both a medical and a non-medical intended purpose should fulfil both the requirements applicable to devices with, and to devices without, an intended medical purpose.

(13) As is the case for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products that contain or consist of viable biological materials or viable organisms of another origin in order to achieve or support the intended purpose of those products are not covered by this Regulation either.

(14) The requirements laid down in Directive 2002/98/EC of the European Parliament and of the Council ([3]) should continue to apply.

(15) There is scientific uncertainty about the risks and benefits of nanomaterials used for devices. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU ([4]), with the necessary flexibility to adapt that definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of devices, manufacturers should take special care when using nanoparticles for which there is a high or medium potential for internal exposure. Such devices should be subject to the most stringent conformity assessment procedures. In preparation of implementing acts regulating the practical and uniform application of the corresponding requirements laid down in this Regulation, the relevant scientific opinions of the relevant scientific committees should be taken into account.

(16) Safety aspects addressed by Directive 2014/30/EU of the European Parliament and of the Council ([5]) are an integral part of the general safety and performance requirements laid down in this Regulation for devices. Consequently, this Regulation should be considered a *lex specialis* in relation to that Directive.

(17) This Regulation should include requirements regarding the design and manufacture of devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom ([6]) which pursues other objectives.

(18) This Regulation should include requirements for devices' design, safety and performance characteristics which are developed in such a way as to prevent occupational injuries, including protection from radiation.

([1]) Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

([2]) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

([3]) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (OJ L 33, 8.2.2003, p. 30).

([4]) Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).

([5]) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014. p. 79).

([6]) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

(19) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

(20) The definitions in this Regulation, regarding devices themselves, the making available of devices, economic operators, users and specific processes, the conformity assessment, clinical investigations and clinical evaluations, post-market surveillance, vigilance and market surveillance, standards and other technical specifications, should be aligned with well-established practice in the field at Union and international level in order to enhance legal certainty.

(21) It should be made clear that it is essential that devices offered to persons in the Union by means of information society services within the meaning of Directive (EU) 2015/1535 of the European Parliament and of the Council ([1]) and devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union comply with the requirements of this Regulation, where the product in question is placed on the market or the service is provided in the Union.

(22) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council ([2]) should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality and risk management, laid down in this Regulation.

(23) Directive 98/79/EC of the European Parliament and of the Council ([3]) allows the Commission to adopt common technical specifications for specific categories of *in vitro* diagnostic medical devices. In areas where no harmonised standards exist or where they are insufficient, the Commission should be empowered to lay down common specifications which provide a means of complying with the general safety and performance requirements, and the requirements for clinical investigations and clinical evaluation and/or post-market clinical follow-up, laid down in this Regulation.

(24) Common specifications ('CS') should be developed after consulting the relevant stakeholders and taking account of European and international standards.

(25) The rules applicable to devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council ([4]) and Decision No 768/2008/EC of the European Parliament and of the Council ([5]).

(26) The rules on Union market surveillance and control of products entering the Union market laid down in Regulation (EC) No 765/2008 apply to devices covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

(27) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, building on the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the various parts of this Regulation, to enhance understanding of the requirements laid down in this Regulation and thus to improve regulatory compliance by the relevant operators.

([1]) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

([2]) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

([3]) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

([4]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

([5]) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(28) For the purpose of this Regulation, the activities of distributors should be deemed to include acquisition, holding and supplying of devices.

(29) Several of the obligations on manufacturers, such as clinical evaluation or vigilance reporting, that were set out only in the Annexes to Directives 90/385/EEC and 93/42/EEC, should be incorporated into the enacting provisions of this Regulation to facilitate its application.

(30) Health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby address, on a non-industrial scale, the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent device available on the market. In that context, it is appropriate to provide that certain rules of this Regulation, as regards medical devices manufactured and used only within health institutions, including hospitals as well as institutions, such as laboratories and public health institutes that support the healthcare system and/or address patient needs, but which do not treat or care for patients directly, should not apply, since the aims of this Regulation would still be met in a proportionate manner. It should be noted that the concept of 'health institution' does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres. As a result, the exemption applicable to health institutions does not apply to such establishments.

(31) In view of the fact that natural or legal persons can claim compensation for damage caused by a defective device in accordance with applicable Union and national law, it is appropriate to require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability under Council Directive 85/374/EEC ([1]). Such measures should be proportionate to the risk class, type of device and the size of the enterprise. In this context, it is also appropriate to lay down rules concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

(32) To ensure that devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of the devices they manufacture is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance system in place which should be proportionate to the risk class and the type of the device in question. In addition, in order to minimize risks or prevent incidents related to devices, manufacturers should establish a system for risk management and a system for reporting of incidents and field safety corrective actions.

(33) The risk management system should be carefully aligned with and reflected in the clinical evaluation for the device, including the clinical risks to be addressed as part of clinical investigations, clinical evaluation and post-market clinical follow up. The risk management and clinical evaluation processes should be inter-dependent and should be regularly updated.

(34) It should be ensured that supervision and control of the manufacture of devices, and the post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification.

(35) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union. Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations. The liability of the authorised representative provided for in this Regulation is without prejudice to the provisions of Directive 85/374/EEC, and accordingly the authorised representative should be jointly and severally liable with the importer and the manufacturer. The tasks of an authorised representative should be defined in a written mandate. Considering the role of authorised representatives, the minimum requirements they should meet should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's person responsible for regulatory compliance.

([1]) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

(36) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of a device.

(37) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 TFEU subject to the limitations arising from the need for protection of health and safety and from the need for protection of intellectual property rights provided for under Article 36 TFEU. Application of the principle of parallel trade is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging, should therefore be specified in this Regulation, taking into account the case-law of the Court of Justice ([1]) in other relevant sectors and existing good practice in the field of medical devices.

(38) The reprocessing and further use of single-use devices should only take place where permitted by national law and while complying with the requirements laid down in this Regulation. The reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device and should assume the obligations incumbent on manufacturers under this Regulation. Nevertheless, Member States should have the possibility of deciding that the obligations relating to reprocessing and re-use of single-use devices within a health institution or by an external reprocessor acting on its behalf may differ from the obligations on a manufacturer described in this Regulation. In principle, such divergence should only be permitted where reprocessing and reuse of single-use devices within a health institution or by an external reprocessor are compliant with CS that have been adopted, or, in the absence of such CS, with relevant harmonised standards and national provisions. The reprocessing of such devices should ensure an equivalent level of safety and performance to that of the corresponding initial single-use device.

(39) Patients who are implanted with a device should be given clear and easily accessible essential information allowing the implanted device to be identified and other relevant information about the device, including any necessary health risk warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

(40) Devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation. However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.

(41) The traceability of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly enhance the effectiveness of the post-market safety-related activities for devices, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against falsified devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.

(42) The UDI system should apply to all devices placed on the market except custom-made devices, and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the UDI system to become functional in time for the application of this Regulation, detailed rules should be laid down in this Regulation.

(43) Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

(44) One key aspect in fulfilling the objectives of this Regulation is the creation of a European database on medical devices (Eudamed) that should integrate different electronic systems to collate and process information regarding devices on the market and the relevant economic operators, certain aspects of conformity assessment, notified

([1]) Judgment of 28 July 2011 in Orifarm and Paranova, joined cases C-400/09 and C-207/10, ECLI:EU:C:2011:519.

bodies, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to avoid multiple reporting requirements, to enhance coordination between Member States and to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission. Within the internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices set up by Commission Decision 2010/227/EU ([1]).

(45) To facilitate the functioning of Eudamed, an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. Furthermore, that nomenclature should be available, where reasonably practicable, free of charge also to other stakeholders.

(46) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical investigations should serve as a tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and to report serious adverse events, device deficiencies and related updates. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of the evaluation of such incidents and events by competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

(47) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC of the European Parliament and of the Council ([2]) applies to the processing of personal data carried out in the Member States, under the supervision of the Member States' competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001 of the European Parliament and of the Council ([3]) applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.

(48) For implantable devices and for class III devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.

(49) The summary of safety and clinical performance for a device should include in particular the place of the device in the context of diagnostic or therapeutic options taking into account the clinical evaluation of that device when compared to the diagnostic or therapeutic alternatives and the specific conditions under which that device and its alternatives can be considered.

(50) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

(51) Notified bodies' assessments of manufacturers' technical documentation, in particular documentation on clinical evaluation, should be critically evaluated by the authority responsible for notified bodies. That evaluation should be part of the risk-based approach to the oversight and monitoring activities of notified bodies and should be based on sampling of the relevant documentation.

(52) The position of notified bodies vis-à-vis manufacturers should be strengthened, including with regard to their right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on devices to ensure continuous compliance by manufacturers after receipt of the original certification.

([1]) Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices (OJ L 102, 23.4.2010, p. 45).
([2]) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).
([3]) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(53) To increase transparency with regard to the oversight of notified bodies by national authorities, the authorities responsible for notified bodies should publish information on the national measures governing the assessment, designation and monitoring of notified bodies. In accordance with good administrative practice, this information should be kept up to date by those authorities in particular to reflect relevant, significant or substantive changes to the procedures in question.

(54) The Member State in which a notified body is established should be responsible for enforcing the requirements of this Regulation with regard to that notified body.

(55) In view, in particular, of the responsibility of Member States for the organisation and delivery of health services and medical care, they should be allowed to lay down additional requirements on notified bodies designated for the conformity assessment of devices and established on their territory as far as issues that are not regulated in this Regulation are concerned. Any such additional requirements laid down should not affect more specific horizontal Union legislation on notified bodies and equal treatment of notified bodies.

(56) For class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, notified bodies should, except in certain cases, be obliged to request expert panels to scrutinise their clinical evaluation assessment report. Competent authorities should be informed about devices that have been granted a certificate following a conformity assessment procedure involving an expert panel. The consultation of expert panels in relation to the clinical evaluation should lead to a harmonised evaluation of high-risk medical devices by sharing expertise on clinical aspects and developing CS on categories of devices that have undergone that consultation process.

(57) For class III devices and for certain class IIb devices, a manufacturer should be able to consult voluntarily an expert panel, prior to that manufacturer's clinical evaluation and/or investigation, on its clinical development strategy and on proposals for clinical investigations.

(58) It is necessary, in particular for the purpose of the conformity assessment procedures, to maintain the division of devices into four product classes in line with international practice. The classification rules, which are based on the vulnerability of the human body, should take into account the potential risks associated with the technical design and manufacture of the devices. To maintain the same level of safety as provided by Directive 90/385/EEC, active implantable devices should be in the highest risk class.

(59) Rules under the old regime applied to invasive devices do not sufficiently take account of the level of invasiveness and potential toxicity of certain devices which are introduced into the human body. In order to obtain a suitable risk-based classification of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body, it is necessary to introduce specific classification rules for such devices. The classification rules should take into account the place where the device performs its action in or on the human body, where it is introduced or applied, and whether a systemic absorption of the substances of which the device is composed, or of the products of metabolism in the human body of those substances occurs.

(60) The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. For class IIa, class IIb and class III devices, an appropriate level of involvement of a notified body should be compulsory.

(61) The conformity assessment procedures for devices should be further strengthened and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

(62) It is appropriate that certificates of free sale contain information that makes it possible to use Eudamed in order to obtain information on the device, in particular with regard to whether it is on the market, withdrawn from the market or recalled, and on any certificate on its conformity.

(63) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation.

(64) The rules on clinical investigations should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects, so as to make it easier for the results of clinical investigations conducted in the Union to be accepted as documentation outside the Union and to make it easier for the results of clinical investigations conducted outside the Union in accordance with international guidelines to be accepted within the Union. In addition, the rules should be in line with the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

(65) It should be left to the Member State where a clinical investigation is to be conducted to determine the appropriate authority to be involved in the assessment of the application to conduct a clinical investigation and to organise the involvement of ethics committees within the timelines for the authorisation of that clinical investigation as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. In that context, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available.

(66) Where, in the course of a clinical investigation, harm caused to a subject leads to the civil or criminal liability of the investigator or the sponsor being invoked, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law.

(67) An electronic system should be set up at Union level to ensure that every clinical investigation is recorded and reported in a publicly accessible database. To protect the right to the protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union ('the Charter'), no personal data of subjects participating in a clinical investigation should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical investigations should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

(68) Where a clinical investigation is to be conducted in more than one Member State, the sponsor should have the possibility of submitting a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety-related aspects of the investigational device and of the scientific design of that clinical investigation, the procedure for the assessment of such single application should be coordinated between the Member States under the direction of a coordinating Member State. Such coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical investigation, including informed consent. For an initial period of seven years from the date of application of this Regulation, Member States should be able to participate on a voluntary basis in the coordinated assessment. After that period, all Member States should be obliged to participate in the coordinated assessment. The Commission, based on the experience gained from the voluntary coordination between Member States, should draw up a report on the application of the relevant provisions regarding the coordinated assessment procedure. In the event that the findings of the report are negative, the Commission should submit a proposal to extend the period of participation on a voluntary basis in the coordinated assessment procedure.

(69) Sponsors should report certain adverse events and device deficiencies that occur during clinical investigations to the Member States in which those clinical investigations are being conducted. Member States should have the possibility of terminating or suspending the investigations or revoking the authorisation for those investigations, if considered necessary to ensure a high level of protection of the subjects participating in a clinical investigation. Such information should be communicated to the other Member States.

(70) The sponsor of a clinical investigation should submit a summary of results of the clinical investigation that is easily understandable for the intended user together with the clinical investigation report, where applicable, within the timelines laid down in this Regulation. Where it is not possible to submit the summary of the results within the defined timelines for scientific reasons, the sponsor should justify this and specify when the results will be submitted.

(71) This Regulation should cover clinical investigations intended to gather clinical evidence for the purpose of demonstrating conformity of devices and should also lay down basic requirements regarding ethical and scientific assessments for other types of clinical investigations of medical devices.

(72) Incapacitated subjects, minors, pregnant women and breastfeeding women require specific protection measures. However, it should be left to Member States to determine the legally designated representatives of incapacitated subjects and minors.

(73) The principles of replacement, reduction and refinement in the area of animal experimentation laid down in the Directive 2010/63/EU of the European Parliament and of the Council [1] should be observed. In particular, the unnecessary duplication of tests and studies should be avoided.

(74) Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities. To this end, manufacturers should establish a comprehensive post-market surveillance system, set up under their quality management system and based on a post-market surveillance plan. Relevant data and information gathered through post-market surveillance, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as those relating to risk assessment and clinical evaluation, and should also serve the purpose of transparency.

(75) In order to better protect health and safety regarding devices on the market, the electronic system on vigilance for devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

(76) Member States should take appropriate measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents. Healthcare professionals, users and patients should be encouraged and enabled to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers of any suspected serious incidents and, where a manufacturer confirms that such an incident has occurred, the authorities concerned should ensure that appropriate follow-up action is taken in order to minimise recurrence of such incidents.

(77) The evaluation of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State, with the objective of sharing resources and ensuring consistency regarding the corrective action.

(78) In the context of the investigation of incidents, the competent authorities should take into account, where appropriate, the information provided by and views of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.

(79) The reporting of serious adverse events or device deficiencies during clinical investigations and the reporting of serious incidents occurring after a device has been placed on the market should be clearly distinguished to avoid double reporting.

(80) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

(81) Any statistically significant increase in the number or severity of incidents that are not serious or in expected side-effects that could have a significant impact on the benefit-risk analysis and which could lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.

(82) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States based on their role and expertise in the field of medical devices including *in vitro* diagnostic medical devices, should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) 2017/746 of the European Parliament and of the Council [2], to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. The MDCG should be able to establish subgroups in order to have access to necessary in-depth

[1] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (see page 176 of this Official Journal).

technical expertise in the field of medical devices including *in vitro* diagnostic medical devices. When establishing subgroups, appropriate consideration should be given to the possibility of involving existing groups at Union level in the field of medical devices.

(83) Expert panels and expert laboratories should be designated by the Commission on the basis of their up-to-date clinical, scientific or technical expertise, with the aim of providing scientific, technical and clinical assistance to the Commission, the MDCG, manufacturers and notified bodies in relation to the implementation of this Regulation. Moreover, expert panels should fulfil the tasks of providing an opinion on clinical evaluation assessment reports of notified bodies in the case of certain high-risk devices.

(84) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is essential for ensuring a consistently high level of health and safety protection within the internal market, in particular in the areas of clinical investigations and vigilance. The principle of coordinated exchange and assessment should also apply across other authority activities described in this Regulation, such as the designation of notified bodies and should be encouraged in the area of market surveillance of devices. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level.

(85) The Commission should provide scientific, technical and corresponding logistical support to coordinating national authorities and ensure that the regulatory system for devices is effectively and uniformly implemented at Union level based on sound scientific evidence.

(86) The Union and, where appropriate, the Member States should actively participate in international regulatory cooperation in the field of medical devices to facilitate the exchange of safety-related information regarding medical devices and to foster the further development of international regulatory guidelines that promote the adoption in other jurisdictions of regulations that lead to a level of health and safety protection equivalent to that set by this Regulation.

(87) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement.

(88) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should, in order to ensure transparency, inform the Commission and the other Member States before they decide on the level and structure of such fees. In order to further ensure transparency, the structure and level of the fees should be publicly available on request.

(89) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

(90) The power to adopt delegated acts in accordance with Article 290 TFEU should be delegated to the Commission in order to amend certain non-essential provisions of this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([1]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with preparation of delegated acts.

(91) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([2]).

([1]) OJ L 123, 12.5.2016, p. 1.
([2]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(92) The advisory procedure should be used for implementing acts that set out the form and presentation of the data elements of manufacturers' summaries of safety and clinical performance, and that establish the model for certificates of free sale, given that such implementing acts are of a procedural nature and do not directly have an impact on health and safety at Union level.

(93) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures, imperative grounds of urgency so require.

(94) In order to enable it to designate issuing entities, expert panels and expert laboratories, implementing powers should be conferred on the Commission.

(95) To allow economic operators, especially SMEs, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation and to ensure its proper application, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements that are to be made. However, certain parts of the Regulation that directly affect Member States and the Commission should be implemented as soon as possible. It is also particularly important that, by the date of application of this Regulation, a sufficient number of notified bodies be designated in accordance with the new requirements so as to avoid any shortage of medical devices on the market. Nonetheless, it is necessary that any designation of a notified body in accordance with the requirements of this Regulation prior to the date of its application be without prejudice to the validity of the designation of those notified bodies under Directives 90/385/EEC and 93/42/EEC and to their capacity to continue issuing valid certificates under those two Directives until the date of application of this Regulation.

(96) In order to ensure a smooth transition to the new rules for registration of devices and of certificates, the obligation to submit the relevant information to the electronic systems set up at Union level pursuant to this Regulation should, in the event that the corresponding IT systems are developed according to plan, only become fully effective from 18 months after the date of application of this Regulation. During this transitional period, certain provisions of Directives 90/385/EEC and 93/42/EEC should remain in force. However, in order to avoid multiple registrations, economic operators and notified bodies who register in the relevant electronic systems set up at Union level pursuant to this Regulation should be considered to be in compliance with the registration requirements adopted by the Member States pursuant to those provisions.

(97) In order to provide for a smooth introduction of the UDI system, the moment of application of the obligation to place the UDI carrier on the label of the device should vary from one to five years after the date of application of this Regulation depending upon the class of the device concerned.

(98) Directives 90/385/EEC and 93/42/EEC should be repealed to ensure that only one set of rules applies to the placing of medical devices on the market and the related aspects covered by this Regulation. Manufacturers' obligations as regards the making available of documentation regarding devices they placed on the market and manufacturers' and Member States' obligations as regards vigilance activities for devices placed on the market pursuant to those Directives should however continue to apply. While it should be left to Member States to decide how to organise vigilance activities, it is desirable for them to have the possibility of reporting incidents related to devices placed on the market pursuant to the Directives using the same tools as those for reporting on devices placed on the market pursuant to this Regulation. It is furthermore appropriate, in order to ensure a smooth transition from the old regime to the new regime, to provide that Commission Regulation (EU) No 207/2012 ([1]) and Commission Regulation (EU) No 722/2012 ([2]) should remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

([1]) Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).

([2]) Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.2012, p. 3).

Decision 2010/227/EU adopted in implementation of those Directives and Directive 98/79/EC should also remain in force and continue to apply until the date when Eudamed becomes fully functional. Conversely, no such maintenance in force is required for Commission Directives 2003/12/EC [1] and 2005/50/EC [2] and Commission Implementing Regulation (EU) No 920/2013 [3].

(99) The requirements of this Regulation should be applicable to all devices placed on the market or put into service from the date of application of this Regulation. However, in order to provide for a smooth transition it should be possible, for a limited period of time from that date, for devices to be placed on the market or put into service by virtue of a valid certificate issued pursuant to Directive 90/385/EEC or pursuant to Directive 93/42/EEC.

(100) The European Data Protection Supervisor has given an opinion [4] pursuant to Article 28(2) of Regulation (EC) No 45/2001.

(101) Since the objectives of this Regulation, namely to ensure the smooth functioning of the internal market as regards medical devices and to ensure high standards of quality and safety for medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. This Regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.

2. This Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology. The common specifications for each of the groups of products listed in Annex XVI shall address, at least, application of risk management as set out in Annex I for the group of products in question and, where necessary, clinical evaluation regarding safety.

The necessary common specifications shall be adopted by 26 May 2020. They shall apply as from six months after the date of their entry into force or from 26 May 2020, whichever is the latest.

Notwithstanding Article 122, Member States' measures regarding the qualification of the products covered by Annex XVI as medical devices pursuant to Directive 93/42/EEC shall remain valid until the date of application, as referred to in the first subparagraph, of the relevant common specifications for that group of products.

This Regulation also applies to clinical investigations conducted in the Union concerning the products referred to in the first subparagraph.

3. Devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.

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[1] Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43).

[2] Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41).

[3] Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8).

[4] OJ C 358, 7.12.2013, p. 10.

4. For the purposes of this Regulation, medical devices, accessories for medical devices, and products listed in Annex XVI to which this Regulation applies pursuant to paragraph 2 shall hereinafter be referred to as 'devices'.

5. Where justified on account of the similarity between a device with an intended medical purpose placed on the market and a product without an intended medical purpose in respect of their characteristics and risks, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the list in Annex XVI, by adding new groups of products, in order to protect the health and safety of users or other persons or other aspects of public health.

6. This Regulation does not apply to:

(a) *in vitro* diagnostic medical devices covered by Regulation (EU) 2017/746;

(b) medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC. In deciding whether a product falls under Directive 2001/83/EC or under this Regulation, particular account shall be taken of the principal mode of action of the product;

(c) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;

(d) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or put into service, such blood products, plasma or cells, except for devices referred to in paragraph 8 of this Article;

(e) cosmetic products covered by Regulation (EC) No 1223/2009;

(f) transplants, tissues or cells of animal origin, or their derivatives, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or are rendered non-viable;

(g) transplants, tissues or cells of human origin, or their derivatives, covered by Directive 2004/23/EC, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;

(h) products, other than those referred to in points (d), (f) and (g), that contain or consist of viable biological material or viable organisms, including living micro-organisms, bacteria, fungi or viruses in order to achieve or support the intended purpose of the product;

(i) food covered by Regulation (EC) No 178/2002.

7. Any device which, when placed on the market or put into service, incorporates as an integral part an *in vitro* diagnostic medical device as defined in point 2 of Article 2 of Regulation (EU) 2017/746, shall be governed by this Regulation. The requirements of Regulation (EU) 2017/746 shall apply to the *in vitro* diagnostic medical device part of the device.

8. Any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the device, shall be assessed and authorised in accordance with this Regulation.

However, if the action of that substance is principal and not ancillary to that of the device, the integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004 of the European Parliament and of the Council [1], as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part are concerned.

9. Any device which is intended to administer a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC shall be governed by this Regulation, without prejudice to the provisions of that Directive and of Regulation (EC) No 726/2004 with regard to the medicinal product.

However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part of the single integral product are concerned.

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[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

10. Any device which, when placed on the market or put into service, incorporates, as an integral part, non-viable tissues or cells of human origin or their derivatives that have an action ancillary to that of the device shall be assessed and authorised in accordance with this Regulation. In that case, the provisions for donation, procurement and testing laid down in Directive 2004/23/EC shall apply.

However, if the action of those tissues or cells or their derivatives is principal and not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by Directive 2004/23/EC. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part are concerned.

11. This Regulation is specific Union legislation within the meaning of Article 2(3) of Directive 2014/30/EU.

12. Devices that are also machinery within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council [1] shall, where a hazard relevant under that Directive exists, also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation.

13. This Regulation shall not affect the application of Directive 2013/59/Euratom.

14. This Regulation shall not affect the right of a Member State to restrict the use of any specific type of device in relation to aspects not covered by this Regulation.

15. This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or healthcare institutions may dispense or use certain devices or that their use be accompanied by specific professional counselling.

16. Nothing in this Regulation shall restrict the freedom of the press or the freedom of expression in the media in so far as those freedoms are guaranteed in the Union and in the Member States, in particular under Article 11 of the Charter of Fundamental Rights of the European Union.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

[1] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

(2) 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

(3) 'custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;

(4) 'active device' means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.

Software shall also be deemed to be an active device;

(5) 'implantable device' means any device, including those that are partially or wholly absorbed, which is intended:

— to be totally introduced into the human body, or

— to replace an epithelial surface or the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device;

(6) 'invasive device' means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;

(7) 'generic device group' means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(8) 'single-use device' means a device that is intended to be used on one individual during a single procedure;

(9) 'falsified device' means any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;

(10) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;

(11) 'system' means a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose;

(12) 'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;

(13) 'label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

(14) 'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;

(15) 'Unique Device Identifier' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

(16) 'non-viable' means having no potential for metabolism or multiplication;

(17) 'derivative' means a 'non-cellular substance' extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues;

(18) 'nanomaterial' means a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm;

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials;

(19) 'particle', for the purposes of the definition of nanomaterial in point (18), means a minute piece of matter with defined physical boundaries;

(20) 'agglomerate', for the purposes of the definition of nanomaterial in point (18), means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

(21) 'aggregate', for the purposes of the definition of nanomaterial in point (18), means a particle comprising of strongly bound or fused particles;

(22) 'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer;

(23) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;

(24) 'benefit-risk determination' means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

(25) 'compatibility' is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:

(a) perform without losing or compromising the ability to perform as intended, and/or

(b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or

(c) be used together without conflict/interference or adverse reaction.

(26) 'interoperability' is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:

(a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or

(b) communicate with each other, and/or

(c) work together as intended.

(27) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(28) 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market;

(29) 'putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

(30) 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

(31) 'fully refurbishing', for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

(32) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(33) 'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market;

(34) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

(35) 'economic operator' means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);

(36) 'health institution' means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

(37) 'user' means any healthcare professional or lay person who uses a device;

(38) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

(39) 'reprocessing' means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device;

(40) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

(41) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

(42) 'notified body' means a conformity assessment body designated in accordance with this Regulation;

(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

(44) 'clinical evaluation' means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;

(45) 'clinical investigation' means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device;

(46) 'investigational device' means a device that is assessed in a clinical investigation;

(47) 'clinical investigation plan' means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation;

(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

— clinical investigation(s) of the device concerned,

— clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,

— reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,

— clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

(49) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation;

(50) 'subject' means an individual who participates in a clinical investigation;

(51) 'clinical evidence' means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer;

(52) 'clinical performance' means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer;

(53) 'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health;

(54) 'investigator' means an individual responsible for the conduct of a clinical investigation at a clinical investigation site;

(55) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation;

(56) 'ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;

(57) 'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device;

(58) 'serious adverse event' means any adverse event that led to any of the following:

(a) death,

(b) serious deterioration in the health of the subject, that resulted in any of the following:

(i) life-threatening illness or injury,

(ii) permanent impairment of a body structure or a body function,

(iii) hospitalisation or prolongation of patient hospitalisation,

(iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

(v) chronic disease,

(c) foetal distress, foetal death or a congenital physical or mental impairment or birth defect;

(59) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer;

(60) 'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

(61) 'market surveillance' means the activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

(62) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;

(63) 'withdrawal' means any measure aimed at preventing a device in the supply chain from being further made available on the market;

(64) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;

(65) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person,

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

(c) a serious public health threat;

(66) 'serious public health threat' means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time;

(67) 'corrective action' means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;

(68) 'field safety corrective action' means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

(69) 'field safety notice' means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action;

(70) 'harmonised standard' means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012;

(71) 'common specifications' (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.

Article 3

Amendment of certain definitions

The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend the definition of nanomaterial set out in point (18) and the related definitions in points (19), (20) and (21) of Article 2 in the light of technical and scientific progress and taking into account definitions agreed at Union and international level.

Article 4

Regulatory status of products

1. Without prejudice to Article 2(2) of Directive 2001/83/EC, upon a duly substantiated request of a Member State, the Commission shall, after consulting the Medical Device Coordination Group established under Article 103 of this Regulation ('MDCG'), by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3) of this Regulation.

2. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

3. The Commission shall ensure that Member States share expertise in the fields of medical devices, *in vitro* diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products, in order to determine the appropriate regulatory status of a product, or category or group of products.

4. When deliberating on the possible regulatory status as a device of products involving medicinal products, human tissues and cells, biocides or food products, the Commission shall ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA), as relevant.

CHAPTER II

MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT

Article 5

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.

4. Devices that are manufactured and used within health institutions shall be considered as having been put into service.

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

(a) the devices are not transferred to another legal entity,

(b) manufacture and use of the devices occur under appropriate quality management systems,

(c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,

(d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

(e) the health institution draws up a declaration which it shall make publicly available, including:

  (i) the name and address of the manufacturing health institution;

  (ii) the details necessary to identify the devices;

  (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,

(f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;

(g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and

(h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.

6. In order to ensure the uniform application of Annex I, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 6

Distance sales

1. A device offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation.

2. Without prejudice to national law regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.

3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.

4. A Member State may, on grounds of protection of public health, require a provider of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to cease its activity.

Article 7

Claims

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

(a) ascribing functions and properties to the device which the device does not have;

(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;

(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

Article 8

Use of harmonised standards

1. Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

The first subparagraph shall also apply to system or process requirements to be fulfilled in accordance with this Regulation by economic operators or sponsors, including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up ('PMCF').

References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the *Official Journal of the European Union*.

2. References in this Regulation to harmonised standards shall also include the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, in particular on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, provided that references to those monographs have been published in the *Official Journal of the European Union*.

Article 9

Common specifications

1. Without prejudice to Article 1(2) and 17(5) and the deadline laid down in those provisions, where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the clinical evaluation and post-market clinical follow-up set out in Annex XIV or the requirements regarding clinical investigation set out in Annex XV. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

2. Devices that are in conformity with the CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CS or the relevant parts of those CS.

3. Manufacturers shall comply with the CS referred to in paragraph 1 unless they can duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto.

4. Notwithstanding paragraph 3, manufacturers of products listed in Annex XVI shall comply with the relevant CS for those products.

Article 10

General obligations of manufacturers

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

3. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.

4. Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.

The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress, the Annexes II and III.

5. Manufacturers of custom-made devices shall draw up, keep up to date and keep available for competent authorities documentation in accordance with Section 2 of Annex XIII.

6. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 19, and affix the CE marking of conformity in accordance with Article 20.

7. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.

8. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available.

9. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.

The quality management system shall address at least the following aspects:

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(c) responsibility of the management;

(d) resource management, including selection and control of suppliers and sub-contractors;

(e) risk management as set out in in Section 3 of Annex I;

(f) clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;

(g) product realisation, including planning, design, development, production and service provision;

(h) verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;

(i) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) management of corrective and preventive actions and verification of their effectiveness;

(m) processes for monitoring and measurement of output, data analysis and product improvement.

10. Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83.

11. Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

12. Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly.

Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56, in particular, of the non-compliance and of any corrective action taken.

13. Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88.

14. Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable, grant access to the device. Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may, in order to ensure the protection of public health and patient safety, take all appropriate measures to prohibit or restrict the device's being made available on its national market, to withdraw the device from that market or to recall it until the manufacturer cooperates or provides complete and correct information.

If a competent authority considers or has reason to believe that a device has caused damage, it shall, upon request, facilitate the provision of the information and documentation referred to in the first subparagraph to the potentially injured patient or user and, as appropriate, the patient's or user's successor in title, the patient's or user's health insurance company or other third parties affected by the damage caused to the patient or user, without prejudice to data protection rules and, unless there is an overriding public interest in disclosure, without prejudice to the protection of intellectual property rights.

The competent authority need not comply with the obligation laid down in the third subparagraph where disclosure of the information and documentation referred to in the first subparagraph is ordinarily dealt with in the context of legal proceedings.

15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1).

16. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

Article 11

Authorised representative

1. Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative.

2. The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.

3. The authorised representative shall perform the tasks specified in the mandate agreed between it and the manufacturer. The authorised representative shall provide a copy of the mandate to the competent authority, upon request.

The mandate shall require, and the manufacturer shall enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:

(a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

(c) comply with the registration obligations laid down in Article 31 and verify that the manufacturer has complied with the registration obligations laid down in Articles 27 and 29;

(d) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

(e) forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

(f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(h) terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

4. The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12).

5. Without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

6. An authorised representative who terminates its mandate on the ground referred to in point (h) of paragraph 3 shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

7. Any reference in this Regulation to the competent authority of the Member State in which the manufacturer has its registered place of business shall be understood as a reference to the competent authority of the Member State in which the authorised representative, designated by a manufacturer referred to in paragraph 1, has its registered place of business.

Article 12

Change of authorised representative

The detailed arrangements for a change of authorised representative shall be clearly defined in an agreement between the manufacturer, where practicable the outgoing authorised representative, and the incoming authorised representative. That agreement shall address at least the following aspects:

(a) the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative;

(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative.

Article 13

General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.

2. In order to place a device on the market, importers shall verify that:

(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) a manufacturer is identified and that an authorised representative in accordance with Article 11 has been designated by the manufacturer;

(c) the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;

(d) where applicable, a UDI has been assigned by the manufacturer in accordance with Article 27.

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. Where the importer considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which the importer is established.

3. Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall verify that the device is registered in the electronic system in accordance with Article 29. Importers shall add their details to the registration in accordance with Article 31.

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.

6. Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 56 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.

8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.

9. Importers shall, for the period referred to in Article 10(8), keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56.

10. Importers shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.

Article 14

General obligations of distributors

1. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2. Before making a device available on the market, distributors shall verify that all of the following requirements are met:

(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11);

(c) for imported devices, the importer has complied with the requirements set out in Article 13(3);

(d) that, where applicable, a UDI has been assigned by the manufacturer.

In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.

3. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

4. Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

5. Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

6. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

Article 15

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.

2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC [1] shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.

[1] Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

3. The person responsible for regulatory compliance shall at least be responsible for ensuring that:

(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;

(c) the post-market surveillance obligations are complied with in accordance with Article 10(10);

(d) the reporting obligations referred to in Articles 87 to 91 are fulfilled;

(e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.

4. If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1, 2 and 3, their respective areas of responsibility shall be stipulated in writing.

5. The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation.

6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Article 16

Cases in which obligations of manufacturers apply to importers, distributors or other persons

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:

(a) makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;

(b) changes the intended purpose of a device already placed on the market or put into service;

(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in point (30) of Article 2, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

(a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;

(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.

Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, *inter alia*, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.

4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.

Article 17

Single-use devices and their reprocessing

1. Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.

2. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.

3. By way of derogation from paragraph 2, as regards single-use devices that are reprocessed and used within a health institution, Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation provided that they ensure that:

(a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (a), (b), (d), (e), (f), (g) and (h) of Article 5(5) are complied with;

(b) the reprocessing is performed in accordance with CS detailing the requirements concerning:

— risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing,

— the validation of procedures for the entire process, including cleaning steps,

— the product release and performance testing,

— the quality management system,

— the reporting of incidents involving devices that have been reprocessed, and

— the traceability of reprocessed devices.

Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

Member States shall notify the Commission and the other Member States of the national provisions introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.

4. Member States may choose to apply the provisions referred to in paragraph 3 also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements referred to in points (a) and (b) of paragraph 3.

5. The Commission shall adopt, in accordance with Article 9(1), the necessary CS referred to in point (b) of paragraph 3 by 26 May 2020. Those CS shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this Regulation. In the event that those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions that cover the aspects outlined in point (b) of paragraph 3. Compliance with CS or, in the absence of CS, with any relevant harmonised standards and national provisions, shall be certified by a notified body.

6. Only single-use devices that have been placed on the market in accordance with this Regulation, or prior to 26 May 2020 in accordance with Directive 93/42/EEC, may be reprocessed.

7. Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.

8. The name and address of the legal or natural person referred to in paragraph 2 and the other relevant information referred to in Section 23 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

9. A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

10. The Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. On the basis of that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.

Article 18

Implant card and information to be supplied to the patient with an implanted device

1. The manufacturer of an implantable device shall provide together with the device the following:

(a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

(c) any information about the expected lifetime of the device and any necessary follow-up;

(d) any other information to ensure safe use of the device by the patient, including the information in point (u) of Section 23.4 of Annex I.

The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow rapid access to that information and shall be stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate. Updates of the information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph.

In addition, the manufacturer shall provide the information referred to in point (a) of the first subparagraph on an implant card delivered with the device.

2. Member States shall require health institutions to make the information referred to in paragraph 1 available, by any means that allow rapid access to that information, to any patients who have been implanted with the device, together with the implant card, which shall bear their identity.

3. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom.

Article 19

EU declaration of conformity

1. The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device. The declaration shall contain all the information required for identification of the Union legislation to which the declaration relates.

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. The Commission is empowered to adopt delegated acts in accordance with Article 115 amending the minimum content of the EU declaration of conformity set out in Annex IV in the light of technical progress.

Article 20

CE marking of conformity

1. Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex V.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 52. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

6. Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.

Article 21

Devices for special purposes

1. Member States shall not create obstacles to:

(a) investigational devices being supplied to an investigator for the purpose of a clinical investigation if they meet the conditions laid down in Articles 62 to 80 and Article 82, in the implementing acts adopted pursuant to Article 81 and in Annex XV;

(b) custom-made devices being made available on the market if Article 52(8) and Annex XIII have been complied with.

The devices referred to in the first subparagraph shall not bear the CE marking, with the exception of the devices referred to in Article 74.

2. Custom-made devices shall be accompanied by the statement referred to in Section 1 of Annex XIII, which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been made available in their territory.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create obstacles to the showing of devices which do not comply with this Regulation, provided a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with this Regulation.

Article 22

Systems and procedure packs

1. Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:

(a) other devices bearing the CE marking;

(b) *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746;

(c) other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.

2. In the statement made pursuant to paragraph 1, the natural or legal person concerned shall declare that:

(a) they verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;

(b) they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

(c) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at their choice, apply one of the procedures set out in Annex IX or the procedure set out in Part A of Annex XI. The application of those procedures and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged. The natural or legal person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.

4. Where the system or procedure pack incorporates devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, or where the sterilisation has not been carried out in accordance with the manufacturer's instructions, the system or procedure pack shall be treated as a device in its own right and shall be subject to the relevant conformity assessment procedure pursuant to Article 52. The natural or legal person shall assume the obligations incumbent on manufacturers.

5. The systems or procedure packs referred to in paragraph 1 of this Article shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraphs 1 and 3 of this Article as well as the address at which that person can be contacted, so that the person's location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 23 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable under Article 10(8) to the devices that have been combined. Where those periods differ, the longest period shall apply.

Article 23

Parts and components

1. Any natural or legal person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available for the competent authorities of the Member States.

2. An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in this Regulation.

Article 24

Free movement

Except where otherwise provided for in this Regulation, Member States shall not refuse, prohibit or restrict the making available on the market or putting into service within their territory of devices which comply with the requirements of this Regulation.

CHAPTER III

IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES

Article 25

Identification within the supply chain

1. Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.

2. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8):

(a) any economic operator to whom they have directly supplied a device;

(b) any economic operator who has directly supplied them with a device;

(c) any health institution or healthcare professional to which they have directly supplied a device.

Article 26

Medical devices nomenclature

To facilitate the functioning of the European database on medical devices ('Eudamed') as referred to in Article 33, the Commission shall ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

Article 27

Unique Device Identification system

1. The Unique Device Identification system ('UDI system') described in Part C of Annex VI shall allow the identification and facilitate the traceability of devices, other than custom-made and investigational devices, and shall consist of the following:

(a) production of a UDI that comprises the following:

(i) a UDI device identifier ('UDI-DI') specific to a manufacturer and a device, providing access to the information laid down in Part B of Annex VI;

(ii) a UDI production identifier ('UDI-PI') that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Annex VI;

(b) placing of the UDI on the label of the device or on its packaging;

(c) storage of the UDI by economic operators, health institutions and healthcare professionals, in accordance with the conditions laid down in paragraphs 8 and 9 of this Article respectively;

(d) establishment of an electronic system for Unique Device Identification ('UDI database') in accordance with Article 28.

2. The Commission shall, by means of implementing acts, designate one or several entities to operate a system for assignment of UDIs pursuant to this Regulation ('issuing entity'). That entity or those entities shall satisfy all of the following criteria:

(a) the entity is an organisation with legal personality;

(b) its system for the assignment of UDIs is adequate to identify a device throughout its distribution and use in accordance with the requirements of this Regulation;

(c) its system for the assignment of UDIs conforms to the relevant international standards;

(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions;

(e) the entity undertakes to do the following:

(i) operate its system for the assignment of UDIs for at least 10 years after its designation;

(ii) make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;

(iii) remain in compliance with the criteria for designation and the terms of designation.

When designating issuing entities, the Commission shall endeavour to ensure that UDI carriers, as defined in Part C of Annex VI, are universally readable regardless of the system used by the issuing entity, with a view to minimising financial and administrative burdens for economic operators and health institutions.

3. Before placing a device, other than a custom-made device, on the market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging, a UDI created in compliance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2.

Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer shall ensure that the information referred to in Part B of Annex VI of the device in question are correctly submitted and transferred to the UDI database referred to in Article 28.

4. UDI carriers shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers.

5. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.

6. The Basic UDI-DI, as defined in Part C of Annex VI, of the device shall appear on the EU declaration of conformity referred to in Article 19.

7. As part of the technical documentation referred to in Annex II, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned.

8. Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to:

— class III implantable devices;

— the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 11.

9. Health institutions shall store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to class III implantable devices.

For devices other than class III implantable devices, Member States shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

Member States shall encourage, and may require, healthcare professionals to store and keep preferably by electronic means, the UDI of the devices with which they have been supplied with.

10. The Commission is empowered to adopt delegated acts in accordance with Article 115:

(a) amending the list of information set out in Part B of Annex VI in the light of technical progress; and

(b) amending Annex VI in the light of international developments and technical progress in the field of Unique Device Identification.

11. The Commission may, by means of implementing acts, specify the detailed arrangements and the procedural aspects for the UDI system with a view to ensuring its harmonised application in relation to any of the following:

(a) determining the devices, categories or groups of devices to which the obligation laid down in paragraph 8 is to apply;

(b) specifying the data to be included in the UDI-PI of specific devices or device groups;

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

12. When adopting the measures referred to in paragraph 11, the Commission shall take into account all of the following:

(a) confidentiality and data protection as referred to in Articles 109 and 110 respectively;

(b) the risk-based approach;

(c) the cost-effectiveness of the measures;

(d) the convergence of UDI systems developed at international level;

(e) the need to avoid duplications in the UDI system;

(f) the needs of the healthcare systems of the Member States, and where possible, compatibility with other medical device identification systems that are used by stakeholders.

Article 28

UDI database

1. The Commission, after consulting the MDCG shall set up and manage a UDI database to validate, collate, process and make available to the public the information mentioned in Part B of Annex VI.

2. When designing the UDI database, the Commission shall take into account the general principles set out in Section 5 of Part C of Annex VI. The UDI database shall be designed in particular such that no UDI-PIs and no commercially confidential product information can be included therein.

3. The core data elements to be provided to the UDI database, referred to in Part B of Annex VI, shall be accessible to the public free of charge.

4. The technical design of the UDI database shall ensure maximum accessibility to information stored therein, including multi-user access and automatic uploads and downloads of that information. The Commission shall provide for technical and administrative support to manufacturers and other users of the UDI database.

Article 29

Registration of devices

1. Before placing a device, other than a custom-made device, on the market, the manufacturer shall, in accordance with the rules of the issuing entity referred to in Article 27(2), assign a Basic UDI-DI as defined in Part C of Annex VI to the device and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

2. Before placing on the market a system or procedure pack pursuant to Article 22(1) and (3), that is not a custom-made device, the natural or legal person responsible shall assign to the system or procedure pack, in compliance with the rules of the issuing entity, a Basic UDI-DI and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that system or procedure pack.

3. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in the second and third subparagraphs of Article 52(4), the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment.

For the devices referred to in the first subparagraph, the notified body shall include a reference to the Basic UDI-DI on the certificate issued in accordance with point (a) of Section 4 of Chapter I of Annex XII and confirm in Eudamed that the information referred to in Section 2.2 of Part A of Annex VI is correct. After the issuing of the relevant certificate and before placing the device on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

4. Before placing a device on the market, other than a custom-made device, the manufacturer shall enter or if, already provided, verify in Eudamed the information referred to in Section 2 of Part A of Annex VI, with the exception of Section 2.2 thereof, and shall thereafter keep the information updated.

Article 30

Electronic system for registration of economic operators

1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be provided to that electronic system by the economic operators are laid down in Section 1 of Part A of Annex VI.

2. Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory.

3. Within two weeks of placing a device, other than a custom-made device, on the market, importers shall verify that the manufacturer or authorised representative has provided to the electronic system the information referred to in paragraph 1.

Where applicable, importers shall inform the relevant authorised representative or manufacturer if the information referred to in paragraph 1 is not included or is incorrect. Importers shall add their details to the relevant entry/entries.

Article 31

Registration of manufacturers, authorised representatives and importers

1. Before placing a device, other than a custom-made device, on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 30 the information referred to in Section 1 of Part A of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 52, the information referred to in Section 1 of Part A of Annex VI shall be provided to that electronic system before applying to the notified body.

2. After having verified the data entered pursuant to paragraph 1, the competent authority shall obtain a single registration number ('SRN') from the electronic system referred to in Article 30 and issue it to the manufacturer, the authorised representative or the importer.

3. The manufacturer shall use the SRN when applying to a notified body for conformity assessment and for accessing Eudamed in order to fulfil its obligations under Article 29.

4. Within one week of any change occurring in relation to the information referred to in paragraph 1 of this Article, the economic operator shall update the data in the electronic system referred to in Article 30.

5. Not later than one year after submission of the information in accordance with paragraph 1, and every second year thereafter, the economic operator shall confirm the accuracy of the data. In the event of a failure to do so within six months of those deadlines, any Member State may take appropriate corrective measures within its territory until that economic operator complies with that obligation.

6. Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in Section 1 of Part A of Annex VI.

7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 30 shall be accessible to the public.

8. The competent authority may use the data to charge the manufacturer, the authorised representative or the importer a fee pursuant to Article 111.

Article 32

Summary of safety and clinical performance

1. For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.

The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.

The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary is available.

2. The summary of safety and clinical performance shall include at least the following aspects:

(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN;

(b) the intended purpose of the device and any indications, contraindications and target populations;

(c) a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device;

(d) possible diagnostic or therapeutic alternatives;

(e) reference to any harmonised standards and CS applied;

(f) the summary of clinical evaluation as referred to in Annex XIV, and relevant information on post-market clinical follow-up;

(g) suggested profile and training for users;

(h) information on any residual risks and any undesirable effects, warnings and precautions.

3. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2).

Article 33

European database on medical devices

1. The Commission, after consulting the MDCG, shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes:

(a) to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators;

(b) to enable unique identification of devices within the internal market and to facilitate their traceability;

(c) to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with obligations under Articles 62 to 80, Article 82, and any acts adopted pursuant to Article 81;

(d) to enable manufacturers to comply with the information obligations laid down in Articles 87 to 90 or in any acts adopted pursuant to Article 91;

(e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them.

2. Eudamed shall include the following electronic systems:

(a) the electronic system for registration of devices referred to in Article 29(4);

(b) the UDI-database referred to in Article 28;

(c) the electronic system on registration of economic operators referred to in Article 30;

(d) the electronic system on notified bodies and on certificates referred to in Article 57;

(e) the electronic system on clinical investigations referred to in Article 73;

(f) the electronic system on vigilance and post-market surveillance referred to in Article 92;

(g) the electronic system on market surveillance referred to in Article 100.

3. When designing Eudamed the Commission shall give due consideration to compatibility with national databases and national web-interfaces to allow for import and export of data.

4. The data shall be entered into Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions on the electronic systems referred to in paragraph 2. The Commission shall provide for technical and administrative support to users of Eudamed.

5. All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent specified in the provisions on the electronic systems referred to in paragraph 2.

The Commission shall ensure that public parts of Eudamed are presented in a user-friendly and easily-searchable format.

6. Eudamed shall contain personal data only insofar as necessary for the electronic systems referred to in paragraph 2 of this Article to collate and process information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of data subjects for periods no longer than those referred to in Article 10(8).

7. The Commission and the Member States shall ensure that data subjects may effectively exercise their rights to information, of access, to rectification and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall also ensure that data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data are deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than 60 days after a request is made by a data subject.

8. The Commission shall, by means of implementing acts, lay down the detailed arrangements necessary for the setting up and maintenance of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). When adopting those implementing acts, the Commission shall ensure that, as far as possible, the system is developed in such a way as to avoid having to enter the same information twice within the same module or in different modules of the system.

9. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered to be the controller of Eudamed and its electronic systems.

Article 34

Functionality of Eudamed

1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed. The Commission shall draw up a plan for the implementation of those specifications by 26 May 2018. That plan shall seek to ensure that Eudamed is fully functional at a date that allows the Commission to publish the notice referred to in paragraph 3 of this Article by 25 March 2020 and that all other relevant deadlines laid down in Article 123 of this Regulation and in Article 113 of Regulation (EU) 2017/746 are met.

2. The Commission shall, on the basis of an independent audit report, inform the MDCG when it has verified that Eudamed has achieved full functionality and Eudamed meets the functional specifications drawn up pursuant to paragraph 1.

3. The Commission shall, after consultation with the MDCG and when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the *Official Journal of the European Union*.

CHAPTER IV

NOTIFIED BODIES

Article 35

Authorities responsible for notified bodies

1. Any Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall appoint an authority ('authority responsible for notified bodies'), which may consist of separate constituent entities under national law and shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.

2. The authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.

3. The authority responsible for notified bodies shall be organised in a manner such that each decision relating to designation or notification is taken by personnel different from those who carried out the assessment.

4. The authority responsible for notified bodies shall not perform any activities that notified bodies perform on a commercial or competitive basis.

5. The authority responsible for notified bodies shall safeguard the confidential aspects of the information it obtains. However, it shall exchange information on notified bodies with other Member States, the Commission and, when required, with other regulatory authorities.

6. The authority responsible for notified bodies shall have a sufficient number of competent personnel permanently available for the proper performance of its tasks.

Where the authority responsible for notified bodies is a different authority from the national competent authority for medical devices, it shall ensure that the national authority responsible for medical devices is consulted on relevant matters.

7. Member States shall make publicly available general information on their measures governing the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on such tasks.

8. The authority responsible for notified bodies shall participate in the peer-review activities provided for in Article 48.

Article 36

Requirements relating to notified bodies

1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil those tasks. In particular, notified bodies shall comply with Annex VII.

In order to meet the requirements referred to in the first subparagraph, notified bodies shall have permanent availability of sufficient administrative, technical and scientific personnel in accordance with Section 3.1.1 of Annex VII and personnel with relevant clinical expertise in accordance with Section 3.2.4 of Annex VII, where possible employed by the notified body itself.

The personnel referred to in Sections 3.2.3 and 3.2.7 of Annex VII shall be employed by the notified body itself and shall not be external experts or subcontractors.

2. Notified bodies shall make available and submit upon request all relevant documentation, including the manufacturer's documentation, to the authority responsible for notified bodies to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.

3. In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt implementing acts, to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 37

Subsidiaries and subcontracting

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the applicable requirements set out in Annex VII and shall inform the authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Notified bodies shall make publicly available a list of their subsidiaries.

4. Conformity assessment activities may be subcontracted or carried out by a subsidiary provided that the legal or natural person that applied for conformity assessment has been informed accordingly.

5. Notified bodies shall keep at the disposal of the authority responsible for notified bodies all relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

Article 38

Application by conformity assessment bodies for designation

1. Conformity assessment bodies shall submit an application for designation to the authority responsible for notified bodies.

2. The application shall specify the conformity assessment activities as defined in this Regulation, and the types of devices for which the body is applying to be designated, and shall be supported by documentation demonstrating compliance with Annex VII.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VII, a valid accreditation certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted and shall be taken into consideration during the assessment described in Article 39. However, the applicant shall make available all the documentation referred to in the first subparagraph to demonstrate compliance with those requirements upon request.

3. The notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VII.

Article 39

Assessment of the application

1. The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 38 is complete and shall request the applicant to provide any missing information. Once the application is complete that authority shall send it to the Commission.

The authority responsible for notified bodies shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.

2. The authority responsible for notified bodies shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the MDCG.

3. Within 14 days of the submission referred to in paragraph 2 of this Article, the Commission, in conjunction with the MDCG, shall appoint a joint assessment team made up of three experts, unless the specific circumstances require a different number of experts, chosen from the list referred to in Article 40(2). One of the experts shall be a representative of the Commission who shall coordinate the activities of the joint assessment team. The other two experts shall come from Member States other than the one in which the applicant conformity assessment body is established.

The joint assessment team shall be comprised of experts who are competent to assess the conformity assessment activities and the types of devices which are the subject of the application or, in particular when the assessment procedure is initiated in accordance with Article 47(3), to ensure that the specific concern can be appropriately assessed.

4. Within 90 days of its appointment, the joint assessment team shall review the documentation submitted with the application in accordance with Article 38. The joint assessment team may provide feedback to, or require clarification from, the authority responsible for notified bodies on the application and on the planned on-site assessment.

The authority responsible for notified bodies together with the joint assessment team shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, to be involved in the conformity assessment process.

The on-site assessment of the applicant body shall be led by the authority responsible for notified bodies.

5. Findings regarding non-compliance of an applicant conformity assessment body with the requirements set out in Annex VII shall be raised during the assessment process and discussed between the authority responsible for notified bodies and the joint assessment team with a view to reaching consensus and resolving any diverging opinions, with respect to the assessment of the application.

At the end of the on-site assessment, the authority responsible for notified bodies shall list for the applicant conformity assessment body the non-compliances resulting from the assessment and summarise the assessment by the joint assessment team.

Within a specified timeframe, the applicant conformity assessment body shall submit to the national authority a corrective and preventive action plan to address the non-compliances.

6. The joint assessment team shall document any remaining diverging opinions with respect to the assessment within 30 days of completion of the on-site assessment and send them to the authority responsible for notified bodies.

7. The authority responsible for notified bodies shall following receipt of a corrective and preventive action plan from the applicant body assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

The authority responsible for notified bodies shall having confirmed the corrective and preventive action plan forward it and its opinion thereon to the joint assessment team. The joint assessment team may request of the authority responsible for notified bodies further clarification and modifications.

The authority responsible for notified bodies shall draw up its final assessment report which shall include:

— the result of the assessment,

— confirmation that the corrective and preventive actions have been appropriately addressed and, where required, implemented,

— any remaining diverging opinion with the joint assessment team, and, where applicable,

— the recommended scope of designation.

8. The authority responsible for notified bodies shall submit its final assessment report and, if applicable, the draft designation to the Commission, the MDCG and the joint assessment team.

9. The joint assessment team shall provide a final opinion regarding the assessment report prepared by the authority responsible for notified bodies and, if applicable, the draft designation within 21 days of receipt of those documents to the Commission, which shall immediately submit that final opinion to the MDCG. Within 42 days of receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft designation, which the authority responsible for notified bodies shall duly take into consideration for its decision on the designation of the notified body.

10. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements specifying procedures and reports for the application for designation referred to in Article 38 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 40

Nomination of experts for joint assessment of applications for notification

1. The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of medical devices to participate in the activities referred to in Articles 39 and 48.

2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1 of this Article, together with information on their specific field of competence and expertise. That list shall be made available to Member States competent authorities through the electronic system referred to in Article 57.

Article 41

Language requirements

All documents required pursuant to Articles 38 and 39 shall be drawn up in a language or languages which shall be determined by the Member State concerned.

Member States, in applying the first paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documentation concerned.

The Commission shall provide translations of the documentation pursuant to Articles 38 and 39, or parts thereof into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team appointed in accordance with Article 39(3).

Article 42

Designation and notification procedure

1. Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 39 was completed and which comply with Annex VII.

2. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool within the database of notified bodies developed and managed by the Commission (NANDO).

3. The notification shall clearly specify, using the codes referred to in paragraph 13 of this Article, the scope of the designation indicating the conformity assessment activities as defined in this Regulation and the types of devices which the notified body is authorised to assess and, without prejudice to Article 44, any conditions associated with the designation.

4. The notification shall be accompanied by the final assessment report of the authority responsible for notified bodies, the final opinion of the joint assessment team referred to in Article 39(9) and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.

5. The notifying Member State shall, without prejudice to Article 44, inform the Commission and the other Member States of any conditions associated with the designation and provide documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VII.

6. Within 28 days of the notification referred to in paragraph 2, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the authority responsible for notified bodies. Where no objection is raised, the Commission shall publish in NANDO the notification within 42 days of its having been notified as referred to in paragraph 2.

7. When a Member State or the Commission raises objections in accordance with paragraph 6, the Commission shall bring the matter before the MDCG within 10 days of the expiry of the period referred to in paragraph 6. After consulting the parties involved, the MDCG shall give its opinion at the latest within 40 days of the matter having been brought before it. Where the MDCG is of the opinion that the notification can be accepted, the Commission shall publish in NANDO the notification within 14 days.

8. Where the MDCG, after having been consulted in accordance with paragraph 7, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.

9. Where the notifying Member State decides to uphold its decision to designate the conformity assessment body, having given its reasons in accordance with paragraph 8, the Commission shall publish in NANDO the notification within 14 days of being informed thereof.

10. When publishing the notification in NANDO, the Commission shall also add to the electronic system referred to in Article 57 the information relating to the notification of the notified body along with the documents mentioned in paragraph 4 of this Article and the opinion and responses referred to in paragraphs 7 and 8 of this Article.

11. The designation shall become valid the day after the notification is published in NANDO. The published notification shall state the scope of lawful conformity assessment activity of the notified body.

12. The conformity assessment body concerned may perform the activities of a notified body only after the designation has become valid in accordance with paragraph 11.

13. The Commission shall by 26 November 2017, by means of implementing acts, draw up a list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). The Commission, after consulting the MDCG, may update this list based, *inter alia*, on information arising from the coordination activities described in Article 48.

Article 43

Identification number and list of notified bodies

1. The Commission shall assign an identification number to each notified body for which the notification becomes valid in accordance with Article 42(11). It shall assign a single identification number even when the body is notified under several Union acts. If they are successfully designated in accordance with this Regulation, bodies notified pursuant to Directives 90/385/EEC and 93/42/EEC shall retain the identification number assigned to them pursuant to those Directives.

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the conformity assessment activities as defined in this Regulation and the types of devices for which they have been notified, accessible to the public in NANDO. It shall also make this list available on the electronic system referred to in Article 57. The Commission shall ensure that the list is kept up to date.

Article 44

Monitoring and re-assessment of notified bodies

1. Notified bodies shall, without delay, and at the latest within 15 days, inform the authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VII or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.

2. The authorities responsible for notified bodies shall monitor the notified bodies established on their territory and their subsidiaries and subcontractors to ensure ongoing compliance with the requirements and the fulfilment of its obligations set out in this Regulation. Notified bodies shall, upon request by their authority responsible for notified bodies, supply all relevant information and documents, required to enable the authority, the Commission and other Member States to verify compliance.

3. Where the Commission or the authority of a Member State submits a request to a notified body established on the territory of another Member State relating to a conformity assessment carried out by that notified body, it shall send a copy of that request to the authority responsible for notified bodies of that other Member State. The notified body concerned shall respond without delay and within 15 days at the latest to the request. The authority responsible for notified bodies of the Member State in which the body is established shall ensure that requests submitted by authorities of any other Member State or by the Commission are resolved by the notified body unless there is a legitimate reason for not doing so in which case the matter may be referred to the MDCG.

4. At least once a year, the authorities responsible for notified bodies shall re-assess whether the notified bodies established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in Annex VII. That review shall include an on-site audit of each notified body and, where necessary, of its subsidiaries and subcontractors.

The authority responsible for notified bodies shall conduct its monitoring and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. That plan shall provide a reasoned schedule for the frequency of assessment of the notified body and, in particular, associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.

5. The monitoring of notified bodies by the authority responsible for notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, as that personnel is in the process of conducting quality management system assessments at a manufacturer's facility.

6. The monitoring of notified bodies conducted by the authority responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance to help guide its activities.

The authority responsible for notified bodies shall provide for a systematic follow-up of complaints and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

7. The authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance.

8. The authority responsible for notified bodies shall review the assessments by notified bodies of manufacturers' technical documentation, in particular the clinical evaluation documentation as further outlined in Article 45.

9. The authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VII and shall monitor the timely implementation of corrective and preventive actions.

10. Three years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VII shall be conducted by the authority responsible for notified bodies of the Member State in which the body is established and by a joint assessment team appointed for the purpose of the procedure described in Articles 38 and 39.

11. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend paragraph 10 to modify the frequency at which the complete re-assessment referred to in that paragraph is to be carried out.

12. The Member States shall report to the Commission and to the MDCG, at least once a year, on their monitoring and on-site assessment activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. The report shall provide details of the outcome of those activities, including activities pursuant to paragraph 7, and shall be treated as confidential by the MDCG and the Commission; however it shall contain a summary which shall be made publicly available.

The summary of the report shall be uploaded to the electronic system referred to in Article 57.

Article 45

Review of notified body assessment of technical documentation and clinical evaluation documentation

1. The authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies, shall review an appropriate number of notified body assessments of manufacturers' technical documentation, in particular the clinical evaluation documentation as referred to in points (c) and (d) of Section 6.1 of Annex II to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. The reviews by the authority responsible for notified bodies shall be conducted both off-site and on-site.

2. The sampling of files to be reviewed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body, in particular high-risk devices, and be appropriately justified and documented in a sampling plan, which shall be made available by the authority responsible for notified bodies to the MDCG upon request.

3. The authority responsible for notified bodies shall review whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such checking shall include the technical documentation and clinical evaluation documentation of the manufacturer upon which the notified body has based its assessment. Such reviews shall be conducted utilising CS.

4. Those reviews shall also form part of the re-assessment of notified bodies in accordance with Article 44(10) and the joint assessment activities referred to in Article 47(3). The reviews shall be conducted utilising appropriate expertise.

5. Based on the reports of the reviews and assessments by the authority responsible for notified bodies or joint assessment teams, on input from the market surveillance, vigilance and post-market surveillance activities described in Chapter VII, on the continuous monitoring of technical progress, or on the identification of concerns and emerging issues concerning the safety and performance of devices, the MDCG may recommend that the sampling, carried out under this Article, cover a greater or lesser proportion of the technical documentation and clinical evaluation documentation assessed by a notified body.

6. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements, associated documents for, and coordination of, the review of assessments of technical documentation and clinical evaluation documentation, as referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 46

Changes to designations and notifications

1. The authority responsible for notified bodies shall notify the Commission and the other Member States of any relevant changes to the designation of a notified body.

The procedures described in Article 39 and in Article 42 shall apply to extensions of the scope of the designation.

For changes to the designation other than extensions of its scope, the procedures laid down in the following paragraphs shall apply.

2. The Commission shall immediately publish the amended notification in NANDO. The Commission shall immediately enter information on the changes to the designation of the notified body in the electronic system referred to in Article 57.

3. Where a notified body decides to cease its conformity assessment activities it shall inform the authority responsible for notified bodies and the manufacturers concerned as soon as possible and in the case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of the notified body's activities on condition that another notified body has confirmed in writing that it will assume responsibilities for the devices covered by those certificates. The new notified body shall complete a full assessment of the devices affected by the end of that period before issuing new certificates for those devices. Where the notified body has ceased its activity, the authority responsible for notified bodies shall withdraw the designation.

4. Where a authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VII, or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period.

The authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a designation.

5. Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the manufacturers concerned at the latest within 10 days.

6. In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall take appropriate steps to ensure that the files of the notified body concerned are kept and make them available to authorities in other Member States responsible for notified bodies and to authorities responsible for market surveillance at their request.

7. In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall:

(a) assess the impact on the certificates issued by the notified body;

(b) submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the designation;

(c) require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued to ensure the safety of devices on the market;

(d) enter into the electronic system referred to in Article 57 information in relation to certificates of which it has required their suspension or withdrawal;

(e) inform the competent authority for medical devices of the Member State in which the manufacturer has its registered place of business through the electronic system referred to in Article 57 of the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.

8. With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in the following circumstances:

(a) the authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue in relation to certificates affected by the suspension or restriction, and the authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction; or

(b) the authority responsible for notified bodies has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In the event that the authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide, to the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business, within three months of the suspension or restriction, a written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.

9. With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:

(a) where the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business has confirmed that there is no safety issue associated with the devices in question; and

(b) another notified body has confirmed in writing that it will assume immediate responsibilities for those devices and will have completed assessment of them within twelve months of the withdrawal of the designation.

In the circumstances referred to in the first subparagraph, the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its place of business may extend the provisional validity of the certificates for further periods of three months, which altogether shall not exceed twelve months.

The authority or the notified body assuming the functions of the notified body affected by the change of designation shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

Article 47

Challenge to the competence of notified bodies

1. The Commission, in conjunction with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in Annex VII or the obligations to which they are subject. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.

2. The notifying Member State shall provide the Commission, on request, with all information regarding the designation of the notified body concerned.

3. The Commission, in conjunction with the MDCG, may initiate, as applicable, the assessment procedure described in Article 39(3) and (4), where there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VII and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles of Article 39. Alternatively, depending on the severity of the issue, the Commission, in conjunction with the MDCG, may request that the authority responsible for notified bodies allow the participation of up to two experts from the list established pursuant to Article 40 in an on-site assessment as part of the planned monitoring and assessment activities in accordance with Article 44 and as outlined in the annual assessment plan described in Article 44(4).

4. Where the Commission ascertains that a notified body no longer meets the requirements for its designation, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the designation if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the designation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). It shall notify the Member State concerned of its decision and update NANDO and the electronic system referred to in Article 57.

5. The Commission shall ensure that all confidential information obtained in the course of its investigations is treated accordingly.

Article 48

Peer review and exchange of experience between authorities responsible for notified bodies

1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the authorities responsible for notified bodies. Such exchange shall cover elements including:

(a) development of best practice documents relating to the activities of the authorities responsible for notified bodies;

(b) development of guidance documents for notified bodies in relation to the implementation of this Regulation;

(c) training and qualification of the experts referred to in Article 40;

(d) monitoring of trends relating to changes to notified body designations and notifications and trends in certificate withdrawals and transfers between notified bodies;

(e) monitoring of the application and applicability of scope codes referred to in Article 42(13);

(f) development of a mechanism for peer reviews between authorities and the Commission;

(g) methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies.

2. The authorities responsible for notified bodies shall participate in a peer review every third year through the mechanism developed pursuant to paragraph 1 of this Article. Such reviews shall normally be conducted in parallel with the on-site joint assessments described in Article 39. Alternatively, an authority may make the choice of having such reviews take place as part of its monitoring activities referred to in Article 44.

3. The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism.

4. The Commission shall compile an annual summary report of the peer review activities, which shall be made publicly available.

5. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements and related documents for the peer review mechanism and training and qualification as referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 49

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices. This group shall meet on a regular basis and at least annually.

The bodies notified under this Regulation shall participate in the work of that group.

The Commission may establish the specific arrangements for the functioning of the coordination group of notified bodies.

Article 50

List of standard fees

Notified bodies shall establish lists of their standard fees for the conformity assessment activities that they carry out and shall make those lists publicly available.

CHAPTER V

CLASSIFICATION AND CONFORMITY ASSESSMENT

SECTION 1

Classification

Article 51

Classification of devices

1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

2. Any dispute between the manufacturer and the notified body concerned, arising from the application of Annex VIII, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in the last indent of point (b) of the second paragraph of Section 2.2 of Annex IX has its registered place of business. Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

3. At the request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:

(a) application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;

(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII.

4. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.

5. In order to ensure the uniform application of Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

6. The implementing acts referred to in paragraphs 3, 4 and 5 of this Article shall be adopted in accordance with the examination procedure referred to in Article 114(3).

SECTION 2

Conformity assessment

Article 52

Conformity assessment procedures

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

2. Prior to putting into service a device that is not placed on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

3. Manufacturers of class III devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Annex IX. Alternatively, the manufacturer may choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI.

4. Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group.

However, for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device.

Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex X coupled with a conformity assessment based on product conformity verification as specified in Annex XI.

5. Where justified in view of well-established technologies, similar to those used in the exempted devices listed in the second subparagraph of paragraph 4 of this Article, being used in other class IIb implantable devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend that list by adding other types of class IIb implantable devices to that list or removing devices therefrom.

6. Manufacturers of class IIa devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device for each category of devices.

Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annexes II and III coupled with a conformity assessment as specified in Section 10 or Section 18 of Annex XI. The assessment of the technical documentation shall apply for at least one representative device for each category of devices.

7. Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III. If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI. However, the involvement of the notified body in those procedures shall be limited:

(a) in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions;

(b) in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements;

(c) in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

8. Manufacturers of custom-made devices shall follow the procedure set out in Annex XIII and draw up the statement set out in Section 1 of that Annex before placing such devices on the market.

In addition to the procedure applicable pursuant to the first subparagraph, manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment as specified in Chapter I of Annex IX. Alternatively, the manufacturer may choose to apply a conformity assessment as specified in Part A of Annex XI.

9. In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7 of this Article, in the case of devices referred to in the first subparagraph of Article 1(8), the procedure specified in Section 5.2 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

10. In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7 of this Article, in the case of devices that are covered by this Regulation in accordance with point (f) or (g) of Article 1(6) and with the first subparagraph of Article 1(10), the procedure specified in Section 5.3 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

11. In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7, in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the procedure specified in Section 5.4 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

12. The Member State in which the notified body is established may require that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 7 and 9 to 11 be made available in an official Union language(s) determined by that Member State. In the absence of such requirement, those documents shall be available in any official Union language acceptable to the notified body.

13. Investigational devices shall be subject to the requirements set out in Articles 62 to 81.

14. The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects with a view to ensuring the harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:

(a) the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in the third paragraph of Section 2.3 and in Section 3.5 of Annex IX in the case of class IIa and class IIb devices, and in Section 10.2 of Annex XI in the case of class IIa devices;

(b) the minimum frequency of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of the technical documentation and type examination in accordance with Sections 3.4 and 4.3 of Annex IX, Section 3 of Annex X and Section 15 of Annex XI.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 53

Involvement of notified bodies in conformity assessment procedures

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned. The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

2. The notified body concerned shall, by means of the electronic system referred to in Article 57, inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment.

3. When applying to a notified body under paragraph 1, manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body and provide information about any previous application for the same conformity assessment that has been refused by another notified body.

4. The notified body may require any information or data from the manufacturer, which is necessary in order to properly conduct the chosen conformity assessment procedure.

5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

Article 54

Clinical evaluation consultation procedure for certain class III and class IIb devices

1. In addition to the procedures applicable pursuant to Article 52, a notified body shall also follow the procedure regarding clinical evaluation consultation as specified in Section 5.1 of Annex IX or as referred to in Section 6 of Annex X, as applicable, when performing a conformity assessment of the following devices:

(a) class III implantable devices, and

(b) class IIb active devices intended to administer and/or remove a medicinal product, as referred to in Section 6.4 of Annex VIII (Rule 12).

2. The procedure referred to in paragraph 1 shall not be required for the devices referred to therein:

(a) in the case of renewal of a certificate issued under this Regulation;

(b) where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device; or

(c) where the principles of the clinical evaluation of the device type or category have been addressed in a CS referred to in Article 9 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant CS for clinical evaluation of that kind of device.

3. The notified body shall notify the competent authorities, the authority responsible for notified bodies and the Commission through the electronic system referred to in Article 57 of whether or not the procedure referred to in paragraph 1 of this Article is to be applied. That notification shall be accompanied by the clinical evaluation assessment report.

4. The Commission shall draw up an annual overview of devices which have been subject to the procedure specified in Section 5.1 of Annex IX and referred to in Section 6 of Annex X. The annual overview shall include the notifications in accordance with paragraph 3 of this Article and point (e) of Section 5.1 of Annex IX and a listing of the cases where the notified body did not follow the advice from the expert panel. The Commission shall submit this overview to the European Parliament, to the Council and to the MDCG.

5. The Commission shall by 27 May 2025 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. The report shall take into account the annual overviews and any available relevant recommendations from the MDCG. On the basis of that report the Commission shall, if appropriate, make proposals for amendments to this Regulation.

Article 55

Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices

1. A notified body shall notify the competent authorities of certificates it has granted to devices for which the conformity assessment has been performed pursuant to Article 54(1). Such notification shall take place through the electronic system referred to in Article 57 and shall include the summary of safety and clinical performance pursuant to Article 32, the assessment report by the notified body, the instructions for use referred to in Section 23.4 of Annex I, and, where applicable, the scientific opinion of the expert panels referred to in Section 5.1 of Annex IX or Section 6 of Annex X, as applicable. In the case of divergent views between the notified body and the expert panels, a full justification shall also be included.

2. A competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures in accordance with Article 44, 45, 46, 47 or 94 and, where deemed necessary, take appropriate measures in accordance with Articles 95 and 97.

3. The MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device.

Article 56

Certificates of conformity

1. The certificates issued by the notified bodies in accordance with Annexes IX, X and XI shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates shall be as set out in Annex XII.

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

3. Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or require manufacturers to undertake specific PMCF studies pursuant to Part B of Annex XIV.

4. Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

5. The notified body shall enter in the electronic system referred to in Article 57 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public.

6. In the light of technical progress, the Commission is empowered to adopt delegated acts in accordance with Article 115 amending the minimum content of the certificates set out in Annex XII.

Article 57

Electronic system on notified bodies and on certificates of conformity

1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to collate and process the following information:

(a) the list of subsidiaries referred to in Article 37(3);

(b) the list of experts referred to in Article 40(2);

(c) the information relating to the notification referred to in Article 42(10) and the amended notifications referred to in Article 46(2);

(d) the list of notified bodies referred to in Article 43(2);

(e) the summary of the report referred to in Article 44(12);

(f) the notifications for conformity assessments and certificates referred to in Articles 54(3) and 55(1);

(g) withdrawal or refusals of applications for the certificates as referred to in Article 53(2) and Section 4.3 of Annex VII;

(h) the information regarding certificates referred to in Article 56(5);

(i) the summary of safety and clinical performance referred to in Article 32.

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission, where appropriate to the notified bodies and where provided elsewhere in this regulation or in Regulation (EU) 2017/746 to the public.

Article 58

Voluntary change of notified body

1. In cases where a manufacturer terminates its contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the detailed arrangements for the change of notified body shall be clearly defined in an agreement between the manufacturer, the incoming notified body and, where practicable the outgoing notified body. That agreement shall cover at least the following aspects:

(a) the date on which the certificates issued by the outgoing notified body become invalid;

(b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the date after which the conformity assessment tasks of the outgoing notified body is assigned to the incoming notified body;

(e) the last serial number or lot number for which the outgoing notified body is responsible.

2. The outgoing notified body shall withdraw the certificates it has issued for the device concerned on the date on which they become invalid.

Article 59

Derogation from the conformity assessment procedures

1. By way of derogation from Article 52, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in that Article have not been carried out but use of which is in the interest of public health or patient safety or health.

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

3. Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).

Article 60

Certificate of free sale

1. For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the CE marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall set out the Basic UDI-DI of the device as provided to the UDI database under Article 29. Where a notified body has issued a certificate pursuant to Article 56, the certificate of free sale shall set out the unique number identifying the certificate issued by the notified body, as referred to in Section 3 of Chapter II of Annex XII.

2. The Commission may, by means of implementing acts, establish a model for certificates of free sale, taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2).

CHAPTER VI

CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

Article 61

Clinical evaluation

1. Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

To that end, manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and Part A of Annex XIV.

2. For all class III devices and for the class IIb devices referred to in point (b) of Article 54(1), the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation. The manufacturer shall give due consideration to the views expressed by the expert panel. Such consideration shall be documented in the clinical evaluation report referred to in paragraph 12 of this Article.

The manufacturer may not invoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure.

3. A clinical evaluation shall follow a defined and methodologically sound procedure based on the following:

(a) a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions are satisfied:

— it is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate, in accordance with Section 3 of Annex XIV, and

— the data adequately demonstrate compliance with the relevant general safety and performance requirements;

(b) a critical evaluation of the results of all available clinical investigations, taking duly into consideration whether the investigations were performed under Articles 62 to 80, any acts adopted pursuant to Article 81, and Annex XV; and

(c) a consideration of currently available alternative treatment options for that purpose, if any.

4. In the case of implantable devices and class III devices, clinical investigations shall be performed, except if:

— the device has been designed by modifications of a device already marketed by the same manufacturer,

— the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with Section 3 of Annex XIV and this demonstration has been endorsed by the notified body, and

— the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

In this case, the notified body shall check that the PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

In addition, clinical investigations need not be performed in the cases referred to in paragraph 6.

5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:

— the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and

— the original clinical evaluation has been performed in compliance with the requirements of this Regulation,

and the manufacturer of the second device provides clear evidence thereof to the notified body.

6. The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and class III devices:

(a) which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation:

— is based on sufficient clinical data, and

— is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device, where such a CS is available; or

(b) that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available.

7. Cases in which paragraph 4 is not applied by virtue of paragraph 6 shall be justified in the clinical evaluation report by the manufacturer and in the clinical evaluation assessment report by the notified body.

8. Where justified in view of well-established technologies, similar to those used in the exempted devices listed in point (b) of paragraph 6 of this Article, being used in other devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the list of exempted devices referred to in the second subparagraph of Article 52(4) and in point (b) of paragraph 6 of this Article, by adding other types of implantable or class III devices to that list or removing devices therefrom.

9. In the case of the products without an intended medical purpose listed in Annex XVI, the requirement to demonstrate a clinical benefit in accordance with this Chapter and Annexes XIV and XV shall be understood as a requirement to demonstrate the performance of the device. Clinical evaluations of those products shall be based on relevant data concerning safety, including data from post-market surveillance, PMCF, and, where applicable, specific clinical investigation. Clinical investigations shall be performed for those products unless reliance on existing clinical data from an analogous medical device is duly justified.

10. Without prejudice to paragraph 4, where the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, to be adequate.

11. The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84.

For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data.

12. The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned.

13. Where necessary to ensure the uniform application of Annex XIV, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 62

General requirements regarding clinical investigations conducted to demonstrate conformity of devices

1. Clinical investigations shall be designed, authorised, conducted, recorded and reported in accordance with the provisions of this Article and of Articles 63 to 80, the acts adopted pursuant to Article 81, and Annex XV, where carried out as part of the clinical evaluation for conformity assessment purposes, for one or more of the following purposes:

(a) to establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that it is suitable for one or more of the specific purposes listed in point (1) of Article 2, and achieves the performance intended as specified by its manufacturer;

(b) to establish and verify the clinical benefits of a device as specified by its manufacturer;

(c) to establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.

2. Where the sponsor of a clinical investigation is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication with that legal representative shall be deemed to be a communication with the sponsor.

Member States may choose not to apply the first subparagraph to clinical investigations to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that clinical investigation who shall be the addressee for all communications with the sponsor provided for in this Regulation.

3. Clinical investigations shall be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects participating in a clinical investigation are protected and prevail over all other interests and the clinical data generated are scientifically valid, reliable and robust.

Clinical investigations shall be subject to scientific and ethical review. The ethical review shall be performed by an ethics committee in accordance with national law. Member States shall ensure that the procedures for review by ethics committees are compatible with the procedures set out in this Regulation for the assessment of the application for authorisation of a clinical investigation. At least one lay person shall participate in the ethical review.

4. A clinical investigation as referred to in paragraph 1 may be conducted only where all of the following conditions are met:

(a) the clinical investigation is the subject of an authorisation by the Member State(s) in which the clinical investigation is to be conducted, in accordance with this Regulation, unless otherwise stated;

(b) an ethics committee, set up in accordance with national law, has not issued a negative opinion in relation to the clinical investigation, which is valid for that entire Member State under its national law;

(c) the sponsor, or its legal representative or a contact person pursuant to paragraph 2, is established in the Union;

(d) vulnerable populations and subjects are appropriately protected in accordance with Articles 64 to 68;

(e) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;

(f) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent in accordance with Article 63;

(g) the subject or, where the subject is not able to give informed consent, his or her legally designated representative, has been provided with the contact details of an entity where further information can be received in case of need;

(h) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;

(i) the clinical investigation has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the degree of distress are specifically defined in the clinical investigation plan and constantly monitored;

(j) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner or any other person entitled by national law to provide the relevant patient care under clinical investigation conditions;

(k) no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the clinical investigation;

(l) the investigational device(s) in question conform(s) to the applicable general safety and performance requirements set out in Annex I apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, technical and biological safety testing and pre-clinical evaluation, as well as provisions in the field of occupational safety and accident prevention, taking into consideration the state of the art;

(m) the requirements of Annex XV are fulfilled.

5. Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical investigation at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

6. The investigator shall be a person exercising a profession which is recognised in the Member State concerned as qualifying for the role of investigator on account of having the necessary scientific knowledge and experience in patient care. Other personnel involved in conducting a clinical investigation shall be suitably qualified, by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.

7. The facilities where the clinical investigation is to be conducted shall be suitable for the clinical investigation and shall be similar to the facilities where the device is intended to be used.

Article 63

Informed consent

1. Informed consent shall be written, dated and signed by the person performing the interview referred to in point (c) of paragraph 2, and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 2. Where the subject is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. In that case, the witness shall sign and date the informed consent document. The subject or, where the subject is not able to give informed consent, his or her legally designated representative shall be provided with a copy of the document or the record, as appropriate, by which informed consent has been given. The informed consent shall be documented. Adequate time shall be given for the subject or his or her legally designated representative to consider his or her decision to participate in the clinical investigation.

2. Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:

(a) enable the subject or his or her legally designated representative to understand:

  (i) the nature, objectives, benefits, implications, risks and inconveniences of the clinical investigations;

  (ii) the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate in and the right to withdraw from the clinical investigation at any time without any resulting detriment and without having to provide any justification;

  (iii) the conditions under which the clinical investigations is to be conducted, including the expected duration of the subject's participation in the clinical investigation; and

  (iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical investigation is discontinued;

(b) be kept comprehensive, concise, clear, relevant, and understandable to the subject or his or her legally designated representative;

(c) be provided in a prior interview with a member of the investigating team who is appropriately qualified under national law;

(d) include information about the applicable damage compensation system referred to in Article 69; and

(e) include the Union-wide unique single identification number of the clinical investigation referred to in Article 70(1) and information about the availability of the clinical investigation results in accordance with paragraph 6 of this Article.

3. The information referred to in paragraph 2 shall be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.

4. In the interview referred to in point (c) of paragraph 2, special attention shall be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information.

5. In the interview referred to in point (c) of paragraph 2, it shall be verified that the subject has understood the information.

6. The subject shall be informed that a clinical investigation report and a summary presented in terms understandable to the intended user will be made available pursuant to Article 77(5) in the electronic system on clinical investigations referred to in Article 73 irrespective of the outcome of the clinical investigation, and shall be informed, to the extent possible, when they have become available.

7. This Regulation is without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a clinical investigation.

Article 64

Clinical investigations on incapacitated subjects

1. In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a clinical investigation may be conducted only where, in addition to the conditions set out in Article 62(4), all of the following conditions are met:

(a) the informed consent of their legally designated representative has been obtained;

(b) the incapacitated subjects have received the information referred to in Article 63(2) in a way that is adequate in view of their capacity to understand it;

(c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in Article 63(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;

(e) the clinical investigation is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in clinical investigations on persons able to give informed consent, or by other research methods;

(f) the clinical investigation relates directly to a medical condition from which the subject suffers;

(g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the incapacitated subject outweighing the risks and burdens involved.

2. The subject shall as far as possible take part in the informed consent procedure.

Article 65

Clinical investigations on minors

A clinical investigation on minors may be conducted only where, in addition to the conditions set out in Article 62(4), all of the following conditions are met:

(a) the informed consent of their legally designated representative has been obtained;

(b) the minors have received the information referred to in Article 63(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;

(c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 63(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to the subject or his or her legally designated representative except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;

(e) the clinical investigation is intended to investigate treatments for a medical condition that only occurs in minors or the clinical investigation is essential with respect to minors to validate data obtained in clinical investigations on persons able to give informed consent or by other research methods;

(f) the clinical investigation either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;

(g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the minor subject outweighing the risks and burdens involved;

(h) the minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity;

(i) if during a clinical investigation the minor reaches the age of legal competence to give informed consent as defined in national law, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical investigation.

Article 66

Clinical investigations on pregnant or breastfeeding women

A clinical investigation on pregnant or breastfeeding women may be conducted only where, in addition to the conditions set out in Article 62(4), all of the following conditions are met:

(a) the clinical investigation has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;

(b) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child;

(c) no incentives or financial inducements are given to the subject except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation.

Article 67

Additional national measures

Member States may maintain additional measures regarding persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in clinical investigations, or persons in residential care institutions.

Article 68

Clinical investigations in emergency situations

1. By way of derogation from point (f) of Article 62(4), from points (a) and (b) of Article 64(1) and from points (a) and (b) of Article 65, informed consent to participate in a clinical investigation may be obtained, and information on the clinical investigation may be given, after the decision to include the subject in the clinical investigation, provided that that decision is taken at the time of the first intervention on the subject, in accordance with the clinical investigation plan for that clinical investigation and that all of the following conditions are fulfilled:

(a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical investigation;

(b) there are scientific grounds to expect that participation of the subject in the clinical investigation will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;

(c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;

(d) the investigator certifies that he or she is not aware of any objections to participate in the clinical investigation previously expressed by the subject;

(e) the clinical investigation relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the clinical investigation is of such a nature that it may be conducted exclusively in emergency situations;

(f) the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

2. Following an intervention pursuant to paragraph 1 of this Article, informed consent in accordance with Article 63 shall be sought to continue the participation of the subject in the clinical investigation, and information on the clinical investigation shall be given, in accordance with the following requirements:

(a) regarding incapacitated subjects and minors, the informed consent shall be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in Article 63(2) shall be given as soon as possible to the subject and to his or her legally designated representative;

(b) regarding other subjects, the informed consent shall be sought by the investigator without undue delay from the subject or his or her legally designated representative, whichever can be done sooner, and the information referred to in Article 63(2) shall be given as soon as possible to the subject or his or her legally designated representative, as applicable.

For the purposes of point (b) where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the clinical investigation shall be obtained from the subject as soon as he or she is capable of giving informed consent.

3. If the subject or, where applicable, his or her legally designated representative does not give consent, he or she shall be informed of the right to object to the use of data obtained from the clinical investigation.

Article 69

Damage compensation

1. Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical investigation conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.

2. The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State in which the clinical investigation is conducted.

Article 70

Application for clinical investigations

1. The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the clinical investigation is to be conducted (referred to for the purposes of this Article as 'Member State concerned') accompanied by the documentation referred to in Chapter II of Annex XV.

The application shall be submitted by means of the electronic system referred to in Article 73, which shall generate a Union-wide unique single identification number for the clinical investigation, which shall be used for all relevant communication in relation to that clinical investigation. Within 10 days of it receiving the application, the Member State concerned shall notify the sponsor as to whether the clinical investigation falls within the scope of this Regulation and as to whether the application dossier is complete in accordance with Chapter II of Annex XV.

2. Within one week of any change occurring in relation to the documentation referred to in Chapter II of Annex XV, the sponsor shall update the relevant data in the electronic system referred to in Article 73 and make that change to the documentation clearly identifiable. The Member State concerned shall be notified of the update by means of that electronic system.

3. Where the Member State concerned finds that the clinical investigation applied for does not fall within the scope of this Regulation or that the application dossier is not complete, it shall inform the sponsor thereof and shall set a time limit of maximum 10 days for the sponsor to comment or to complete the application by means of the electronic system referred to in Article 73. The Member State concerned may extend this period by a maximum of 20 days where appropriate.

Where the sponsor has not provided comments nor completed the application within the time limit referred to in the first subparagraph, the application shall be deemed to have lapsed. Where the sponsor considers the application does fall under the scope of this Regulation and/or is complete but the Member State concerned does not, the application shall be considered to have been rejected. The Member State concerned shall provide for an appeal procedure in respect of such refusal.

The Member State concerned shall notify the sponsor within five days of receipt of the comments or of the requested additional information, whether the clinical investigation is considered as falling within the scope of this Regulation and the application is complete.

4. The Member State concerned may also extend the period referred to in paragraph 1 and 3 each by a further five days.

5. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 1 or 3 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the periods referred to in paragraphs 1, 3 and 4 respectively.

6. During the period when the application is being assessed, the Member State may request additional information from the sponsor. The expiry of the period laid down in point (b) of paragraph 7 shall be suspended from the date of the first request until such time as the additional information has been received.

7. The sponsor may start the clinical investigation in the following circumstances:

(a) in the case of investigational class I devices or in the case of non-invasive class IIa and class IIb devices, unless otherwise stated by national law, immediately after the validation date of the application pursuant to paragraph 5, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation;

(b) in the case of investigational devices, other than those referred to in point (a), as soon as the Member State concerned has notified the sponsor of its authorisation, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation. The Member State shall notify the sponsor of the authorisation within 45 days of the validation date referred to in paragraph 5. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.

8. The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress and global regulatory developments, the requirements laid down in Chapter II of Annex XV.

9. In order to ensure the uniform application of the requirements laid down in Chapter II of Annex XV, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 71

Assessment by Member States

1. Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of natural or legal persons financing the clinical investigation, as well as free of any other undue influence.

2. Member States shall ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.

3. Member States shall assess whether the clinical investigation is designed in such a way that potential remaining risks to subjects or third persons, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall, while taking into account applicable CS or harmonised standards, examine in particular:

(a) the demonstration of compliance of the investigational device(s) with the applicable general safety and performance requirements, apart from the aspects covered by the clinical investigation, and whether, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, assurance of technical and biological safety testing and pre-clinical evaluation;

(b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, whether the risk-minimisation solutions provide a level of protection that is equivalent to that provided by harmonised standards;

(c) whether the measures planned for the safe installation, putting into service and maintenance of the investigational device are adequate;

(d) the reliability and robustness of the data generated in the clinical investigation, taking account of statistical approaches, design of the investigation and methodological aspects, including sample size, comparator and endpoints;

(e) whether the requirements of Annex XV are met;

(f) in the case of devices for sterile use, evidence of the validation of the manufacturer's sterilisation procedures or information on the reconditioning and sterilisation procedures which have to be conducted by the investigation site;

(g) the demonstration of the safety, quality and usefulness of any components of animal or human origin or of substances, which may be considered medicinal products in accordance with Directive 2001/83/EC.

4. Member States shall refuse the authorisation of the clinical investigation if:

(a) the application dossier submitted pursuant to Article 70(1) remains incomplete;

(b) the device or the submitted documents, especially the investigation plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the clinical investigation, in particular, is not suitable for providing evidence for the safety, performance characteristics or benefit of the device on subjects or patients,

(c) the requirements of Article 62 are not met, or

(d) any assessment under paragraph 3 is negative.

Member States shall provide for an appeal procedure in respect of a refusal pursuant to the first subparagraph.

Article 72

Conduct of a clinical investigation

1. The sponsor and the investigator shall ensure that the clinical investigation is conducted in accordance with the approved clinical investigation plan.

2. In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the clinical investigation is in compliance with the requirements of this Regulation, the sponsor shall ensure adequate monitoring of the conduct of a clinical investigation. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the clinical investigation including the following:

(a) the objective and methodology of the clinical investigation; and

(b) the degree of deviation of the intervention from normal clinical practice.

3. All clinical investigation information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.

4. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves transmission over a network.

5. Member States shall inspect, at an appropriate level, investigation site(s) to check that clinical investigations are conducted in accordance with the requirements of this Regulation and with the approved investigation plan.

6. The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the investigation.

Article 73

Electronic system on clinical investigations

1. The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system:

(a) to create the single identification numbers for clinical investigations referred to in Article 70(1);

(b) to be used as an entry point for the submission of all applications or notifications for clinical investigations referred to in Articles 70, 74, 75 and 78 and for all other submission of data, or processing of data in this context;

(c) for the exchange of information relating to clinical investigations in accordance with this Regulation between the Member States and between them and the Commission including the exchange of information referred to in Articles 70 and 76;

(d) for information to be provided by the sponsor in accordance with Article 77, including the clinical investigation report and its summary as required in paragraph 5 of that Article;

(e) for reporting on serious adverse events and device deficiencies and related updates referred to in Article 80.

2. When setting up the electronic system referred in paragraph 1 of this Article, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article 81 of Regulation (EU) No 536/2014 of the European Parliament and of the Council ([1]) as concerns combined clinical investigations of devices with a clinical trial under that Regulation.

3. The information referred to in point (c) of paragraph 1 shall only be accessible to the Member States and the Commission. The information referred to in the other points of that paragraph shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:

(a) protection of personal data in accordance with Regulation (EC) No 45/2001;

(b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure;

(c) effective supervision of the conduct of the clinical investigation by the Member State(s) concerned.

4. No personal data of subjects shall be publicly available.

5. The user interface of the electronic system referred to in paragraph 1 shall be available in all official languages of the Union.

([1]) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Article 74

Clinical investigations regarding devices bearing the CE marking

1. Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 20(1), ('PMCF investigation'), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73. The sponsor shall include the documentation referred to in Chapter II of Annex XV as part of the notification. Points (b) to (k) and (m) of Article 62(4), Article 75, Article 76, Article 77, Article 80(5) and the relevant provisions of Annex XV shall apply to PMCF investigations.

2. Where a clinical investigation is to be conducted to assess, outside the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 20(1), Articles 62 to 81 shall apply.

Article 75

Substantial modifications to clinical investigations

1. If a sponsor intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, it shall notify, within one week, by means of the electronic system referred to in Article 73 the Member State(s) in which the clinical investigation is being or is to be conducted of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation referred to in Chapter II of Annex XV as part of the notification. Changes to the relevant documentation shall be clearly identifiable.

2. The Member State shall assess any substantial modification to the clinical investigation in accordance with the procedure laid down in Article 71.

3. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 38 days after the notification referred to in that paragraph, unless:

(a) the Member State in which the clinical investigation is being or is to be conducted has notified the sponsor of its refusal based on the grounds referred to in Article 71(4) or on considerations of public health, subject and user safety or health, of public policy, or

(b) an ethics committee in that Member State has issued a negative opinion in relation to the substantial modification to the clinical investigation, which, in accordance with national law, is valid for that entire Member State.

4. The Member State(s) concerned may extend the period referred to in paragraph 3 by a further seven days, for the purpose of consulting with experts.

Article 76

Corrective measures to be taken by Member States and information exchange between Member States

1. Where a Member State in which a clinical investigation is being or is to be conducted has grounds for considering that the requirements set out in this Regulation are not met, it may take at least any of the following measures on its territory:

(a) revoke the authorisation for the clinical investigation;

(b) suspend or terminate the clinical investigation;

(c) require the sponsor to modify any aspect of the clinical investigation.

2. Before the Member State concerned takes any of the measures referred to in paragraph 1 it shall, except where immediate action is required, ask the sponsor or the investigator or both for their opinion. That opinion shall be delivered within seven days.

3. Where a Member State has taken a measure referred to in paragraph 1 of this Article or has refused a clinical investigation, or has been notified by the sponsor of the early termination of a clinical investigation on safety grounds, that Member State shall communicate the corresponding decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 73.

4. Where an application is withdrawn by the sponsor prior to a decision by a Member State, that information shall be made available through the electronic system referred to in Article 73 to all Member States and the Commission.

Article 77

Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination

1. If the sponsor has temporarily halted a clinical investigation or has terminated a clinical investigation early, it shall inform within 15 days the Member State in which that clinical investigation has been temporarily halted or terminated early, through the electronic system referred to in Article 73, of the temporary halt or early termination, providing a justification. In the event that the sponsor has temporarily halted or terminated early the clinical investigation on safety grounds, it shall inform all Member States in which that clinical investigation is being conducted thereof within 24 hours.

2. The end of a clinical investigation shall be deemed to coincide with the last visit of the last subject unless another point in time for such end is set out in the clinical investigation plan.

3. The sponsor shall notify each Member State in which a clinical investigation was being conducted of the end of that clinical investigation in that Member State. That notification shall be made within 15 days of the end of the clinical investigation in relation to that Member State.

4. If an investigation is conducted in more than one Member State, the sponsor shall notify all Member States in which that clinical investigation was conducted of the end of the clinical investigation in all Member States. That notification shall be made within 15 days of that end of the clinical investigation.

5. Irrespective of the outcome of the clinical investigation, within one year of the end of the clinical investigation or within three months of the early termination or temporary halt, the sponsor shall submit to the Member States in which a clinical investigation was conducted a clinical investigation report as referred to in Section 2.8 of Chapter I and Section 7 of Chapter III of Annex XV.

The clinical investigation report shall be accompanied by a summary presented in terms that are easily understandable to the intended user. Both the report and summary shall be submitted by the sponsor by means of the electronic system referred to in Article 73.

Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year of the end of the investigation, it shall be submitted as soon as it is available. In such case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XV shall specify when the results of the clinical investigation are going to be available, together with a justification.

6. The Commission shall issue guidelines regarding the content and structure of the summary of the clinical investigation report.

In addition, the Commission may issue guidelines for the formatting and sharing of raw data, for cases where the sponsor decides to share raw data on a voluntary basis. Those guidelines may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of clinical investigations.

7. The summary and the clinical investigation report referred to in paragraph 5 of this Article shall become publicly accessible through the electronic system referred to in Article 73, at the latest when the device is registered in accordance with Article 29 and before it is placed on the market. In cases of early termination or temporary halt, the summary and the report shall become publicly accessible immediately after submission.

If the device is not registered in accordance with Article 29 within one year of the summary and the report having been entered into the electronic system pursuant to paragraph 5 of this Article, they shall become publicly accessible at that point in time.

Article 78

Coordinated assessment procedure for clinical investigations

1. By means of the electronic system referred to in Article 73, the sponsor of a clinical investigation to be conducted in more than one Member State may submit, for the purpose of Article 70, a single application that, upon receipt, is transmitted electronically to all Member States in which the clinical investigation is to be conducted.

2. The sponsor shall propose in the single application referred to in paragraph 1 that one of the Member States in which the clinical investigation is to be conducted acts as coordinating Member State. The Member States in which the clinical investigation is to be conducted shall, within six days of submission of the application, agree on one of them taking the role of the coordinating Member State. If they do not agree on a coordinating Member State, the coordinating Member State proposed by the sponsor shall assume that role.

3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation referred to in Chapter II of Annex XV.

However, the completeness of the documentation referred to in Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV shall be assessed separately by each Member State concerned in accordance with Article 70(1) to (5).

4. With regard to documentation other than that referred to in the second subparagraph of paragraph 3, the coordinating Member State shall:

(a) within six days of receipt of the single application, notify the sponsor that it is the coordinating Member State ('notification date');

(b) for the purpose of the validation of the application, take into account any considerations submitted within seven days of the notification date by any Member State concerned;

(c) within 10 days of the notification date, assess whether the clinical investigation falls within the scope of this Regulation and whether the application is complete, and shall notify the sponsor accordingly. Article 70(1) and (3) to (5) shall apply to the coordinating Member State in relation to that assessment;

(d) establish the results of its assessment in a draft assessment report to be transmitted within 26 days of the validation date to the Member States concerned. By day 38 after the validation date, the other Member States concerned shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State which shall take due account of those comments and proposals in its finalisation of the final assessment report, to be transmitted within 45 days of the validation date to the sponsor and the other Member States concerned.

The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with Article 70(7).

5. As regards the assessment of the documentation referred to in the second subparagraph of paragraph 3, each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed 12 days from the receipt of the request. The expiry of the last deadline pursuant to point (d) of paragraph 4 shall be suspended from the date of the request until such time as the additional information has been received.

6. For class IIb and class III devices, the coordinating Member State may also extend the periods referred to in paragraph 4 by a further 50 days, for the purpose of consulting with experts.

7. The Commission may, by means of implementing acts, further specify the procedures and timescales for coordinated assessments to be taken into account by Member States concerned when deciding on the sponsor's application. Such implementing acts may also set out the procedures and timescales for coordinated assessment in the case of substantial modifications pursuant to paragraph 12 of this Article, in the case of reporting of adverse events pursuant to Article 80(4) and in the case of clinical investigations of combination products between medical devices and medicinal products, where the latter are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) No 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

8. Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the conduct of the clinical investigation is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of all Member States concerned.

Notwithstanding the first subparagraph, a Member State concerned may only disagree with the conclusion of the coordinating Member State concerning the area of coordinated assessment on the following grounds:

(a) when it considers that participation in the clinical investigation would lead to a subject receiving treatment inferior to that received in normal clinical practice in that Member State concerned;

(b) infringement of national law; or

(c) considerations as regards subject safety and data reliability and robustness submitted under point (b) of paragraph 4.

Where one of the Member States concerned disagrees with the conclusion on the basis of the second subparagraph of this paragraph, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 73, to the Commission, to all other Member States concerned and to the sponsor.

9. Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the clinical investigation is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.

10. A Member State concerned shall refuse to authorise a clinical investigation if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 8, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV are not complied with, or where an ethics committee has issued a negative opinion in relation to that clinical investigation, which is valid, in accordance with national law, for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

11. Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 73 as to whether the clinical investigation is authorised, whether it is authorised subject to conditions, or whether authorisation has been refused. Notification shall be done by way of one single decision within five days of the transmission, pursuant to point (d) of paragraph 4, by the coordinating Member State of the final assessment report. Where an authorisation of a clinical investigation is subject to conditions, those conditions may only be such that, by their nature, they cannot be fulfilled at the time of that authorisation.

12. Any substantial modifications as referred to in Article 75 shall be notified to the Member States concerned by means of the electronic system referred to in Article 73. Any assessment as to whether there are grounds for disagreement as referred to in the second subparagraph of paragraph 8 of this Article shall be carried out under the direction of the coordinating Member State, except for substantial modifications concerning Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV, which shall be assessed separately by each Member State concerned.

13. The Commission shall provide administrative support to the coordinating Member State in the accomplishment of its tasks under this Chapter.

14. The procedure set out in this Article shall, until 27 May 2027, be applied only by those of the Member States in which the clinical investigation is to be conducted which have agreed to apply it. After 27 May 2027, all Member States shall be required to apply that procedure.

Article 79

Review of coordinated assessment procedure

By 27 May 2026, the Commission shall submit to the European Parliament and to the Council a report on experience gained from the application of Article 78 and, if necessary, propose a review of Article 78(14) and point (h) of Article 123(3).

Article 80

Recording and reporting of adverse events that occur during clinical investigations

1. The sponsor shall fully record all of the following:

(a) any adverse event of a type identified in the clinical investigation plan as being critical to the evaluation of the results of that clinical investigation;

(b) any serious adverse event;

(c) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(d) any new findings in relation to any event referred to in points (a) to (c).

2. The sponsor shall report, without delay to all Member States in which the clinical investigation is being conducted, all of the following by means of the electronic system referred to in Article 73:

(a) any serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;

(b) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(c) any new findings in relation to any event referred to in points (a) and (b).

The period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report.

Upon request by any Member State in which the clinical investigation is being conducted, the sponsor shall provide all information referred to in paragraph 1.

3. The sponsor shall also report to the Member States in which the clinical investigation is being conducted any event referred to in paragraph 2 of this Article that occurred in third countries in which a clinical investigation is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Regulation by means of the electronic system referred to in Article 73.

4. In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 78, the sponsor shall report any event as referred to in paragraph 2 of this Article by means of the electronic system referred to in Article 73. Upon receipt, this report shall be transmitted electronically to all Member States in which the clinical investigation is being conducted.

Under the direction of the coordinating Member State referred to in Article 78(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether to modify, suspend or terminate the clinical investigation or whether to revoke the authorisation for that clinical investigation.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of PMCF investigations referred to in Article 74(1), the provisions on vigilance laid down in Articles 87 to 90 and in the acts adopted pursuant to Article 91 shall apply instead of this Article.

6. Notwithstanding paragraph 5, this Article shall apply where a causal relationship between the serious adverse event and the preceding investigational procedure has been established.

Article 81

Implementing acts

The Commission may, by means of implementing acts, establish the detailed arrangements and procedural aspects necessary for the implementation of this Chapter as regards the following:

(a) harmonised electronic forms for the application for clinical investigations and their assessment as referred to in Articles 70 and 78, taking into account specific categories or groups of devices;

(b) the functioning of the electronic system referred to in Article 73;

(c) harmonised electronic forms for the notification of PMCF investigations as referred to in Article 74(1), and of substantial modifications as referred to in Article 75;

(d) the exchange of information between Member States as referred to in Article 76;

(e) harmonised electronic forms for the reporting of serious adverse events and device deficiencies as referred to in Article 80;

(f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 80;

(g) uniform application of the requirements regarding the clinical evidence or data needed to demonstrate compliance with the general safety and performance requirements set out in Annex I.

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 82

Requirements regarding other clinical investigations

1. Clinical investigations, not performed pursuant to any of the purposes listed in Article 62(1), shall comply with the provisions of Article 62 (2) and (3), points (b), (c), (d), (f), (h), and (l) of Article 62(4) and Article 62(6).

2. In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in Article 62(1), each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned.

CHAPTER VII

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

SECTION 1

Post-market surveillance

Article 83

Post-market surveillance system of the manufacturer

1. For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).

2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

(a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

(b) to update the design and manufacturing information, the instructions for use and the labelling;

(c) to update the clinical evaluation;

(d) to update the summary of safety and clinical performance referred to in Article 32;

(e) for the identification of needs for preventive, corrective or field safety corrective action;

(f) for the identification of options to improve the usability, performance and safety of the device;

(g) when relevant, to contribute to the post-market surveillance of other devices; and

(h) to detect and report trends in accordance with Article 88.

The technical documentation shall be updated accordingly.

4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.

Article 84

Post-market surveillance plan

The post-market surveillance system referred to in Article 83 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1.1 of Annex III. For devices other than custom-made devices, the post-market surveillance plan shall be part of the technical documentation specified in Annex II.

Article 85

Post-market surveillance report

Manufacturers of class I devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.

Article 86

Periodic safety update report

1. Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) the conclusions of the benefit-risk determination;

(b) the main findings of the PMCF; and

(c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of class IIb and class III devices shall update the PSUR at least annually. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

Manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.

2. For class III devices or implantable devices, manufacturers shall submit PSURs by means of the electronic system referred to in Article 92 to the notified body involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by the notified body shall be made available to competent authorities through that electronic system.

3. For devices other than those referred to in paragraph 2, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

SECTION 2

Vigilance

Article 87

Reporting of serious incidents and field safety corrective actions

1. Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7), the following:

(a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 92.

2. As a general rule, the period for the reporting referred to in paragraph 1 shall take account of the severity of the serious incident.

3. Manufacturers shall report any serious incident as referred to in point (a) of paragraph 1 immediately after they have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 15 days after they become aware of the incident.

4. Notwithstanding paragraph 3, in the event of a serious public health threat the report referred to in paragraph 1 shall be provided immediately, and not later than 2 days after the manufacturer becomes aware of that threat.

5. Notwithstanding paragraph 3, in the event of death or an unanticipated serious deterioration in a person's state of health the report shall be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

6. Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

7. If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with paragraphs 2 to 5.

8. Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field safety corrective action referred to in point (b) of paragraph 1 in advance of the field safety corrective action being undertaken.

9. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 89(9), in consultation with the competent authorities referred to in point (a) of Article 92(8), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 92(8), the manufacturer may provide periodic summary reports following agreement with that competent authority.

10. The Member States shall take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents referred to in point (a) of paragraph 1.

The competent authorities shall record centrally at national level reports they receive from healthcare professionals, users and patients.

11. Where a competent authority of a Member State obtains such reports on suspected serious incidents referred to in point (a) of paragraph 1 from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide a report in accordance with paragraphs 1 to 5 of this Article on that serious incident to the competent authority of the Member State in which that serious incident occurred and shall take the appropriate follow-up action in accordance with Article 89.

Where the manufacturer of the device concerned considers that the incident is not a serious incident or is an expected undesirable side-effect, which will be covered by trend reporting in accordance with Article 88, it shall provide an explanatory statement. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with paragraphs 1 to 5 of this Article and require it to ensure that appropriate follow-up action is taken in accordance with Article 89.

Article 88

Trend reporting

1. Manufacturers shall report, by means of the electronic system referred to in Article 92, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.

The manufacturer shall specify how to manage the incidents referred to in the first subparagraph and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan referred to in Article 84.

2. The competent authorities may conduct their own assessments on the trend reports referred to in paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. Each competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such assessment and of the adoption of such measures.

Article 89

Analysis of serious incidents and field safety corrective actions

1. Following the reporting of a serious incident pursuant to Article 87(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include a risk assessment of the incident and field safety corrective action taking into account criteria as referred to in paragraph 3 of this Article as appropriate.

The manufacturer shall co-operate with the competent authorities and where relevant with the notified body concerned during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 87 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer, and, where relevant, the notified body concerned.

3. In the context of the evaluation referred to in paragraph 2, the competent authority shall evaluate the risks arising from the reported serious incident and evaluate any related field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm, the severity of that harm, the clinical benefit of the device, intended and potential users, and population affected. The competent authority shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety contained in Annex I.

Upon request by the national competent authority, manufacturers shall provide all documents necessary for the risk assessment.

4. The competent authority shall monitor the manufacturer's investigation of a serious incident. Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.

5. The manufacturer shall provide a final report to the competent authority setting out its findings from the investigation by means of the electronic system referred to in Article 92. The report shall set out conclusions and where relevant indicate corrective actions to be taken.

6. In the case of devices referred to in the first subparagraph of Article 1(8) and where the serious incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall, inform the national competent authority or the EMA, depending on which issued the scientific opinion on that substance under Article 52(9), of that serious incident or field safety corrective action.

In the case of devices covered by this Regulation in accordance with point (g) of Article 1(6) and where the serious incident or field safety corrective action may be related to the derivatives of tissues or cells of human origin utilised for the manufacture of the device, and in the case of devices falling under this Regulation pursuant to Article 1(10), the competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall inform the competent authority for human tissues and cells that was consulted by the notified body in accordance with Article 52(10).

7. After carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority shall, through the electronic system referred to in Article 92, inform, without delay, the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying events and the outcome of its assessment.

8. The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The field safety notice shall be edited in an official Union language or languages determined by the Member State in which the field safety corrective action is taken. Except in cases of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in the cases referred to in paragraph 9, to the coordinating competent authority to allow it to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

The field safety notice shall allow the correct identification of the device or devices involved, in particular by including the relevant UDIs, and the correct identification, in particular, by including the SRN, if already issued, of the manufacturer that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons, and shall clearly indicate all the actions to be taken by users.

The manufacturer shall enter the field safety notice in the electronic system referred to in Article 92 through which that notice shall be accessible to the public.

9. The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 in the following cases:

(a) where there is concern regarding a particular serious incident or cluster of serious incidents relating to the same device or type of device of the same manufacturer in more than one Member State;

(b) where the appropriateness of a field safety corrective action that is proposed by a manufacturer in more than one Member State is in question.

That coordinated procedure shall cover the following:

— designation of a coordinating competent authority on a case by case basis, when required;

— defining the coordinated assessment process, including the tasks and responsibilities of the coordinating competent authority and the involvement of other competent authorities.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the competent authority of the Member State in which the manufacturer has its registered place of business.

The coordinating competent authority shall, through the electronic system referred to in Article 92, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

10. The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.

11. The Commission shall provide administrative support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

Article 90

Analysis of vigilance data

The Commission shall, in collaboration with the Member States, put in place systems and processes to actively monitor the data available in the electronic system referred to in Article 92, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, which shall then take the necessary corrective actions.

Article 91

Implementing acts

The Commission may, by means of implementing acts, and after consultation of the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 85 to 90 and 92 as regards the following:

(a) the typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision of periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 85, 86, 87, 88 and 89 respectively;

(c) standard structured forms for electronic and non-electronic reporting, including a minimum data set for reporting of suspected serious incidents by healthcare professionals, users and patients;

(d) timelines for the reporting of field safety corrective actions, and for the provision by manufacturers of periodic summary reports and trend reports, taking into account the severity of the incident to be reported as referred to in Article 87;

(e) harmonised forms for the exchange of information between competent authorities as referred to in Article 89;

(f) procedures for the designation of a coordinating competent authority; the coordinated evaluation process, including tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 92

Electronic system on vigilance and on post-market surveillance

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 87(1) and Article 89(5);

(b) the periodic summary reports by manufacturers referred to in Article 87(9);

(c) the reports by manufacturers on trends referred to in Article 88;

(d) the PSURs referred to in Article 86;

(e) the field safety notices by manufacturers referred to in Article 89(8);

(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 89(7) and (9).

That electronic system shall include relevant links to the UDI database.

2. The information referred to in paragraph 1 of this Article shall be made available through the electronic system to the competent authorities of the Member States and to the Commission. The notified bodies shall also have access to that information to the extent that it relates to devices for which they issued a certificate in accordance with Article 53.

3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system referred to in paragraph 1.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the electronic system referred to in paragraph 1 at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents referred to in point (a) of Article 87(1) shall be automatically transmitted, upon receipt, via the electronic system referred to in paragraph 1 of this Article, to the competent authority of the Member State in which the incident occurred.

6. The trend reports referred to in Article 88(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the Member State in which the incidents occurred.

7. The reports on field safety corrective actions referred to in point (b) of Article 87(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the following Member States:

(a) the Member States in which the field safety corrective action is being or is to be undertaken;

(b) the Member State in which the manufacturer has its registered place of business.

8. The periodic summary reports referred to in Article 87(9) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authority of:

(a) the Member State or Member States participating in the coordination procedure in accordance with Article 89(9) and which have agreed on the periodic summary report;

(b) the Member State in which the manufacturer has its registered place of business.

9. The information referred to in paragraphs 5 to 8 of this Article shall be automatically transmitted, upon receipt, through the electronic system referred to in paragraph 1 of this Article, to the notified body that issued the certificate for the device in question in accordance with Article 56.

SECTION 3

Market surveillance

Article 93

Market surveillance activities

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

2. The competent authorities shall draw up annual surveillance activity plans and allocate a sufficient number of material and competent human resources in order to carry out those activities taking into account the European market surveillance programme developed by the MDCG pursuant to Article 105 and local circumstances.

3. In order to fulfil the obligations laid down in paragraph 1, the competent authorities:

(a) may require economic operators to, *inter alia*, make available the documentation and information necessary for the purpose of carrying out the authorities' activities and, where justified, to provide the necessary samples of devices or access to devices free of charge; and

(b) shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.

4. The competent authorities shall prepare an annual summary of the results of their surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 100.

5. The competent authorities may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk or falsified devices where they deem it necessary to do so in the interests of the protection of public health.

6. Following each inspection carried out for the purposes referred to in paragraph 1, the competent authority shall draw up a report on the findings of the inspection that concern compliance with the legal and technical requirements applicable under this Regulation. The report shall set out any corrective actions needed.

7. The competent authority which carried out the inspection shall communicate the content of the report referred to in paragraph 6 of this Article to the economic operator that has been the subject of the inspection. Before adopting the final report, the competent authority shall give that economic operator the opportunity to submit comments. That final inspection report shall be entered in the electronic system provided for in Article 100.

8. The Member States shall review and assess the functioning of their market surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. Each Member State shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 100.

9. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States.

Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.

10. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.

11. Where appropriate, the competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

Article 94

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe that a device:

(a) may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health; or

(b) otherwise does not comply with the requirements laid down in this Regulation,

they shall carry out an evaluation of the device concerned covering all requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device.

The relevant economic operators shall cooperate with the competent authorities.

Article 95

Procedure for dealing with devices presenting an unacceptable risk to health and safety

1. Where, having performed an evaluation pursuant to Article 94, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, its authorised representative and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Regulation relating to the risk presented by the device and, in a manner that is proportionate to the nature of the risk, to restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator.

2. The competent authorities shall, without delay, notify the Commission, the other Member States and, where a certificate has been issued in accordance with Article 56 for the device concerned, the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 100.

3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken throughout the Union in respect of all the devices concerned that they have made available on the market.

4. Where the economic operator as referred to in paragraph 1 does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it.

The competent authorities shall notify the Commission, the other Member States and the notified body referred to in paragraph 2 of this Article, without delay, of those measures, by means of the electronic system referred to in Article 100.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.

6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 100, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned.

In the event of disagreement with the notified national measure, they shall, without delay, inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 100.

7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified.

In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market, are taken without delay in respect of the device concerned.

Article 96

Procedure for evaluating national measures at Union level

1. Where, within two months of receipt of the notification referred to in Article 95(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall, after consulting the competent authorities concerned and, where necessary, the economic operators concerned, evaluate that national measure. On the basis of the results of that evaluation, the Commission may decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

2. Where the Commission considers the national measure to be justified as referred to in paragraph 1 of this Article, the second subparagraph of Article 95(7) shall apply. If the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure.

Where the Commission does not adopt a decision pursuant to paragraph 1 of this Article within eight months of receipt of the notification referred to in Article 95(4), the national measure shall be considered to be justified.

3. Where a Member State or the Commission considers that the risk to health and safety emanating from a device cannot be mitigated satisfactorily by means of measures taken by the Member State or Member States concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 97

Other non-compliance

1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 of this Article, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 100.

3. In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 98

Preventive health protection measures

1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices, considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, it may take any necessary and justified measures.

2. The Member State referred to in paragraph 1 shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 100.

3. The Commission, in consultation with the MDCG and, where necessary, the economic operators concerned, shall assess the national measures taken. The Commission may decide, by means of implementing acts, whether the national measures are justified or not. In the absence of a Commission decision within six months of their notification, the national measures shall be considered to be justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

4. Where the assessment referred to in paragraph 3 of this Article demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission may adopt implementing acts to take the necessary and duly justified measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 99

Good administrative practice

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 95 to 98 shall state the exact grounds on which it is based. Where such a measure is addressed to a specific economic operator, the competent authority shall notify without delay the economic operator concerned of that measure, and shall at the same time inform that economic operator of the remedies available under the law or the administrative practice of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general applicability, it shall be appropriately published.

2. Except in cases where immediate action is necessary for reasons of unacceptable risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time that is clearly defined before any measure is adopted.

Where action has been taken without the economic operator having had the opportunity to make submissions as referred to in the first subparagraph, it shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that it has taken effective corrective action and that the device is in compliance with the requirements of this Regulation.

4. Where a measure adopted pursuant to Articles 95 to 98 concerns a device for which a notified body has been involved in the conformity assessment, the competent authorities shall by means of the electronic system referred to in Article 100 inform the relevant notified body and the authority responsible for the notified body of the measure taken.

Article 100

Electronic system on market surveillance

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:

(a) summaries of the results of the surveillance activities referred to in Article 93(4);

(b) the final inspection report referred to in Article 93(7);

(c) information in relation to devices presenting an unacceptable risk to health and safety as referred to in Article 95(2), (4) and (6);

(d) information in relation to non-compliance of products as referred to in Article 97(2);

(e) information in relation to the preventive health protection measures referred to in Article 98(2);

(f) summaries of the results of the reviews and assessments of the market surveillance activities of the Member States referred to in 93(8).

2. The information referred to in paragraph 1 of this Article shall be immediately transmitted through the electronic system to all competent authorities concerned and, where applicable, to the notified body that issued a certificate in accordance with Article 56 for the device concerned and be accessible to the Member States and to the Commission.

3. Information exchanged between Member States shall not be made public where to do so might impair market surveillance activities and co-operation between Member States.

CHAPTER VIII

COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS

Article 101

Competent authorities

The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.

Article 102

Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.

2. Member States shall, with the support of the Commission, participate, where appropriate, in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

Article 103

Medical Device Coordination Group

1. A Medical Device Coordination Group ('MDCG') is hereby established.

2. Each Member State shall appoint to the MDCG, for a three-year term which may be renewed, one member and one alternate each with expertise in the field of medical devices, and one member and one alternate with expertise in the field of *in vitro* diagnostic medical devices. A Member State may choose to appoint only one member and one alternate, each with expertise in both fields.

The members of the MDCG shall be chosen for their competence and experience in the field of medical devices and *in vitro* diagnostic medical devices. They shall represent the competent authorities of the Member States. The names and affiliation of members shall be made public by the Commission.

The alternates shall represent and vote for the members in their absence.

3. The MDCG shall meet at regular intervals and, where the situation requires, upon request by the Commission or a Member State. The meetings shall be attended either by the members appointed for their role and expertise in the field of medical devices, or by the members appointed for their expertise in the field of *in vitro* diagnostic medical devices, or by the members appointed for their expertise in both fields, or their alternates, as appropriate.

4. The MDCG shall use its best endeavours to reach consensus. If such consensus cannot be reached, the MDCG shall decide by a majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the MDCG's position.

5. The MDCG shall be chaired by a representative of the Commission. The chair shall not take part in votes of the MDCG.

6. The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.

7. The MDCG may establish standing or temporary sub-groups. Where appropriate, organisations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level shall be invited to such sub-groups in the capacity of observers.

8. The MDCG shall establish its rules of procedure which shall, in particular, lay down procedures for the following:

— the adoption of opinions or recommendations or other positions, including in cases of urgency;

— the delegation of tasks to reporting and co-reporting members;

— the implementation of Article 107 regarding conflict of interests;

— the functioning of sub-groups.

9. The MDCG shall have the tasks laid down in Article 105 of this Regulation and Article 99 of Regulation (EU) 2017/746.

Article 104

Support by the Commission

The Commission shall support the functioning of the cooperation between national competent authorities. It shall, in particular, provide for the organisation of exchanges of experience between the competent authorities and provide technical, scientific and logistic support to the MDCG and its sub-groups. It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings and ensure the appropriate follow-up.

Article 105

Tasks of the MDCG

Under this Regulation, the MDCG shall have the following tasks:

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 49;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of clinical evaluations and investigations by manufacturers, assessment by notified bodies and vigilance activities;

(d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation and Regulation (EU) 2017/746 are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation;

(e) to contribute to the development of device standards, of CS and of scientific guidelines, including product specific guidelines, on clinical investigation of certain devices in particular implantable devices and class III devices;

(f) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93;

(g) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;

(h) to contribute to harmonised administrative practice with regard to devices in the Member States.

Article 106

Provision of scientific, technical and clinical opinions and advice

1. The Commission shall, by means of implementing acts and in consultation with the MDCG, make provision for expert panels to be designated for the assessment of the clinical evaluation in relevant medical fields as referred to in paragraph 9 of this Article and to provide views in accordance with Article 48(6) of Regulation (EU) 2017/746 on the performance evaluation of certain *in vitro* diagnostic medical devices and, where necessary, for categories or groups of devices, or for specific hazards relating to categories or groups of devices, observing the principles of highest scientific competence, impartiality, independence and transparency. The same principles shall apply where the Commission decides to appoint expert laboratories in accordance with paragraph 7 of this Article.

2. Expert panels and expert laboratories may be designated in areas where the Commission, in consultation with the MDCG, has identified a need for the provision of consistent scientific, technical and/or clinical advice or laboratory expertise in relation to the implementation of this Regulation. Expert panels and expert laboratories may be appointed on a standing or temporary basis.

3. Expert panels shall consist of advisors appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union. The Commission shall determine the number of members of each panel in accordance with the requisite needs.

The members of expert panels shall perform their tasks with impartiality and objectivity. They shall neither seek nor take instructions from notified bodies or manufacturers. Each member shall draw up a declaration of interests, which shall be made publicly available.

The Commission shall establish systems and procedures to actively manage and prevent potential conflicts of interest.

4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals when preparing their scientific opinions.

5. The Commission, following consultation with the MDCG, may appoint advisors to expert panels following publication in the *Official Journal of the European Union* and on the Commission website following a call for expressions of interest. Depending on the type of task and the need for specific expertise, advisors may be appointed to the expert panels for a maximum period of three years and their appointment may be renewed.

6. The Commission, following consultation with the MDCG, may include advisors on a central list of available experts who, whilst not being formally appointed to a panel, are available to provide advice and to support the work of the expert panel as needed. That list shall be published on the Commission website.

7. The Commission may, by means of implementing acts and following consultation with the MDCG, designate expert laboratories, on the basis of their expertise in:

— physico-chemical characterisation, or

— microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical biological and toxicological testing

of specific devices, categories or groups of devices.

The Commission shall only designate expert laboratories for which a Member State or the Joint Research Centre has submitted an application for designation.

8. Expert laboratories shall satisfy the following criteria:

(a) have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the devices for which they are designated;

(b) possess the necessary equipment to carry out the tasks assigned to them;

(c) have the necessary knowledge of international standards and best practices;

(d) have an appropriate administrative organisation and structure;

(e) ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks.

9. Expert panels appointed for clinical evaluation in relevant medical fields shall fulfil the tasks provided for in Article 54(1) and Article 61(2) and Section 5.1 of Annex IX or Section 6 of Annex X, as applicable.

10. Expert panels and expert laboratories may have the following tasks, depending on the requisite needs:

(a) to provide scientific, technical and clinical assistance to the Commission and the MDCG in relation to the implementation of this Regulation;

(b) to contribute to the development and maintenance of appropriate guidance and CS for:

— clinical investigations,

— clinical evaluation and PMCF,

— performance studies,

— performance evaluation and post-market performance follow-up,

— physico-chemical characterisation, and

— microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing

for specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices;

(c) to develop and review clinical evaluation guidance and performance evaluation guidance for performance of conformity assessment in line with the state of the art with regard to clinical evaluation, performance evaluation, physico-chemical characterisation, and microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing;

(d) to contribute to the development of standards at international level, ensuring that such standards reflect the state of the art;

(e) to provide opinions in response to consultations by manufacturers in accordance with Article 61(2), notified bodies and Member States in accordance with paragraphs 11 to 13 of this Article.

(f) to contribute to identification of concerns and emerging issues on the safety and performance of medical devices;

(g) to provide views in accordance with Article 48(4) of Regulation (EU) 2017/746 on the performance evaluation of certain *in vitro* diagnostic medical devices.

11. The Commission, shall facilitate the access of Member States and notified bodies and manufacturers to advice provided by expert panels and expert laboratories concerning, *inter alia*, the criteria for an appropriate data set for assessment of the conformity of a device, in particular with regard to the clinical data required for clinical evaluation, with regard to physico-chemical characterisation, and with regard to microbiological, biocompatibility, mechanical, electrical, electronic and non-clinical toxicological testing.

12. When adopting its scientific opinion in accordance with paragraph 9, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by a majority of their members, and the scientific opinion shall mention the divergent positions and the grounds on which they are based.

The Commission shall publish the scientific opinion and advice delivered in accordance with paragraphs 9 and 11 of this Article, ensuring consideration of aspects of confidentiality as set out in Article 109. The clinical evaluation guidance referred to in point (c) of paragraph 10 shall be published following consultation with the MDCG.

13. The Commission may require manufacturers and notified bodies to pay fees for the advice provided by expert panels and expert laboratories. The structure and the level of fees as well as the scale and structure of recoverable costs shall be adopted by the Commission by means of implementing acts, taking into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

14. The fees payable to the Commission in accordance with the procedure under paragraph 13 of this Article shall be set in a transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation consultation procedure initiated in accordance with point (c) of Section 5.1 of Annex IX involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC.

15. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the tasks of expert panels and expert laboratories referred to in paragraph 10 of this Article.

Article 107

Conflict of interests

1. Members of the MDCG, its sub-groups, and members of expert panels and expert laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct or indirect interests they may have in the medical device industry and update that declaration whenever a relevant change occurs. The declaration of interests shall be made publicly available on the Commission website. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.

2. Experts and other third parties invited by the MDCG on a case-by-case basis shall declare any interests they may have in the issue in question.

Article 108

Device registers and databanks

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices setting common principles to collect comparable information. Such registers and databanks shall contribute to the independent evaluation of the long-term safety and performance of devices, or the traceability of implantable devices, or all of such characteristics.

CHAPTER IX

CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES

Article 109

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

(a) personal data, in accordance with Article 110;

(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights; unless disclosure is in the public interest;

(c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.

2. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission shall not be disclosed without the prior agreement of the originating authority.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 110

Data protection

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

Article 111

Levying of fees

1. This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.

2. Member States shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. The structure and level of fees shall be made publicly available on request.

Article 112

Funding of activities related to designation and monitoring of notified bodies

The costs associated with joint assessment activities shall be covered by the Commission. The Commission shall, by means of implementing acts, lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 113

Penalties

The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify the Commission of those rules and of those measures by 25 February 2020 and shall notify it, without delay, of any subsequent amendment affecting them.

CHAPTER X

FINAL PROVISIONS

Article 114

Committee procedure

1. The Commission shall be assisted by a Committee on Medical Devices. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or 5 thereof, as appropriate, shall apply.

Article 115

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) shall be conferred on the Commission for a period of five years from 25 May 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Article 116

Separate delegated acts for different delegated powers

The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.

Article 117

Amendment to Directive 2001/83/EC

In Annex I to Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

'(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council (*), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.

(*) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).'.

Article 118

Amendment to Regulation (EC) No 178/2002

In the third paragraph of Article 2 of Regulation (EC) No 178/2002, the following point is added:

'(i) medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council (*).

(*) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).'.

Article 119

Amendment to Regulation (EC) No 1223/2009

In Article 2 of Regulation (EC) No 1223/2009, the following paragraph is added:

'4. The Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition 'cosmetic product'. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 32(2).'.

Article 120

Transitional provisions

1. From 26 May 2020, any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.

2. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022.

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.

5. By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market prior to 26 May 2020.

6. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior 26 May 2020. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2020.

7. As regards devices subject to the consultation procedure laid down in Article 54, paragraph 5 of this Article shall apply provided that the necessary appointments to the MDCG and expert panels have been made.

8. By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to point (d) of Article 123(3) and ending 18 months later, comply with Article 29(4) and Article 56(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Decision 2010/227/EU.

9. Authorisations granted by the competent authorities of the Member States in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC shall keep the validity indicated in the authorisation.

10. Devices falling within the scope of this Regulation in accordance with points (f) and (g) of Article 1(6) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to 26 May 2020 may continue to be placed on the market and put into service in the Member States concerned.

11. Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to 26 May 2020 may continue to be conducted. As of 26 May 2020, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with this Regulation.

12. Until the Commission has designated, pursuant to Article 27(2), issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities.

Article 121

Evaluation

By 27 May 2027, the Commission shall assess the application of this Regulation and produce an evaluation report on the progress towards achievement of the objectives contained herein including an assessment of the resources required to implement this Regulation. Special attention shall be given to the traceability of medical devices through the storage, pursuant to Article 27, of the UDI by economic operators, health institutions and health professionals.

Article 122

Repeal

Without prejudice to Articles 120(3) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2020, with the exception of:

— Articles 8 and 10, points (b) and (c) of Article 10b(1), Article 10b(2) and Article 10b(3) of Directive 90/385/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation;

— Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation;

— Article 10, points (c) and (d) of Article 14a(1), Article 14a(2), Article 14a(3) and Article 15 of Directive 93/42/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation; and

— Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation.

As regards the devices referred to in Article 120 (3) and (4) of this Regulation, the Directives referred to in the first paragraph shall continue to apply until 27 May 2025 to the extent necessary for the application of those paragraphs.

Notwithstanding the first paragraph, Regulations (EU) No 207/2012 and (EU) No 722/2012 shall remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

References to the repealed Directives shall be understood as references to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVII to this Regulation.

Article 123

Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from 26 May 2020.

3. By way of derogation from paragraph 2:

(a) Articles 35 to 50 shall apply from 26 November 2017. However, from that date until 26 May 2020, the obligations on notified bodies pursuant to Articles 35 to 50 shall apply only to those bodies which submit an application for designation in accordance with Article 38;

(b) Articles 101 and 103 shall apply from 26 November 2017;

(c) Article 102 shall apply from 26 May 2018;

(d) without prejudice to the obligations on the Commission pursuant to Article 34, where, due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 34(1), Eudamed is not fully functional on 26 May 2020, the obligations and requirements that relate to Eudamed shall apply from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3). The provisions referred to in the preceding sentence are:

— Article 29,

— Article 31,

— Article 32,

— Article 33(4),

— the second sentence of Article 40(2),

— Article 42(10),

— Article 43(2),

— the second subparagraph of Article 44(12),

— points (d) and (e) of Article 46(7),

— Article 53(2),

— Article 54(3),

— Article 55(1),

— Articles 70 to 77,

— paragraphs 1 to 13 of Article 78,

— Articles 79 to 82,

— Article 86(2),

— Articles 87 and 88,

— Article 89(5) and (7), and the third subparagraph of Article 89(8),

— Article 90,

— Article 93(4), (7) and (8),

— Article 95(2) and (4),

— the last sentence of Article 97(2),

— Article 99(4),

— the second sentence of the first subparagraph of Article 120(3).

Until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and 93/42/EEC shall continue to apply for the purpose of meeting the obligations laid down in the provisions listed in the first paragraph of this point regarding exchange of information including, and in particular, information regarding vigilance reporting, clinical investigations, registration of devices and economic operators, and certificate notifications.

(e) Article 29(4) and Article 56(5) shall apply from 18 months after the later of the dates referred to in point (d);

(f) for implantable devices and for class III devices Article 27(4) shall apply from 26 May 2021. For class IIa and class IIb devices Article 27(4) shall apply from 26 May 2023. For class I devices Article 27(4) shall apply from 26 May 2025;

(g) for reusable devices that shall bear the UDI carrier on the device itself, Article 27(4) shall apply from two years after the date referred to in point (f) of this paragraph for the respective class of devices in that point;

(h) The procedure set out in Article 78 shall apply from 26 May 2027, without prejudice to Article 78(14);

(i) Article 120(12) shall apply from 26 May 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 5 April 2017.

For the European Parliament	*For the Council*
The President	*The President*
A. TAJANI	I. BORG

ANNEXES

I General safety and performance requirements

II Technical documentation

III Technical documentation on post-market surveillance

IV EU declaration of conformity

V CE marking of conformity

VI Information to be submitted upon the registration of devices and economic operators in accordance with Articles 29(4) and 31; core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 28 and 29;and the UDI system

VII Requirements to be met by notified bodies

VIII Classification rules

IX Conformity assessment based on a quality management system and assessment of the technical documentation

X Conformity assessment based on type examination

XI Conformity assessment based on product conformity verification

XII Certificates issued by a notified body

XIII Procedure for custom-made devices

XIV Clinical evaluation and post-market clinical follow-up

XV Clinical investigations

XVI List of groups of products without an intended medical purpose referred to in Article 1(2)

XVII Correlation table

ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

CHAPTER I

GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

3. Manufacturers shall establish, implement, document and maintain a risk management system.

Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

(a) establish and document a risk management plan for each device;

(b) identify and analyse the known and foreseeable hazards associated with each device;

(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;

(d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;

(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and

(f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:

(a) eliminate or reduce risks as far as possible through safe design and manufacture;

(b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and

(c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

Manufacturers shall inform users of any residual risks.

5. In eliminating or reducing risks related to use error, the manufacturer shall:

(a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

6. The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

8. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

9. For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.

CHAPTER II

REQUIREMENTS REGARDING DESIGN AND MANUFACTURE

10. Chemical, physical and biological properties

10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:

(a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;

(b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;

(c) the compatibility between the different parts of a device which consists of more than one implantable part;

(d) the impact of processes on material properties;

(e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;

(f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;

(g) surface properties; and

(h) the confirmation that the device meets any defined chemical and/or physical specifications.

10.2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.

10.3. Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.

10.4. Substances

10.4.1. Design and manufacture of devices

Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.

Devices, or those parts thereof or those materials used therein that:

— are invasive and come into direct contact with the human body,

— (re)administer medicines, body liquids or other substances, including gases, to/from the body, or

— transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,

shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:

(a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([1]), or

(b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council ([3]), in accordance with the criteria that are relevant to human health amongst the criteria established therein.

10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances

The justification for the presence of such substances shall be based upon:

(a) an analysis and estimation of potential patient or user exposure to the substance;

(b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;

(c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and

(d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.

10.4.3. Guidelines on phthalates

For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.

([1]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([2]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).

([3]) Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

10.4.4. Guidelines on other CMR and endocrine-disrupting substances

Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.

10.4.5. Labelling

Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.

10.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

10.6. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.

11. Infection and microbial contamination

11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:

(a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,

(b) allow easy and safe handling,

(c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and

(d) prevent microbial contamination of the device or its content such as specimens or fluids.

11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.

11.3. Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

11.4. Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.

11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.

11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.

11.7. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

11.8. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.

12. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.

12.1. In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation.

12.2. Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.

13. Devices incorporating materials of biological origin

13.1. For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply:

(a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC;

(b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;

(c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.

13.2. For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:

(a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers;

(b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;

(c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.

13.3. For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

14. Construction of devices and interaction with their environment

14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.

14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

(a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;

(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;

(c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

(d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;

(e) the risks of accidental ingress of substances into the device;

(f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and

(g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

14.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.

14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.

14.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

14.6 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

14.7. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.

15. Devices with a diagnostic or measuring function

15.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.

15.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC [1].

[1] Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).

16. Protection against radiation

16.1. General

(a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

(b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.

16.2. Intended radiation

(a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

(b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.

16.3. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.

16.4. Ionising radiation

(a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

(b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment.

(c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user.

(d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.

17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

17.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).

17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

18. Active devices and devices connected to them

18.1. For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.

18.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.

18.3. Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.

18.4. Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

18.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.

18.6. Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.

18.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

18.8. Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.

19. Particular requirements for active implantable devices

19.1. Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:

(a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,

(b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and

(c) risks which may arise where maintenance and calibration are impossible, including:

— excessive increase of leakage currents,

— ageing of the materials used,

— excess heat generated by the device,

— decreased accuracy of any measuring or control mechanism.

19.2. Active implantable devices shall be designed and manufactured in such a way as to ensure

— if applicable, the compatibility of the devices with the substances they are intended to administer, and

— the reliability of the source of energy.

19.3. Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.

19.4. Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.

20. Protection against mechanical and thermal risks

20.1. Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

20.2. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

20.3. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

20.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.

20.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

20.6. Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

21. Protection against the risks posed to the patient or user by devices supplying energy or substances

21.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.

21.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

21.3. The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.

22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

22.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.

22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to:

— ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,

— reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and

— reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.

22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:

— can verify that, at the time of use, the device will perform as intended by the manufacturer, and

— if applicable, is warned if the device has failed to provide a valid result.

CHAPTER III

REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE

23. Label and instructions for use

23.1. General requirements regarding the information supplied by the manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.

(d) Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.

(e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.

(f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.

(g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.

(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

23.2. Information on the label

The label shall bear all of the following particulars:

(a) the name or trade name of the device;

(b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;

(c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;

(d) if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;

(e) where applicable, an indication that the device contains or incorporates:

— a medicinal substance, including a human blood or plasma derivative, or

— tissues or cells, or their derivatives, of human origin, or

— tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;

(f) where applicable, information labelled in accordance with Section 10.4.5.;

(g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;

(h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII;

(i) an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;

(j) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;

(k) an indication of any special storage and/or handling condition that applies;

(l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method;

(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;

(n) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;

(o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;

(p) if the device is custom-made, the words 'custom-made device';

(q) an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation';

(r) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action;

(s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.

23.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging')

The following particulars shall appear on the sterile packaging:

(a) an indication permitting the sterile packaging to be recognised as such,

(b) a declaration that the device is in a sterile condition,

(c) the method of sterilisation,

(d) the name and address of the manufacturer,

(e) a description of the device,

(f) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations',

(g) if the device is custom-made, the words 'custom-made device',

(h) the month and year of manufacture,

(i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and

(j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.

23.4. Information in the instructions for use

The instructions for use shall contain all of the following particulars:

(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2;

(b) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;

(c) where applicable, a specification of the clinical benefits to be expected.

(d) where applicable, links to the summary of safety and clinical performance referred to in Article 32;

(e) the performance characteristics of the device;

(f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;

(g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;

(h) specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it;

(i) details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;

(j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;

(k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

— details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,

— identification of any consumable components and how to replace them,

— information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and

— methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;

(l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;

(m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;

(n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;

(o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;

(p) if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request;

(q) for devices intended for use together with other devices and/or general purpose equipment:

— information to identify such devices or equipment, in order to obtain a safe combination, and/or

— information on any known restrictions to combinations of devices and equipment;

(r) if the device emits radiation for medical purposes:

— detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation,

— the means of protecting the patient, user, or other person from unintended radiation during use of the device;

(s) information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:

— warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,

— warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro-magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,

— warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,

— if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,

— warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and

— precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;

(t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose;

(u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;

(v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate:

— infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and

— physical hazards such as from sharps.

If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;

(w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;

(x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;

(y) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;

(z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

(aa) information to be supplied to the patient with an implanted device in accordance with Article 18;

(ab) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

(a) product or trade name and a general description of the device including its intended purpose and intended users;

(b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;

(c) the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;

(d) principles of operation of the device and its mode of action, scientifically demonstrated if necessary;

(e) the rationale for the qualification of the product as a device;

(f) the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;

(g) an explanation of any novel features;

(h) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;

(i) a description or complete list of the various configurations/variants of the device that are intended to be made available on the market;

(j) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

(k) a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;

(l) technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.

1.2. Reference to previous and similar generations of the device

(a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;

(b) an overview of identified similar devices available on the Union or international markets, where such devices exist.

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

A complete set of:

— the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; and

— the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.

3. DESIGN AND MANUFACTURING INFORMATION

(a) information to allow the design stages applied to the device to be understood;

(b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;

(c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:

(a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;

(b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;

(c) the harmonised standards, CS or other solutions applied; and

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

The documentation shall contain information on:

(a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and

(b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.

6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

6.1. Pre-clinical and clinical data

(a) results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;

(b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:

— the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;

— physical, chemical and microbiological characterisation;

— electrical safety and electromagnetic compatibility;

— software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);

— stability, including shelf life; and

— performance and safety.

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council ([1]) shall be demonstrated.

Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service;

(c) the clinical evaluation report and its updates and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV;

(d) the PMCF plan and PMCF evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable.

6.2. Additional information required in specific cases

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8), a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.

(b) Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6, and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first subparagraph of Article 1(10), a statement indicating this fact. In such a case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 13.1. or 13.2., respectively, of Annex I.

(c) In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:

— absorption, distribution, metabolism and excretion;

— possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions;

— local tolerance; and

— toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device.

In the absence of such studies, a justification shall be provided.

(d) In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I, the justification referred to in Section 10.4.2 of that Annex.

([1]) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

(e) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

(f) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

(g) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

ANNEX III

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

1.1. The post-market surveillance plan drawn up in accordance with Article 84.

The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 83.

(a) The post-market surveillance plan shall address the collection and utilization of available information, in particular:

— information concerning serious incidents, including information from PSURs, and field safety corrective actions;

— records referring to non-serious incidents and data on any undesirable side-effects;

— information from trend reporting;

— relevant specialist or technical literature, databases and/or registers;

— information, including feedbacks and complaints, provided by users, distributors and importers; and

— publicly available information about similar medical devices.

(b) The post-market surveillance plan shall cover at least:

— a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;

— effective and appropriate methods and processes to assess the collected data;

— suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I;

— effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;

— methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;

— methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;

— reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86;

— systematic procedures to identify and initiate appropriate measures including corrective actions;

— effective tools to trace and identify devices for which corrective actions might be necessary; and

— a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.

1.2. The PSUR referred to in Article 86 and the post-market surveillance report referred to in Article 85.

ANNEX IV

EU DECLARATION OF CONFORMITY

The EU declaration of conformity shall contain all of the following information:

1. Name, registered trade name or registered trade mark and, if already issued, SRN as referred to in Article 31 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;

2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;

3. The Basic UDI-DI as referred to in Part C of Annex VI;

4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;

5. Risk class of the device in accordance with the rules set out in Annex VIII;

6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;

7. References to any CS used and in relation to which conformity is declared;

8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;

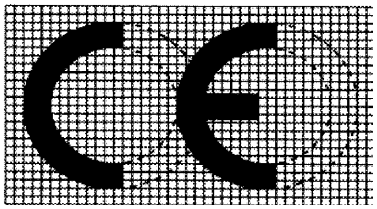
9. Where applicable, additional information;

10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

ANNEX V

CE MARKING OF CONFORMITY

1. The CE marking shall consist of the initials 'CE' taking the following form:



2. If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing shall be respected.

3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

ANNEX VI

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI SYSTEM

PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the information referred to in Section 1 and shall ensure that the information on their devices referred to in Section 2 is complete, correct and updated by the relevant party.

1. Information relating to the economic operator

1.1. type of economic operator(manufacturer, authorised representative, or importer),

1.2. name, address and contact details of the economic operator,

1.3. where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details of that person,

1.4. name address and contact details of the person or persons responsible for regulatory compliance referred to in Article 15.

2. Information relating to the device

2.1. Basic UDI-DI,

2.2. type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,

2.3. Member State in which the device is to or has been placed on the market in the Union,

2.4. in the case of class IIa, class IIb or class III devices: Member States where the device is or is to be made available,

2.5. risk class of the device,

2.6. reprocessed single-use device (y/n),

2.7. presence of a substance which, if used separately, may be considered to be a medicinal product and name of that substance,

2.8. presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma and name of this substance,

2.9. presence of tissues or cells of human origin, or their derivatives (y/n),

2.10. presence of tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 (y/n),

2.11. where applicable, the single identification number of the clinical investigation or investigations conducted in relation to the device or a link to the clinical investigation registration in the electronic system on clinical investigations,

2.12. in the case of devices listed in Annex XVI, specification as to whether the intended purpose of the device is other than a medical purpose,

2.13. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15), the name, address and contact details of that legal or natural person,

2.14. in the case of class III or implantable devices, the summary of safety and clinical performance,

2.15. status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29

The manufacturer shall provide to the UDI database the UDI-DI and all of the following information relating to the manufacturer and the device:

1. quantity per package configuration,
2. the Basic UDI-DI as referred to in Article 29 and any additional UDI-DIs,
3. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),
4. if applicable, the unit of use UDI-DI (where a UDI is not labelled on the device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a device with a patient),
5. name and address of the manufacturer (as indicated on the label),
6. the SRN issued in accordance with Article 31(2),
7. if applicable, name and address of the authorised representative (as indicated on the label),
8. the medical device nomenclature code as provided for in Article 26,
9. risk class of the device,
10. if applicable, name or trade name,
11. if applicable, device model, reference, or catalogue number,
12. if applicable, clinical size (including volume, length, gauge, diameter),
13. additional product description (optional),
14. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
15. if applicable, additional trade names of the device,
16. labelled as a single-use device (y/n),
17. if applicable, the maximum number of reuses,
18. device labelled sterile (y/n),
19. need for sterilisation before use (y/n),
20. containing latex (y/n),
21. where applicable, information labelled in accordance with Section 10.4.5 of Annex I,
22. URL for additional information, such as electronic instructions for use (optional),
23. if applicable, critical warnings or contra-indications,
24. status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

PART C

THE UDI SYSTEM

1. Definitions

Automatic identification and data capture ('AIDC')

AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

Unit of Use DI

The Unit of Use DI serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.

Configurable device

A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves.

Configurable devices include computed tomography (CT) systems, ultrasound systems, anaesthesia systems, physiological Monitoring systems, radiology information systems (RIS).

Configuration

Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together as a device to achieve an intended purpose. The combination of items may be modified, adjusted or customized to meet specific needs.

Configurations include *inter alia*:

— gantries, tubes, tables, consoles and other items of equipment that can be configured/combined to deliver an intended function in computed tomography.

— ventilators, breathing circuits, vaporizers combined to deliver an intended function in anaesthesia.

UDI-DI

The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database.

Human Readable Interpretation ('HRI')

HRI is a legible interpretation of the data characters encoded in the UDI carrier.

Packaging levels

Packaging levels means the various levels of device packaging that contain a defined quantity of devices, such as a carton or case.

UDI-PI

The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production.

The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.

Radio Frequency Identification RFID

RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

Shipping containers

A shipping container is a container in relation to which traceability is controlled by a process specific to logistics systems.

Unique Device Identifier ('UDI')

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

The word 'Unique' does not imply serialisation of individual production units.

UDI carrier

The UDI carrier is the means of conveying the UDI by using AIDC and, if applicable, its HRI.

UDI carriers include, *inter alia*, ID/linear bar code, 2D/Matrix bar code, RFID.

2. General requirements

2.1. The affixing of the UDI is an additional requirement — it does not replace any other marking or labelling requirements laid down in Annex I to this Regulation.

2.2. The manufacturer shall assign and maintain unique UDIs for its devices.

2.3. Only the manufacturer may place the UDI on the device or its packaging.

2.4. Only coding standards provided by issuing entities designated by the Commission pursuant to Article 27(2) may be used.

3. The UDI

3.1. A UDI shall be assigned to the device itself or its packaging. Higher levels of packaging shall have their own UDI.

3.2. Shipping containers shall be exempted from the requirement in Section 3.1. By way of example, a UDI shall not be required on a logistics unit; where a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) shall not be subject to UDI requirements.

3.3. The UDI shall contain two parts: a UDI-DI and a UDI-PI.

3.4. The UDI-DI shall be unique at each level of device packaging.

3.5. If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.

3.6. Each component that is considered to be a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.

3.7. Systems and procedure packs as referred to in Article 22 shall be assigned and bear their own UDI.

3.8. The manufacturer shall assign the UDI to a device following the relevant coding standard.

3.9. A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability; in particular, any change of one of the following UDI database data elements shall require a new UDI-DI:

(a) name or trade name,

(b) device version or model,

(c) labelled as single use,

(d) packaged sterile,

(e) need for sterilization before use,

(f) quantity of devices provided in a package,

(g) critical warnings or contra-indications: e.g. containing latex or DEHP.

3.10. Manufacturers that repackage and/or relabel devices, with their own label shall retain a record of the original device manufacturer's UDI.

4. UDI carrier

4.1. The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label or on the device itself and on all higher levels of device packaging. Higher levels do not include shipping containers.

4.2. In the event of there being significant space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level.

4.3. For single-use devices of classes I and IIa packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging but it shall appear on a higher level of packaging, e.g. a carton containing several individually packaged devices. However, when the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI shall be placed on the packaging of the individual device.

4.4. For devices exclusively intended for retail point of sale the UDI-PIs in AIDC shall not be required to appear on the point of sale packaging.

4.5. When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable.

4.6. If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.

4.7. If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI shall however appear on the label even if this results in there being no space for the AIDC.

4.8. The HRI format shall follow the rules of the UDI code-issuing entity.

4.9. If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities shall also be provided on the label.

4.10. Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device. The requirement of this Section shall not apply to devices in the following circumstances:

(a) any type of direct marking would interfere with the safety or performance of the device;

(b) the device cannot be directly marked because it is not technologically feasible.

4.11. The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device.

4.12. If the UDI carrier is readily readable or, in the case of AIDC, scannable, through the device's packaging, the placing of the UDI carrier on the packaging shall not be required.

4.13. In the case of single finished devices made up of multiple parts that must be assembled before their first use, it shall be sufficient to place the UDI carrier on only one part of each device.

4.14. The UDI carrier shall be placed in a manner such that the AIDC can be accessed during normal operation or storage.

4.15. Bar code carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data.

5. General principles of the UDI database

5.1. The UDI database shall support the use of all core UDI database data elements referred to in Part B of this Annex.

5.2. Manufacturers shall be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.

5.3. Appropriate methods/procedures for validation of the data provided shall be implemented.

5.4. Manufacturers shall periodically verify the correctness of all of the data relevant to devices they have placed on the market, except for devices that are no longer available on the market.

5.5. The presence of the device UDI-DI in the UDI database shall not be assumed to mean that the device is in conformity with this Regulation.

5.6. The database shall allow for the linking of all the packaging levels of the device.

5.7. The data for new UDI-DIs shall be available at the time the device is placed on the market.

5.8. Manufacturers shall update the relevant UDI database record within 30 days of a change being made to an element, which does not require a new UDI-DI.

5.9. Internationally-accepted standards for data submission and updates shall, wherever possible, be used by the UDI database.

5.10. The user interface of the UDI database shall be available in all official languages of the Union. The use of free-text fields shall, however, be minimized in order to reduce translations.

5.11. Data relating to devices that are no longer available on the market shall be retained in the UDI database.

6. Rules for specific device types

6.1. Implantable devices:

6.1.1. Implantable devices shall, at their lowest level of packaging ('unit packs'), be identified, or marked using AIDC, with a UDI (UDI-DI + UDI-PI);

6.1.2. The UDI-PI shall have at least the following characteristics:

(a) the serial number for active implantable devices,

(b) the serial number or lot number for other implantable devices.

6.1.3. The UDI of the implantable device shall be identifiable prior to implantation.

6.2. Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing between uses

6.2.1. The UDI of such devices shall be placed on the device and be readable after each procedure to make the device ready for the next use.

6.2.2. The UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer.

6.3. Systems and procedure packs as referred to in Article 22

6.3.1. The natural or legal person referred to in Article 22 shall be responsible for identifying the system or procedure pack with a UDI including both UDI-DI and UDI-PI.

6.3.2. Device contents of system or procedure packs shall bear a UDI carrier on their packaging or on the device itself.

Exemptions:

(a) individual single-use disposable devices, the uses of which are generally known to the persons by whom they are intended to be used, which are contained within a system or procedure pack, and which are not intended for individual use outside the context of the system or procedure pack, shall not be required to bear their own UDI carrier;

(b) devices that are exempted from bearing a UDI carrier on the relevant level of packaging shall not be required to bear a UDI carrier when included within a system or procedure pack.

6.3.3. Placement of the UDI carrier on systems or procedure packs

(a) The system or procedure pack UDI carrier shall as a general rule be affixed to the outside of the packaging.

(b) The UDI carrier shall be readable, or, in the case of AIDC, scannable, whether placed on the outside of the packaging of the system or procedure pack or inside transparent packaging.

6.4. Configurable devices:

6.4.1. A UDI shall be assigned to the configurable device in its entirety and shall be called the configurable device UDI.

6.4.2. The configurable device UDI-DI shall be assigned to groups of configurations, not per configuration within the group. A group of configurations is defined as the collection of possible configurations for a given device as described in the technical documentation.

6.4.3. A configurable device UDI-PI shall be assigned to each individual configurable device.

6.4.4. The carrier of the configurable device UDI shall be placed on the assembly that is most unlikely to be exchanged during the lifetime of the system and shall be identified as the configurable device UDI.

6.4.5. Each component that is considered a device and is commercially available on its own shall be assigned a separate UDI.

6.5. Device Software

6.5.1. UDI assignment Criteria

The UDI shall be assigned at the system level of the software. Only software which is commercially available on its own and software which constitutes a device in itself shall be subject to that requirement.

The software identification shall be considered to be the manufacturing control mechanism and shall be displayed in the UDI-PI.

6.5.2. A new UDI-DI shall be required whenever there is a modification that changes:

(a) the original performance;

(b) the safety or the intended use of the software;

(c) interpretation of data.

Such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

6.5.3. Minor software revisions shall require a new UDI-PI and not a new UDI-DI.

Minor software revisions are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency.

Minor software revisions shall be identified by a manufacturer-specific form of identification.

6.5.4. UDI placement criteria for software

(a) where the software is delivered on a physical medium, e.g. CD or DVD, each packaging level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging shall be identical to the UDI assigned to the system level software;

(b) the UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format, such as an 'about' file, or included on the start-up screen;

(c) software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the UDI through an application programming interface (API);

(d) only the human readable portion of the UDI shall be required in electronic displays of the software. The marking of UDI using AIDC shall not be required in the electronic displays, such as 'about' menu, splash screen etc.;

(e) the human readable format of the UDI for the software shall include the Application Identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.

ANNEX VII

REQUIREMENTS TO BE MET BY NOTIFIED BODIES

1. ORGANISATIONAL AND GENERAL REQUIREMENTS

1.1. Legal status and organisational structure

1.1.1. Each notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect. Its legal personality and status shall be fully documented. Such documentation shall include information about ownership and the legal or natural persons exercising control over the notified body.

1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements of Section 1.2 are applicable to both the notified body and the organisation to which it belongs.

1.1.3. If a notified body wholly or partly owns legal entities established in a Member State or in a third country or is owned by another legal entity, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented. Personnel of those entities performing conformity assessment activities under this Regulation shall be subject to the applicable requirements of this Regulation.

1.1.4. The organisational structure, allocation of responsibilities, reporting lines and operation of the notified body shall be such that they ensure that there is confidence in the performance by the notified body and in the results of the conformity assessment activities it conducts.

1.1.5. The notified body shall clearly document its organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel who may have an influence upon the performance by the notified body and upon the results of its conformity assessment activities.

1.1.6. The notified body shall identify the persons in top-level management that have overall authority and responsibility for each of the following:

— the provision of adequate resources for conformity assessment activities;

— the development of procedures and policies for the operation of the notified body;

— the supervision of implementation of the procedures, policies and quality management systems of the notified body;

— the supervision of the notified body's finances;

— the activities and decisions taken by the notified body, including contractual agreements;

— the delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities;

— the interaction with the authority responsible for notified bodies and the obligations regarding communications with other competent authorities, the Commission and other notified bodies.

1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the device in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the device as well as of any competitors of the manufacturer. This does not preclude the notified body from carrying out conformity assessment activities for competing manufacturers.

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall document and implement a structure and procedures for safeguarding impartiality and for promoting and applying the principles of impartiality throughout its organisation, personnel and assessment activities. Such procedures shall provide for the identification, investigation and resolution of any case in which a conflict of interest may arise, including involvement in consultancy services in the field of devices prior to taking up employment with the notified body. The investigation, outcome and its resolution shall be documented.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

(a) be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;

(b) be involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which they are designated, nor represent the parties engaged in those activities;

(c) engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated;

(d) offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment, and

(e) be linked to any organisation which itself provides consultancy services as referred to in point (d). Such restriction does not preclude general training activities that are not client specific and that relate to regulation of devices or to related standards.

1.2.4. Involvement in consultancy services in the field of devices prior to taking up employment with a notified body shall be fully documented at the time of employment and potential conflicts of interest shall be monitored and resolved in accordance with this Annex. Personnel who were formerly employed by a specific client, or provided consultancy services in the field of devices to that specific client prior to taking up employment with a notified body, shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group for a period of three years.

1.2.5. The impartiality of notified bodies, of their top-level management and of the assessment personnel shall be guaranteed. The level of the remuneration of the top-level management and assessment personnel of a notified body and subcontractors, involved in assessment activities shall not depend on the results of the assessments. Notified bodies shall make publicly available the declarations of interest of their top-level management.

1.2.6. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interest shall be ensured and documented between, on the one hand, the authority responsible for notified bodies and/or the competent authority and, on the other hand, the notified body.

1.2.7. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, including the activities of its owners do not affect its independence, impartiality or the objectivity of its conformity assessment activities.

1.2.8. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC in relation to fees.

1.2.9. The requirements laid down in this Section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer applying for conformity assessment.

1.3. Confidentiality

1.3.1. The notified body shall have documented procedures in place ensuring that its personnel, committees, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of conformity assessment activities, except when disclosure is required by law.

1.3.2. The personnel of a notified body shall observe professional secrecy in carrying out their tasks under this Regulation or any provision of national law giving effect to it, except in relation to the authorities responsible for notified bodies, competent authorities for medical devices in the Member States or the Commission. Proprietary rights shall be protected. The notified body shall have documented procedures in place in respect of the requirements of this Section.

1.4. Liability

1.4.1. The notified body shall take out appropriate liability insurance for its conformity assessment activities, unless liability is assumed by the Member State in question in accordance with national law or that Member State is directly responsible for the conformity assessment.

1.4.2. The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates.

1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities within its scope of designation and related business operations. It shall document and provide evidence of its financial capacity and its long-term economic viability, taking into account, where relevant, any specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of, any relevant standardisation activities and in the activities of the notified body coordination group referred to in Article 49 and that its assessment and decision-making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

1.6.2. The notified body shall take into consideration guidance and best practice documents.

2. QUALITY MANAGEMENT REQUIREMENTS

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and is capable of supporting and demonstrating the consistent fulfilment of the requirements of this Regulation.

2.2. The quality management system of the notified body shall address at least the following:

— management system structure and documentation, including policies and objectives for its activities;

— policies for assignment of activities and responsibilities to personnel;

— assessment and decision-making processes in accordance with the tasks, responsibilities and role of the notified body's personnel and top-level management;

— the planning, conduct, evaluation and, if necessary, adaptation of its conformity assessment procedures;

— control of documents;

— control of records;

— management reviews;

— internal audits;

— corrective and preventive actions;

— complaints and appeals; and

— continuous training.

Where documents are used in various languages, the notified body shall ensure and control that they have the same content.

2.3. The top-level management of the notified body shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including subsidiaries and subcontractors involved in conformity assessment activities pursuant to this Regulation.

2.4. The notified body shall require all personnel to formally commit themselves by a signature or equivalent to comply with the procedures defined by the notified body. That commitment shall cover aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with clients. The personnel shall be required to complete written statements indicating their compliance with confidentiality, independence and impartiality principles.

3. RESOURCE REQUIREMENTS

3.1. General

3.1.1. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.

In particular, notified bodies shall have the necessary personnel and possess or have access to all equipment, facilities and competence needed to perform properly the technical, scientific and administrative tasks entailed in the conformity assessment activities in relation to which they have been designated.

Such requirement presupposes at all times and for each conformity assessment procedure and each type of devices in relation to which they have been designated, that the notified body has permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant devices and the corresponding technologies. Such personnel shall be in sufficient numbers to ensure that the notified body in question can perform the conformity assessment tasks, including the assessment of the medical functionality, clinical evaluations and the performance and safety of devices, for which it has been designated, having regard to the requirements of this Regulation, in particular, those set out in Annex I.

A notified body's cumulative competences shall be such as to enable it to assess the types of devices for which it is designated. The notified body shall have sufficient internal competence to critically evaluate assessments conducted by external expertise. Tasks which a notified body is precluded from subcontracting are set out in Section 4.1.

Personnel involved in the management of the operation of a notified body's conformity assessment activities for devices shall have appropriate knowledge to set up and operate a system for the selection of assessment and verification staff, for verification of their competence, for authorisation and allocation of their tasks, for organisation of their initial and ongoing training and for the assignment of their duties and the monitoring of those staff, in order to ensure that personnel who carry out and perform assessment and verification operations are competent to fulfil the tasks required of them.

The notified body shall identify at least one individual within its top-level management as having overall responsibility for all conformity assessment activities in relation to devices.

3.1.2. The notified body shall ensure that personnel involved in conformity assessment activities maintain their qualification and expertise by implementing a system for exchange of experience and a continuous training and education programme.

3.1.3. The notified body shall clearly document the extent and limits of duties and responsibilities and the level of authorisation of the personnel, including any subcontractors and external experts, involved in conformity assessment activities and inform those personnel accordingly.

3.2. Qualification criteria in relation to personnel

3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities, including as regards knowledge, experience and other competence required, and the required initial and ongoing training. The qualification criteria shall address the various functions within the conformity assessment process, such as auditing, product evaluation or testing, technical documentation review and decision-making, as well as the devices, technologies and areas, such as biocompatibility, sterilisation, tissues and cells of human and animal origin and clinical evaluation, covered by the scope of designation.

3.2.2. The qualification criteria referred to in Section 3.2.1 shall refer to the scope of a notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 42(3), providing a sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined at least for the assessment of:

— the pre-clinical evaluation,

— clinical evaluation,

— tissues and cells of human and animal origin,

— functional safety,

— software,

— packaging,

— devices that incorporate as an integral part a medicinal product,

— devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body and

— the different types of sterilisation processes.

3.2.3. The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall be employed by the notified body itself and shall not be external experts or subcontracted. They shall have proven knowledge and experience in all of the following:

— Union devices legislation and relevant guidance documents;

— the conformity assessment procedures provided for in this Regulation;

— a broad base of knowledge of device technologies and the design and manufacture of devices;

— the notified body's quality management system, related procedures and the required qualification criteria;

— training relevant to personnel involved in conformity assessment activities in relation to devices;

— adequate experience in conformity assessments under this Regulation or previously applicable law within a notified body.

3.2.4. The notified body shall have permanent availability of personnel with relevant clinical expertise and where possible such personnel shall be employed by the notified body itself. Such personnel shall be integrated throughout the notified body's assessment and decision-making process in order to:

— identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;

— appropriately train external clinical experts in the relevant requirements of this Regulation, CS, guidance and harmonised standards and ensure that the external clinical experts are fully aware of the context and implications of their assessment and the advice they provide;

— be able to review and scientifically challenge the clinical data contained within the clinical evaluation, and any associated clinical investigations, and appropriately guide external clinical experts in the assessment of the clinical evaluation presented by the manufacturer;

— be able to scientifically evaluate and, if necessary, challenge the clinical evaluation presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

— be able to ascertain the comparability and consistency of the assessments of clinical evaluations conducted by clinical experts;

— be able to make an assessment of the manufacturer's clinical evaluation and a clinical judgement of the opinion provided by any external expert and make a recommendation to the notified body's decision maker; and

— be able to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.5. The personnel responsible for carrying out product-related reviews (product reviewers), such as technical documentation reviews or type examination, including aspects such as clinical evaluation, biological safety, sterilisation and software validation, shall have all of the following proven qualifications:

— successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, pharmacy, engineering or other relevant sciences;

— four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which two years shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;

— knowledge of device legislation, including the general safety and performance requirements set out in Annex I;

— appropriate knowledge and experience of relevant harmonised standards, CS and guidance documents;

— appropriate knowledge and experience of risk management and related device standards and guidance documents;

— appropriate knowledge and experience of clinical evaluation;

— appropriate knowledge of the devices which they are assessing;

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those assessments;

— the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality management system (site auditors) shall have all of the following proven qualifications:

— successful completion of a university or a technical college degree or equivalent qualification in relevant studies, such as medicine, pharmacy, engineering or other relevant sciences;

— four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which two years shall be in the area of quality management;

— appropriate knowledge of devices legislation as well as related harmonised standards, CS and guidance documents;

— appropriate knowledge and experience of risk management and related device standards and guidance documents;

— appropriate knowledge of quality management systems and related standards and guidance documents;

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those audits;

— training in auditing techniques enabling them to challenge quality management systems;

— the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.7. The personnel with overall responsibility for final reviews and decision-making on certification shall be employed by the notified body itself and shall not be external experts or be subcontracted. Those personnel shall, as a group, have proven knowledge and comprehensive experience of all of the following:

— devices legislation and relevant guidance documents;

— the device conformity assessments relevant to this Regulation;

— the types of qualifications, experience and expertise relevant to device conformity assessment;

— a broad base of knowledge of device technologies, including sufficient experience of conformity assessment of devices being reviewed for certification, the device industry and the design and manufacture of devices;

— the notified body's quality management system, related procedures and the required qualifications for personnel involved;

— the ability to draw up records and reports demonstrating that the conformity assessment activities have been appropriately carried out.

3.3. Documentation of qualification, training and authorisation of personnel

3.3.1. The notified body shall have a procedure in place to fully document the qualification of each member of personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2. Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2. cannot be fully demonstrated, the notified body shall justify to the authority responsible for notified bodies the authorisation of those members of personnel to carry out specific conformity assessment activities.

3.3.2. For all of its personnel referred to in Sections 3.2.3 to 3.2.7, the notified body shall establish and maintain up to date:

— a matrix detailing the authorisations and responsibilities of the personnel in respect of conformity assessment activities; and

— records attesting to the required knowledge and experience for the conformity assessment activity for which they are authorised. The records shall contain a rationale for defining the scope of the responsibilities for each of the assessment personnel and records of the conformity assessment activities carried out by each of them.

3.4. Subcontractors and external experts

3.4.1. Notified bodies may, without prejudice to Section 3.2, subcontract certain clearly defined component parts of a conformity assessment activity.

The subcontracting of the auditing of quality management systems or of product related reviews as a whole shall not be permitted; nevertheless parts of those activities may be conducted by subcontractors and external auditors and experts working on behalf of the notified body. The notified body in question shall retain full responsibility for being able to produce appropriate evidence of the competence of subcontractors and experts to fulfil their specific tasks, for making a decision based on a subcontractor's assessment and for the work conducted by subcontractors and experts on its behalf.

The following activities may not be subcontracted by notified bodies:

— review of the qualifications and monitoring of the performance of external experts;

— auditing and certification activities where the subcontracting in question is to auditing or certification organisations;

— allocation of work to external experts for specific conformity assessment activities; and

— final review and decision making functions.

3.4.2. Where a notified body subcontracts certain conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place, and shall ensure that:

— the subcontractor meets the relevant requirements of this Annex;

— subcontractors and external experts do not further subcontract work to organisations or personnel; and

— the natural or legal person that applied for conformity assessment has been informed of the requirements referred to in the first and second indent.

Any subcontracting or consultation of external personnel shall be properly documented, shall not involve any intermediaries and shall be subject to a written agreement covering, among other things, confidentiality and conflicts of interest. The notified body in question shall take full responsibility for the tasks performed by subcontractors.

3.4.3. Where subcontractors or external experts are used in the context of a conformity assessment, in particular regarding novel, invasive and implantable devices or technologies, the notified body in question shall have internal competence in each product area for which it is designated that is adequate for the purpose of leading the overall conformity assessment, verifying the appropriateness and validity of expert opinions and making decisions on certification.

3.5. Monitoring of competences, training and exchange of experience

3.5.1. The notified body shall establish procedures for the initial evaluation and on-going monitoring of the competence, conformity assessment activities and performance of all internal and external personnel, and subcontractors, involved in conformity assessment activities.

3.5.2. Notified bodies shall review at regular intervals, the competence of their personnel, identify training needs and draw up a training plan to maintain the required level of qualification and knowledge of individual personnel. That review shall at a minimum, verify that personnel:

— are aware of Union and national law in force on devices, relevant harmonised standards, CS, guidance documents and the results of the coordination activities referred to in Section 1.6; and

— take part in the internal exchange of experience and the continuous training and education programme referred to in Section 3.1.2.

4. PROCESS REQUIREMENTS

4.1. General

The notified body shall have in place documented processes and sufficiently detailed procedures for the conduct of each conformity assessment activity for which it is designated, comprising the individual steps from pre-application activities up to decision making and surveillance and taking into account, when necessary, the respective specificities of the devices.

The requirements laid down in Sections 4.3, 4.4, 4.7 and 4.8 shall be fulfilled as part of the internal activities of notified bodies and shall not be subcontracted.

4.2. Notified body quotations and pre-application activities

The notified body shall:

(a) publish a publicly available description of the application procedure by which manufacturers can obtain certification from it. That description shall include which languages are acceptable for submission of documentation and for any related correspondence;

(b) have documented procedures relating to, and documented details about, fees charged for specific conformity assessment activities and any other financial conditions relating to notified bodies' assessment activities for devices;

(c) have documented procedures in relation to advertising of their conformity assessment services. Those procedures shall ensure that advertising or promotional activities in no way imply or are capable of leading to an inference that their conformity assessment will offer manufacturers earlier market access or be quicker, easier or less stringent than that of other notified bodies;

(d) have documented procedures requiring the review of pre-application information, including the preliminary verification that the product is covered by this Regulation and its classification, prior to issuing any quotation to the manufacturer relating to a specific conformity assessment; and

(e) ensure that all contracts relating to the conformity assessment activities covered by this Regulation are concluded directly between the manufacturer and the notified body and not with any other organisation.

4.3. Application review and contract

The notified body shall require a formal application signed by a manufacturer or an authorised representative containing all of the information and the manufacturer's declarations required by the relevant conformity assessment as referred to in Annexes IX to XI.

The contract between a notified body and a manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body. This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, restrict or withdraw certificates issued and the duty of the notified body to fulfil its information obligations.

The notified body shall have documented procedures to review applications, addressing:

(a) the completeness of those applications with respect to the requirements of the relevant conformity assessment procedure, as referred to in the corresponding Annex, under which approval has been sought,

(b) the verification of the qualification of products covered by those applications as devices and their respective classifications,

(c) whether the conformity assessment procedures chosen by the applicant are applicable to the device in question under this Regulation,

(d) the ability of the notified body to assess the application based on its designation, and

(e) the availability of sufficient and appropriate resources.

The outcome of each review of an application shall be documented. Refusals or withdrawals of applications shall be notified to the electronic system referred to in Article 57 and shall be accessible to other notified bodies.

4.4. Allocation of resources

The notified body shall have documented procedures to ensure that all conformity assessment activities are conducted by appropriately authorised and qualified personnel who are sufficiently experienced in the evaluation of the devices, systems and processes and related documentation that are subject to conformity assessment.

For each application, the notified body shall determine the resources needed and identify one individual responsible for ensuring that the assessment of that application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources including personnel are utilised for each of the tasks of the assessment. The allocation of tasks required to be carried out as part of the conformity assessment and any changes subsequently made to this allocation shall be documented.

4.5. Conformity assessment activities

4.5.1. General

The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.

The notified body shall have expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements:

— appropriately plan the conduct of each individual project,

— ensure that the composition of the assessment teams is such that there is sufficient experience in relation to the technology concerned, and that there is continuous objectivity and independence, and to provide for rotation of the members of the assessment team at appropriate intervals,

— specify the rationale for fixing time limits for completion of conformity assessment activities,

— assess the manufacturer's technical documentation and the solutions adopted to meet the requirements laid down in Annex I,

— review the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects,

— review the manufacturer's procedures and documentation relating to clinical evaluation,

— address the interface between the manufacturer's risk management process and its appraisal and analysis of the pre-clinical and clinical evaluation and to evaluate their relevance for the demonstration of conformity with the relevant requirements in Annex I,

— carry out the specific procedures referred to in Sections 5.2 to 5.4 of Annex IX,

— in the case of class IIa or class IIb devices, assess the technical documentation of devices selected on a representative basis,

— plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits,

— relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,

— evaluate and verify a manufacturer's compliance with relevant Annexes.

The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.

4.5.2. Quality management system auditing

(a) As part of the assessment of the quality management system, a notified body shall prior to an audit and in accordance with its documented procedures:

— assess the documentation submitted in accordance with the relevant conformity assessment Annex, and draw up an audit programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of a manufacturer's quality management system and to determine whether it meets the requirements of this Regulation,

— identify links between, and allocation of responsibilities among, the various manufacturing sites, and identify relevant suppliers and/or subcontractors of the manufacturer, and consider the need to specifically audit any of those suppliers or subcontractors or both,

— clearly define, for each audit identified in the audit programme, the objectives, criteria and scope of the audit, and draw up an audit plan that adequately addresses and takes account of the specific requirements for the devices, technologies and processes involved,

— draw up and keep up to date, for class IIa and class IIb devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate, and

— select and assign appropriately qualified and authorised personnel for conducting the individual audits. The respective roles, responsibilities and authorities of the team members shall be clearly defined and documented.

(b) Based on the audit programme it has drawn up, the notified body shall, in accordance with its documented procedures:

— audit the manufacturer's quality management system, in order to verify that the quality management system ensures that the devices covered conform to the relevant provisions of this Regulation which apply to devices at every stage, from design through final quality control to ongoing surveillance, and shall determine whether the requirements of this Regulation are met,

— based on relevant technical documentation and in order to determine whether the manufacturer meets the requirements referred to in the relevant conformity assessment Annex, review and audit the manufacturer's processes and subsystems, in particular for:

— design and development,

— production and process controls,

— product documentation,

— purchasing controls including verification of purchased devices,

— corrective and preventive actions, including for post-market surveillance, and

— PMCF,

and review and audit requirements and provisions adopted by the manufacturer, including those in relation to fulfilling the general safety and performance requirements set out in Annex I.

The documentation shall be sampled in such a manner as to reflect the risks associated with the intended use of the device, the complexity of the manufacturing technologies, the range and classes of devices produced and any available post-market surveillance information,

— if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers,

— conduct assessments of the technical documentation based on its sampling plan and taking account of Sections 4.5.4. and 4.5.5. for pre-clinical and clinical evaluations, and

— the notified body shall ensure that audit findings are appropriately and consistently classified in accordance with the requirements of this Regulation and with relevant standards, or with best practice documents developed or adopted by the MDCG.

4.5.3. Product verification

Assessment of the technical documentation

For assessment of the technical documentation conducted in accordance with Chapter II of Annex IX, notified bodies shall have sufficient expertise, facilities and documented procedures for:

— the allocation of appropriately qualified and authorised personnel for the examination of individual aspects such as use of the device, biocompatibility, clinical evaluation, risk management, and sterilisation, and

— the assessment of conformity of the design with this Regulation, and for taking account of Sections 4.5.4. to 4.5.6. That assessment shall include examination of the implementation by manufacturers of incoming, in-process and final checks and the results thereof. If further tests or other evidence is required for the assessment of conformity with the requirements of this Regulation, the notified body in question shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Type-examinations

The notified body shall have documented procedures, sufficient expertise and facilities for the type-examination of devices in accordance with Annex X including the capacity to:

— examine and assess the technical documentation taking account of Sections 4.5.4. to 4.5.6., and verify that the type has been manufactured in conformity with that documentation;

— establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility;

— document its rationale for the selection of those parameters;

— carry out the appropriate examinations and tests in order to verify that the solutions adopted by the manufacturer meet the general safety and performance requirements set out in Annex I. Such examinations and tests shall include all tests necessary to verify that the manufacturer has in fact applied the relevant standards it has opted to use;

— agree with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body; and

— assume full responsibility for test results. Test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

Verification by examination and testing of every product

The notified body shall:

(a) have documented procedures, sufficient expertise and facilities for the verification by examination and testing of every product in accordance with Part B of Annex XI;

(b) establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility in order to:

— verify, for class IIb devices, the conformity of the device with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to those devices,

— confirm, for class IIa devices, the conformity with the technical documentation referred to in Annexes II and III and with the requirements of this Regulation which apply to those devices;

(c) document its rationale for the selection of the parameters referred to in point (b);

(d) have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of this Regulation by examining and testing every product as specified in Section 15 of Annex XI;

(e) have documented procedures providing for the reaching of an agreement with the applicant concerning when and where necessary tests that are not to be carried out by the notified body itself are to be performed; and

(f) assume full responsibility for test results in accordance with documented procedures; test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

4.5.4. Pre-clinical evaluation assessment

The notified body shall have documented procedures in place for the review of the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects. The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address:

(a) the planning, conduct, assessment, reporting and, where appropriate, updating of the pre-clinical evaluation, in particular of

— the scientific pre-clinical literature search, and

— the pre-clinical testing, for example laboratory testing, simulated use testing, computer modelling, the use of animal models,

(b) the nature and duration of body contact and the specific associated biological risks,

(c) the interface with the risk management process, and

(d) the appraisal and analysis of the available pre-clinical data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I.

The notified body's assessment of pre-clinical evaluation procedures and documentation shall address the results of literature searches and all validation, verification and testing performed and conclusions drawn, and shall typically include considering the use of alternative materials and substances and take account of the packaging, stability, including shelf life, of the finished device. Where no new testing has been undertaken by a manufacturer or where there are deviations from procedures, the notified body in question shall critically examine the justification presented by the manufacturer.

4.5.5. Clinical evaluation assessment

The notified body shall have documented procedures in place relating to the assessment of a manufacturer's procedures and documentation relating to clinical evaluation both for initial conformity assessment and on an ongoing basis. The notified body shall examine, validate and verify that manufacturers' procedures and documentation adequately address:

— the planning, conduct, assessment, reporting and updating of the clinical evaluation as referred to in Annex XIV,

— post-market surveillance and PMCF,

— the interface with the risk management process,

— the appraisal and analysis of the available data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I, and

— the conclusions drawn with regard to the clinical evidence and drawing up of the clinical evaluation report.

These procedures referred to in the first paragraph shall take into consideration available CS, guidance and best practice documents.

The notified body's assessment of clinical evaluations as referred to in Annex XIV shall cover:

— the intended use specified by the manufacturer and claims for the device defined by it,

— the planning of the clinical evaluation,

— the methodology for the literature search,

— relevant documentation from the literature search,

— the clinical investigation,

— validity of equivalence claimed in relation to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices,

— post-market surveillance and PMCF,

— the clinical evaluation report, and

— justifications in relation to non-performance of clinical investigations or PMCF.

In relation to clinical data from clinical investigations included within the clinical evaluation, the notified body in question shall ensure that the conclusions drawn by the manufacturer are valid in the light of the approved clinical investigation plan.

The notified body shall ensure that the clinical evaluation adequately addresses the relevant safety and performance requirements provided for in Annex I, that it is appropriately aligned with the risk management requirements, that it is conducted in accordance with Annex XIV and that it is appropriately reflected in the information provided relating to the device.

4.5.6. Specific Procedures

The notified body shall have documented procedures, sufficient expertise and facilities for the procedures referred to in Sections 5 and 6 of Annex IX, Section 6 of Annex X and Section 16 of Annex XI, for which they are designated.

In the case of devices manufactured utilising tissues or cells of animal origin or their derivatives, such as from TSE susceptible species, as referred to in Regulation (EU) No 722/2012, the notified body shall have documented procedures in place that fulfil the requirements laid down in that Regulation, including for the preparation of a summary evaluation report for the relevant competent authority.

4.6. Reporting

The notified body shall:

— ensure that all steps of the conformity assessment are documented so that the conclusions of the assessment are clear and demonstrate compliance with the requirements of this Regulation and can represent objective evidence of such compliance to persons that are not themselves involved in the assessment, for example personnel in designating authorities,

— ensure that records that are sufficient to provide a discernible audit trail are available for quality management system audits,

— clearly document the conclusions of its assessment of clinical evaluation in a clinical evaluation assessment report, and

— for each specific project, provide a detailed report which shall be based on a standard format containing a minimum set of elements determined by the MDCG.

The report of the notified body shall:

— clearly document the outcome of its assessment and draw clear conclusions from the verification of the manufacturer's conformity with the requirements of this Regulation,

— make a recommendation for a final review and for a final decision to be taken by the notified body; this recommendation shall be signed off by the member of personnel responsible in the notified body, and

— be provided to the manufacturer in question.

4.7. Final review

The notified body shall prior to making a final decision:

— ensure that the personnel assigned for the final review and decision-making on specific projects are appropriately authorised and are different from the personnel who have conducted the assessments,

— verify that the report or reports and supporting documentation needed for decision making, including concerning resolution of non-conformities noted during assessment, are complete and sufficient with respect to the scope of the application, and

— verify whether there are any unresolved non-conformities preventing issuance of a certificate.

4.8. Decisions and Certifications

The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, restriction and withdrawal of certificates. Those procedures shall include the notification requirements laid down in Chapter V of this Regulation. The procedures shall allow the notified body in question to:

— decide, based on the assessment documentation and additional information available, whether the requirements of this Regulation are fulfilled,

— decide, based on the results of its assessment of the clinical evaluation and risk management, whether the post-market surveillance plan, including the PMCF plan, is adequate,

— decide on specific milestones for further review by the notified body of the up to date clinical evaluation,

— decide whether specific conditions or provisions need to be defined for the certification,

— decide, based on the novelty, risk classification, clinical evaluation and conclusions from the risk analysis of the device, on a period of certification not exceeding five years,

— clearly document decision making and approval steps including approval by signature of the members of personnel responsible,

— clearly document responsibilities and mechanisms for communication of decisions, in particular, where the final signatory of a certificate differs from the decision maker or decision makers or does not fulfil the requirements laid down in Section 3.2.7,

— issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII for a period of validity not exceeding five years and shall indicate whether there are specific conditions or limitations associated with the certification,

— issue a certificate or certificates for the applicant alone and shall not issue certificates covering multiple entities, and

— ensure that the manufacturer is notified of the outcome of the assessment and the resultant decision and that they are entered into the electronic system referred to in Article 57.

4.9. Changes and modifications

The notified body shall have documented procedures and contractual arrangements with manufacturers in place relating to the manufacturers' information obligations and the assessment of changes to:

— the approved quality management system or systems or to the product-range covered,

— the approved design of a device,

— the intended use of or claims made for the device,

— the approved type of a device, and

— any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.6.

The procedures and contractual arrangements referred to in the first paragraph shall include measures for checking the significance of the changes referred to in the first paragraph.

In accordance with its documented procedures, the notified body in question shall:

— ensure that manufacturers submit for prior approval plans for changes as referred to in the first paragraph and relevant information relating to such changes,

— assess the changes proposed and verify whether, after these changes, the quality management system, or the design of a device or type of a device, still meets the requirements of this Regulation, and

— notify the manufacturer of its decision and provide a report or as applicable a supplementary report, which shall contain the justified conclusions of its assessment.

4.10. Surveillance activities and post-certification monitoring

The notified body shall have documented procedures:

— defining how and when surveillance activities of manufacturers are to be conducted. Those procedures shall include arrangements for unannounced on-site audits of manufacturers and, where applicable, subcontractors and suppliers carrying out product tests and the monitoring of compliance with any conditions binding manufacturers and associated with certification decisions, such as updates to clinical data at defined intervals,

— for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. Such information shall be taken into account in the planning and conduct of surveillance activities, and

— to review vigilance data to which they have access under Article 92(2) in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.

The notified body in question shall, upon receipt of information about vigilance cases from a manufacturer or competent authorities, decide which of the following options to apply:

— not to take action on the basis that the vigilance case is clearly not related to the certification granted,

— observe the manufacturer's and competent authority's activities and the results of the manufacturer's investigation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken,

— perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced audits and product testing, where it is likely that the certification granted is at risk,

— increase the frequency of surveillance audits,

— review specific products or processes on the occasion of the next audit of the manufacturer, or

— take any other relevant measure.

In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to:

— conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in Section 4.5,

— ensure adequate assessment of the manufacturer's documentation on, and application of the provisions on, vigilance, the post-market surveillance, and PMCF,

— sample and test devices and technical documentation, during audits, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved quality management system,

— ensure that the manufacturer complies with the documentation and information obligations laid down in the relevant Annexes and that its procedures take into account best practices in the implementation of quality management systems,

— ensure that the manufacturer does not use quality management system or device approvals in a misleading manner,

— gather sufficient information to determine if the quality management system continues to comply with the requirements of this Regulation,

— ask the manufacturer, if non-conformities are detected, for corrections, corrective actions and, where applicable, preventive actions, and

— where necessary, impose specific restrictions on the relevant certificate, or suspend or withdraw it.

The notified body shall, if listed as part of the conditions for certification:

— conduct an in-depth review of the clinical evaluation as most recently updated by the manufacturer based on the manufacturer's post-market surveillance, on its PMCF and on clinical literature relevant to the condition being treated with the device or on clinical literature relevant to similar devices,

— clearly document the outcome of the in-depth review and address any specific concerns to the manufacturer or impose any specific conditions on it, and

— ensure that the clinical evaluation as most recently updated, is appropriately reflected in the instructions for use and, where applicable, the summary of safety and performance.

4.11. Re-certification

The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates shall occur at least every five years.

The notified body shall have documented procedures relating to renewals of EU technical documentation assessment certificates and EU type-examination certificates and those procedures shall require the manufacturer in question to submit a summary of changes and scientific findings for the device, including:

(a) all changes to the originally approved device, including changes not yet notified,

(b) experience gained from post-market surveillance,

(c) experience from risk management,

(d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,

(e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF,

(f) changes to the requirements, to components of the device or to the scientific or regulatory environment,

(g) changes to applied or new harmonised standards, CS or equivalent documents, and

(h) changes in medical, scientific and technical knowledge, such as:

— new treatments,

— changes in test methods,

— new scientific findings on materials and components, including findings on their biocompatibility,

— experience from studies on comparable devices,

— data from registers and registries,

— experience from clinical investigations with comparable devices.

The notified body shall have documented procedures to assess the information referred to in the second paragraph and shall pay particular attention to clinical data from post-market surveillance and PMCF activities undertaken since the previous certification or re-certification, including appropriate updates to manufacturers' clinical evaluation reports.

For the decision on re-certification, the notified body in question shall use the same methods and principles as for the initial certification decision. If necessary, separate forms shall be established for re-certification taking into account the steps taken for certification such as application and application review.

ANNEX VIII

CLASSIFICATION RULES

CHAPTER I

DEFINITIONS SPECIFIC TO CLASSIFICATION RULES

1. DURATION OF USE

1.1. 'Transient' means normally intended for continuous use for less than 60 minutes.

1.2. 'Short term' means normally intended for continuous use for between 60 minutes and 30 days.

1.3. 'Long term' means normally intended for continuous use for more than 30 days.

2. INVASIVE AND ACTIVE DEVICES

2.1. 'Body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

2.2. 'Surgically invasive device' means:

(a) an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and

(b) a device which produces penetration other than through a body orifice.

2.3. 'Reusable surgical instrument' means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

2.4. 'Active therapeutic device' means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.

2.5. 'Active device intended for diagnosis and monitoring' means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

2.6. 'Central circulatory system' means the following blood vessels: *arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens* to the *bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior* and *vena cava inferior*.

2.7. 'Central nervous system' means the brain, meninges and spinal cord.

2.8. 'Injured skin or mucous membrane' means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.

CHAPTER II

IMPLEMENTING RULES

3.1. Application of the classification rules shall be governed by the intended purpose of the devices.

3.2. If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right separately from the device with which they are used.

3.3. Software, which drives a device or influences the use of a device, shall fall within the same class as the device.

If the software is independent of any other device, it shall be classified in its own right.

3.4. If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.

3.5. If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.

3.6. In calculating the duration referred to in Section 1, continuous use shall mean:

(a) the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed; and

(b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

3.7. A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.

CHAPTER III

CLASSIFICATION RULES

4. NON-INVASIVE DEVICES

4.1. Rule 1

All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.

4.2. Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:

— if they may be connected to a class IIa, class IIb or class III active device; or

— if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb.

In all other cases, such devices are classified as class I.

4.3. Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa.

All non-invasive devices consisting of a substance or a mixture of substances intended to be used *in vitro* in direct contact with human cells, tissues or organs taken from the human body or used *in vitro* with human embryos before their implantation or administration into the body are classified as class III.

4.4. Rule 4

All non-invasive devices which come into contact with injured skin or mucous membrane are classified as:

— class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;

— class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;

— class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and

— class IIa in all other cases.

This rule applies also to the invasive devices that come into contact with injured mucous membrane.

5. INVASIVE DEVICES

5.1. Rule 5

All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as:

— class I if they are intended for transient use;

— class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and

— class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.

5.2. Rule 6

All surgically invasive devices intended for transient use are classified as class IIa unless they:

— are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;

— are reusable surgical instruments, in which case they are classified as class I;

— are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;

— are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb;

— have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or

— are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.

5.3. Rule 7

All surgically invasive devices intended for short-term use are classified as class IIa unless they:

— are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;

— are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;

— are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;

— have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;

— are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or

— are intended to administer medicines, in which case they are classified as class IIb.

5.4. Rule 8

All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

— are intended to be placed in the teeth, in which case they are classified as class IIa;

— are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III;

— have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;

— are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;

— are intended to administer medicinal products, in which case they are classified as class III;

— are active implantable devices or their accessories, in which cases they are classified as class III;

— are breast implants or surgical meshes, in which cases they are classified as class III;

— are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or

— are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.

6. ACTIVE DEVICES

6.1. Rule 9

All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

6.2. Rule 10

Active devices intended for diagnosis and monitoring are classified as class IIa:

— if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;

— if they are intended to image *in vivo* distribution of radiopharmaceuticals; or

— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

6.3. Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

— death or an irreversible deterioration of a person's state of health, in which case it is in class III; or

— a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

6.4. Rule 12

All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.

6.5. Rule 13

All other active devices are classified as class I.

7. SPECIAL RULES

7.1. Rule 14

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.

7.2. Rule 15

All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long term invasive devices, in which case they are classified as class III.

7.3. Rule 16

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb.

All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb.

This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

7.4. Rule 17

Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class IIa.

7.5. Rule 18

All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.

7.6. Rule 19

All devices incorporating or consisting of nanomaterial are classified as:

— class III if they present a high or medium potential for internal exposure;

— class IIb if they present a low potential for internal exposure; and

— class IIa if they present a negligible potential for internal exposure.

7.7. Rule 20

All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as class IIb.

7.8. Rule 21

Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:

— class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;

— class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;

— class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and

— class IIb in all other cases.

7.9. Rule 22

Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

ANNEX IX

CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

CHAPTER I

QUALITY MANAGEMENT SYSTEM

1. The manufacturer shall establish, document and implement a quality management system as described in Article 10(9) and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2 and shall be subject to audit, as laid down in Sections 2.3 and 2.4, and to surveillance as specified in Section 3.

2. Quality management system assessment

2.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

— the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative, the name of the authorised representative and the address of the authorised representative's registered place of business,

— all relevant information on the device or group of devices covered by the quality management system,

— a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,

— a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure,

— the documentation on the manufacturer's quality management system,

— a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures,

— a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,

— the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92,

— a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,

— documentation on the clinical evaluation plan, and

— a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

2.2. Implementation of the quality management system shall ensure compliance with this Regulation. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) the manufacturer's quality objectives;

(b) the organisation of the business and in particular:

— the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority,

— the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform,

— where the design, manufacture and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party, and

— where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate;

(c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover:

— the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures,

— identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS and, where opted for, harmonised standards or other adequate solutions into account,

— risk management as referred to in Section 3 of Annex I,

— the clinical evaluation, pursuant to Article 61 and Annex XIV, including post-market clinical follow-up,

— solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,

— solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I,

— the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture, and

— management of design or quality management system changes; and

(d) the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents; and

(e) the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annexes II and III.

2.3. Audit

The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 2.2. Where the manufacturer uses a harmonised standard or CS related to a quality management system, the notified body shall assess conformity with those standards or CS. The notified body shall assume that a quality management system which satisfies the relevant harmonised standards or CS conforms to the requirements covered by those standards or CS, unless it duly substantiates not doing so.

The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned in accordance with Sections 4.3. to 4.5. of Annex VII. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.

Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis in accordance with Sections 4.4 to 4.8. In choosing representative samples, the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 105 and in particular the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose and the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties, that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken.

If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.

2.4. The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether after those changes the quality management system still meets the requirements referred to in Section 2.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.

3. Surveillance assessment applicable to class IIa, class IIb and class III devices

3.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality management system.

3.2. The manufacturer shall give authorisation to the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular:

— the documentation on its quality management system,

— documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMCF plan, for a representative sample of devices, and of the provisions on vigilance set out in Articles 87 to 92,

— the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 4 of Annex I, and

— the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

3.3. Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

3.4. The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment. The notified body shall establish a plan for such unannounced on-site audits but shall not disclose it to the manufacturer.

Within the context of such unannounced on-site audits, the notified body shall test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8). Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, sampling referred to in the second paragraph, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8). Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer in question with an on-site audit report which shall include, if applicable, the result of the sample test.

3.5. In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the second paragraph of Section 2.3.

In the case of class III devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.

3.6. The notified body shall ensure that the composition of the assessment team is such that there is sufficient experience with the evaluation of the devices, systems and processes concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall neither lead nor attend audits for more than three consecutive years in respect of the same manufacturer.

3.7. If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

CHAPTER II

ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4. Assessment of the technical documentation applicable to class III devices and to the class IIb devices referred to in the second subparagraph of Article 52(4)

4.1. In addition to the obligations laid down in Section 2, the manufacturer shall lodge with the notified body an application for assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in Section 2.

4.2. The application shall describe the design, manufacture and performance of the device in question. It shall include the technical documentation as referred to in Annexes II and III.

4.3. The notified body shall examine the application by using staff, employed by it, with proven knowledge and experience regarding the technology concerned and its clinical application. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

4.4. The notified body shall review the clinical evidence presented by the manufacturer in the clinical evaluation report and the related clinical evaluation that was conducted. The notified body shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or the clinical condition in which it is utilised, for the purposes of that review.

4.5. The notified body shall, in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess to what extent specific claims are supported by specific pre-clinical and clinical data and risk analysis.

4.6. The notified body shall verify that the clinical evidence and the clinical evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. That verification shall include consideration of the adequacy of the benefit-risk determination, the risk management, the instructions for use, the user training and the manufacturer's post-market surveillance plan, and include a review of the need for, and the adequacy of, the PMCF plan proposed, where applicable.

4.7. Based on its assessment of the clinical evidence, the notified body shall consider the clinical evaluation and the benefit-risk determination, and whether specific milestones need to be defined to allow the notified body to review updates to the clinical evidence that result from post-market surveillance and PMCF data.

4.8. The notified body shall clearly document the outcome of its assessment in the clinical evaluation assessment report.

4.9. The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a clinical evaluation assessment report. If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the technical documentation assessment, the conditions of the certificate's validity, the data needed for identification of the approved design, and, where appropriate, a description of the intended purpose of the device.

4.10. Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 52 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

5. Specific additional procedures

5.1. Assessment procedure for certain class III and class IIb devices

(a) For class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product as referred to in Section 6.4. of Annex VIII (Rule 12), the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 61(12), prepare a clinical evaluation assessment report which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan referred to in Article 10(3) and Part B of Annex XIV.

The notified body shall transmit its clinical evaluation assessment report, along with the manufacturer's clinical evaluation documentation, referred to in points (c) and (d) of Section 6.1 of Annex II, to the Commission.

The Commission shall immediately transmit those documents to the relevant expert panel referred to in Article 106.

(b) The notified body may be requested to present its conclusions as referred to in point (a) to the expert panel concerned.

(c) The expert panel shall decide, under the supervision of the Commission, on the basis of all of the following criteria:

(i) the novelty of the device or of the related clinical procedure involved, and the possible major clinical or health impact thereof;

(ii) a significantly adverse change in the benefit-risk profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure of the device;

(iii) a significantly increased rate of serious incidents reported in accordance with Article 87 in respect of a specific category or group of devices,

whether to provide a scientific opinion on the clinical evaluation assessment report of the notified body based on the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the medical indication or indications and the PMCF plan. That scientific opinion shall be provided within a period of 60 days, starting on the day of receipt of the documents from the Commission as referred to in point (a). The reasons for the decision to provide a scientific opinion on the basis of the criteria in points (i), (ii) and (iii) shall be included in the scientific opinion. Where the information submitted is not sufficient for the expert panel to reach a conclusion, this shall be stated in the scientific opinion.

(d) The expert panel may decide, under the supervision of the Commission, on the basis of the criteria laid down in point (c) not to provide a scientific opinion, in which case it shall inform the notified body as soon as possible and in any event within 21 days of receipt of the documents as referred to in point (a) from the Commission. The expert panel shall within that time limit provide the notified body and the Commission with the reasons for its decision, whereupon the notified body may proceed with the certification procedure of that device.

(e) The expert panel shall within 21 days of receipt of the documents from the Commission notify the Commission, through Eudamed whether it intends to provide a scientific opinion, pursuant to point (c), or whether it intends not to provide a scientific opinion, pursuant to point (d).

(f) Where no opinion has been delivered within a period of 60 days, the notified body may proceed with the certification procedure of the device in question.

(g) The notified body shall give due consideration to the views expressed in the scientific opinion of the expert panel. Where the expert panel finds that the level of clinical evidence is not sufficient or otherwise gives rise to serious concerns about the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication(s), and with the PMCF plan, the notified body shall, if necessary, advise the manufacturer to restrict the intended purpose of the device to certain groups of patients or certain medical indications and/or to impose a limit on the duration of validity of the certificate, to undertake specific PMCF studies, to adapt the instructions for use or the summary of safety and performance, or to impose other restrictions in its conformity assessment report, as appropriate. The notified body shall provide a full justification where it has not followed the advice of the expert panel in its conformity assessment report and the Commission shall without prejudice to Article 109 make both the scientific opinion of the expert panel and the written justification provided by the notified body publicly available via Eudamed.

(h) The Commission, after consultation with the Member States and relevant scientific experts shall provide guidance for expert panels for consistent interpretation of the criteria in point (c) before 26 May 2020.

5.2. Procedure in the case of devices incorporating a medicinal substance

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma and that has an action ancillary to that of the device, the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

(b) Before issuing an EU technical documentation assessment certificate, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as 'the medicinal products authority consulted' depending on which has been consulted under this point, on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device. Where the device incorporates a human blood or plasma derivative or a substance that, if used separately, may be considered to be a medicinal product falling exclusively within the scope of the Annex to Regulation (EC) No 726/2004, the notified body shall seek the opinion of the EMA.

(c) When issuing its opinion, the medicinal products authority consulted shall take into account the manufacturing process and the data relating to the usefulness of incorporation of the substance into the device as determined by the notified body.

(d) The medicinal products authority consulted shall provide its opinion to the notified body within 210 days of receipt of all the necessary documentation.

(e) The scientific opinion of the medicinal products authority consulted, and any possible update of that opinion, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable and shall convey its final decision to the medicinal products authority consulted.

(f) Before any change is made with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the manufacturer shall inform the notified body of the changes. That notified body shall seek the opinion of the medicinal products authority consulted, in order to confirm that the quality and safety of the ancillary substance remain unchanged. The medicinal products authority consulted shall take into account the data relating to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the risk or benefit previously established concerning the incorporation of the substance into the device. The medicinal products authority consulted shall provide its opinion within 60 days after receipt of all the necessary documentation regarding the changes. The notified body shall not deliver the supplement to the EU technical documentation assessment certificate if the scientific opinion provided by the medicinal products authority consulted is unfavourable. The notified body shall convey its final decision to the medicinal products authority consulted.

(g) Where the medicinal products authority consulted obtains information on the ancillary substance, which could have an impact on the risk or benefit previously established concerning the incorporation of the substance into the device, it shall advise the notified body as to whether this information has an impact on the risk or benefit previously established concerning the incorporation of the substance into the device. The notified body shall take that advice into account in reconsidering its assessment of the conformity assessment procedure.

5.3. Procedure in the case of devices manufactured utilising, or incorporating, tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable

5.3.1. Tissues or cells of human origin or their derivatives

(a) For devices manufactured utilising derivatives of tissues or cells of human origin that are covered by this Regulation in accordance with point (g) of Article 1(6) and for devices that incorporate, as an integral part, tissues or cells of human origin, or their derivatives, covered by Directive 2004/23/EC, that have an action ancillary to that of the device, the notified body shall, prior to issuing an EU technical documentation assessment certificate, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2004/23/EC ('human tissues and cells competent authority') on the aspects relating to the donation, procurement and testing of tissues or cells of human origin or their derivatives. The notified body shall submit a summary of the preliminary conformity assessment which provides, among other things, information about the non-viability of the human tissues or cells in question, their donation, procurement and testing and the risk or benefit of the incorporation of the tissues or cells of human origin or their derivatives into the device.

(b) Within 120 days of receipt of all the necessary documentation, the human tissues and cells competent authority shall provide to the notified body its opinion.

(c) The scientific opinion of the human tissues and cells competent authority, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the human tissues and cells competent authority when making its decision. The notified body shall not deliver the certificate if that scientific opinion is unfavourable. It shall convey its final decision to the human tissues and cells competent authority concerned.

(d) Before any change is made with respect to non-viable tissues or cells of human origin or their derivatives incorporated in a device, in particular relating to their donation, testing or procurement, the manufacturer shall inform the notified body of the intended changes. The notified body shall consult the authority that was involved in the initial consultation, in order to confirm that the quality and safety of the tissues or cells of human origin or their derivatives incorporated in the device are maintained. The human tissues and cells competent authority concerned shall take into account the data relating to the usefulness of incorporation of the tissues or cells of human origin or their derivatives into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit-risk ratio of the addition of the tissues or cells of human origin or their derivatives in the device. It shall provide its opinion within 60 days of receipt of all the necessary documentation regarding the intended changes. The notified body shall not deliver a supplement to the EU technical documentation assessment certificate if the scientific opinion is unfavourable and shall convey its final decision to the human tissues and cells competent authority concerned.

5.3.2. Tissues or cells of animal origin or their derivatives

In the case of devices manufactured utilising animal tissue which is rendered non-viable or utilising non-viable products derived from animal tissue, as referred to in Regulation (EU) No 722/2012, the notified body shall apply the relevant requirements laid down in that Regulation.

5.4. Procedure in the case of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

(a) The quality and safety of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by, or locally dispersed in, the human body, shall be verified where applicable and only in respect of the requirements not covered by this Regulation, in accordance with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions.

(b) In addition, for devices, or their products of metabolism, that are systemically absorbed by the human body in order to achieve their intended purpose, the notified body shall seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as 'the medicinal products authority consulted' depending on which has been consulted under this point, on the compliance of the device with the relevant requirements laid down in Annex I to Directive 2001/83/EC.

(c) The opinion of the medicinal products authority consulted shall be drawn up within 150 days of receipt of all the necessary documentation.

(d) The scientific opinion of the medicinal products authority consulted, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision and shall convey its final decision to the medicinal products authority consulted.

6. Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma as referred to in Article 1(8)

Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood

or human plasma as referred to in the first subparagraph of Article 1(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

CHAPTER III

ADMINISTRATIVE PROVISIONS

7. The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

   — the EU declaration of conformity,

   — the documentation referred to in the fifth indent of Section 2.1 and in particular the data and records arising from the procedures referred to in point (c) of the second paragraph of Section 2.2,

   — information on the changes referred to in Section 2.4,

   — the documentation referred to in Section 4.2, and

   — the decisions and reports from the notified body as referred to in this Annex.

8. Each Member State shall require that the documentation referred to in Section 7 is kept at the disposal of competent authorities for the period indicated in that Section in case a manufacturer, or its authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of that period.

ANNEX X

CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions of this Regulation.

2. Application

The manufacturer shall lodge an application for assessment with a notified body. The application shall include:

— the name of the manufacturer and address of the registered place of business of the manufacturer and, if the application is lodged by the authorised representative, the name of the authorised representative and the address of its registered place of business,

— the technical documentation referred to in Annexes II and III. The applicant shall make a representative sample of the device production envisaged ('type') available to the notified body. The notified body may request other samples as necessary, and

— a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that was refused by another notified body or was withdrawn by the manufacturer or its authorised representative before that other notified body made its final assessment.

3. Assessment

The notified body shall:

(a) examine the application by using staff with proven knowledge and experience regarding the technology concerned and its clinical application. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests;

(b) examine and assess the technical documentation for conformity with the requirements of this Regulation that are applicable to the device and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable standards referred to in Article 8 or with applicable CS, and record the items not designed on the basis of the relevant standards referred to in Article 8 or of the relevant CS;

(c) review the clinical evidence presented by the manufacturer in the clinical evaluation report in accordance with Section 4 of Annex XIV. The notified body shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or to the clinical condition in which it is utilised, for the purposes of that review;

(d) in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity;

(e) clearly document the outcome of its assessment in a pre-clinical and clinical evaluation assessment report as part of the EU type examination report referred to in point (i);

(f) carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements laid down in this Regulation, in the event that the standards referred to in Article 8 or the CS have not been applied. Where the device has to be connected to another device or devices in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device or devices having the characteristics specified by the manufacturer;

(g) carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, in the event that the manufacturer has chosen to apply the relevant harmonised standards, those standards have actually been applied;

(h) agree with the applicant on the place where the necessary assessments and tests are to be carried out; and

(i) draw up an EU type-examination report on the results of the assessments and tests carried out under points (a) to (g).

4. Certificate

If the type conforms to this Regulation, the notified body shall issue an EU type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the type examination assessment, the conditions of the certificate's validity and the data needed for identification of the type approved. The certificate shall be drawn up in accordance with Annex XII. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.

5. Changes to the type

5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type or of its intended purpose and conditions of use.

5.2. Changes to the approved device including limitations of its intended purpose and conditions of use shall require approval from the notified body which issued the EU type-examination certificate where such changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the EU type-examination certificate.

5.3. Changes to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, shall necessitate a new application for a conformity assessment.

6. Specific additional procedures

Section 5 of Annex IX shall apply with the proviso that any reference to an EU technical documentation assessment certificate shall be understood as a reference to an EU type-examination certificate.

7. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the documentation referred to in the second indent of Section 2,

— information on the changes referred to in Section 5, and

— copies of EU type-examination certificates, scientific opinions and reports and their additions/supplements.

Section 8 of Annex IX shall apply.

ANNEX XI

CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION

1. The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an EU type-examination certificate has been issued, and that they meet the provisions of this Regulation which apply to them.

2. Where an EU type-examination certificate has been issued in accordance with Annex X, the manufacturer may either apply the procedure set out in Part A (production quality assurance) or the procedure set out in Part B (product verification) of this Annex.

3. By way of derogation from Sections 1 and 2 above, the procedures in this Annex coupled with the drawing up of technical documentation as set out in Annexes II and III may also be applied by manufacturers of class IIa devices.

PART A

PRODUCTION QUALITY ASSURANCE

4. The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented, shall carry out a final verification, as specified in Section 6, and shall be subject to the surveillance referred to in Section 7.

5. When the manufacturer fulfils the obligations laid down in Section 4, it shall draw up and keep an EU declaration of conformity in accordance with Article 19 and Annex IV for the device covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer shall be deemed to ensure and to declare that the device concerned conforms to the type described in the EU type-examination certificate and meets the requirements of this Regulation which apply to the device.

6. Quality management system

6.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

— all elements listed in Section 2.1 of Annex IX,

— the technical documentation referred to in Annexes II and III for the types approved, and

— a copy of the EU type-examination certificates referred to in Section 4 of Annex X; if the EU type-examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application.

6.2. Implementation of the quality management system shall be such as to ensure that there is compliance with the type described in the EU type-examination certificate and with the provisions of this Regulation which apply to the devices at each stage. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

That documentation shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 2.2 of Annex IX.

6.3. The first and second paragraph of Section 2.3 of Annex IX shall apply.

If the quality management system is such that it ensures that the devices conform to the type described in the EU type-examination certificate and that it conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality assurance certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. That decision shall contain the conclusions of the notified body's audit and a reasoned assessment.

6.4. Section 2.4 of Annex IX shall apply.

7. Surveillance

Section 3.1, the first, second and fourth indents of Section 3.2, Sections 3.3, 3.4, 3.6 and 3.7 of Annex IX shall apply.

In the case of class III devices, surveillance shall also include a check that the quantities of produced or purchased raw material or crucial components approved for the type and correspond to the quantities of finished devices.

8. Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8).

Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

9. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in the fifth indent of Section 2.1 of Annex IX,

— the documentation referred to in the eighth indent of Section 2.1 of Annex IX, including the EU type-examination certificate referred to in Annex X,

— information on the changes referred to in Section 2.4 of Annex IX, and

— the decisions and reports from the notified body as referred to in Sections 2.3, 3.3 and 3.4 of Annex IX.

Section 8 of Annex IX shall apply.

10. Application to class IIa devices

10.1. By way of derogation from Section 5, by virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

10.2. For class IIa devices the notified body shall assess, as part of the assessment referred to in Section 6.3, whether the technical documentation as referred to in Annexes II and III for the devices selected on a representative basis is compliant with this Regulation.

In choosing a representative sample or samples of devices, the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical, biological or clinical properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample or samples of devices taken.

10.3. Where the assessment under Section 10.2. confirms that the class IIa devices in question conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this Part of this Annex.

10.4. Samples additional to those taken for the initial conformity assessment of devices shall be assessed by the notified body as part of the surveillance assessment referred to in Section 7.

10.5. By way of derogation from Section 6, the manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the technical documentation referred to in Annexes II and III, and

— the certificate referred to in Section 10.3.

Section 8 of Annex IX shall apply.

PART B

PRODUCT VERIFICATION

11. Product verification shall be understood to be the procedure whereby after examination of every manufactured device, the manufacturer, by issuing an EU declaration of conformity in accordance with Article 19 and Annex IV, shall be deemed to ensure and to declare that the devices which have been subject to the procedure set out in Sections 14 and 15 conform to the type described in the EU type-examination certificate and meet the requirements of this Regulation which apply to them.

12. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which conform to the type described in the EU type-examination certificate and to the requirements of the Regulation which apply to them. Prior to the start of manufacture, the manufacturer shall prepare documents defining the manufacturing process, in particular as regards sterilisation where necessary, together with all routine, pre-established procedures to be implemented to ensure homogeneous production and, where appropriate, conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

In addition, for devices placed on the market in a sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 6 and 7.

13. The manufacturer shall undertake to institute and keep up to date a post-market surveillance plan, including a PMCF plan, and the procedures ensuring compliance with the obligations of the manufacturer resulting from the provisions on vigilance and post-market surveillance system set out in Chapter VII.

14. The notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 15.

The examinations and tests referred to in the first paragraph of this Section shall not apply to aspects of the manufacturing process designed to secure sterility.

15. Verification by examination and testing of every product

15.1. Every device shall be examined individually and the appropriate physical or laboratory tests as defined in the relevant standard or standards referred to in Article 8, or equivalent tests and assessments, shall be carried out in order to verify, where appropriate, the conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

15.2. The notified body shall affix, or have affixed, its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests and assessments carried out.

16. Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8).

Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

17. Administrative provisions

The manufacturer or its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in Section 12,

— the certificate referred to in Section 15.2, and

— the EU type-examination certificate referred to in Annex X.

Section 8 of Annex IX shall apply.

18. Application to class IIa devices

18.1. By way of derogation from Section 11, by virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

18.2. The verification conducted by the notified body in accordance with Section 14 is intended to confirm the conformity of the class IIa devices in question with the technical documentation referred to in Annexes II and III and with the requirements of this Regulation which apply to them.

18.3. If the verification referred to in Section 18.2 confirms that the class IIa devices in question conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this Part of this Annex.

18.4. By way of derogation from Section 17, the manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the technical documentation referred to in Annexes II and III, and

— the certificate referred to in Section 18.3.

Section 8 of Annex IX shall apply.

ANNEX XII

CERTIFICATES ISSUED BY A NOTIFIED BODY

CHAPTER I

GENERAL REQUIREMENTS

1. Certificates shall be drawn up in one of the official languages of the Union.

2. Each certificate shall refer to only one conformity assessment procedure.

3. Certificates shall only be issued to one manufacturer. The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system referred to in Article 30.

4. The scope of the certificates shall unambiguously identify the device or devices covered:

   (a) EU technical documentation assessment certificates, EU type-examination certificates and EU product verification certificates shall include a clear identification, including the name, model and type, of the device or devices, the intended purpose, as included by the manufacturer in the instructions for use and in relation to which the device has been assessed in the conformity assessment procedure, risk classification and the Basic UDI-DI as referred to in Article 27(6);

   (b) EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification, and, for class IIb devices, the intended purpose.

5. The notified body shall be able to demonstrate on request, which (individual) devices are covered by the certificate. The notified body shall set up a system that enables the determination of the devices, including their classification, covered by the certificate.

6. Certificates shall contain, if applicable, a note that, for the placing on the market of the device or devices it covers, another certificate issued in accordance with this Regulation is required.

7. EU quality management system certificates and EU quality assurance certificates for class I devices for which the involvement of a notified body is required pursuant to Article 52(7) shall include a statement that the audit by the notified body of the quality management system was limited to the aspects required under that paragraph.

8. Where a certificate is supplemented, modified or re-issued, the new certificate shall contain a reference to the preceding certificate and its date of issue with identification of the changes.

CHAPTER II

MINIMUM CONTENT OF THE CERTIFICATES

1. name, address and identification number of the notified body;

2. name and address of the manufacturer and, if applicable, of the authorised representative;

3. unique number identifying the certificate;

4. if already issued, the SRN of the manufacturer referred to in to Article 31(2);

5. date of issue;

6. date of expiry;

7. data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of Part I;

8. if applicable, reference to any previous certificate as specified in Section 8 of Chapter I;

9. reference to this Regulation and the relevant Annex in accordance with which the conformity assessment has been carried out;

10. examinations and tests performed, e.g. reference to relevant CS, harmonised standards, test reports and audit report(s);

11. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered;

12. if applicable, information about the surveillance by the notified body;

13. conclusions of the notified body's conformity assessment with regard to the relevant Annex;

14. conditions for or limitations to the validity of the certificate;

15. legally binding signature of the notified body in accordance with the applicable national law.

ANNEX XIII

PROCEDURE FOR CUSTOM-MADE DEVICES

1. For custom-made devices, the manufacturer or its authorised representative shall draw up a statement containing all of the following information:

   — the name and address of the manufacturer, and of all manufacturing sites,

   — if applicable, the name and address of the authorised representative,

   — data allowing identification of the device in question,

   — a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code,

   — the name of the person who made out the prescription and who is authorised by national law by virtue of their professional qualifications to do so, and, where applicable, the name of the health institution concerned,

   — the specific characteristics of the product as indicated by the prescription,

   — a statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds,

   — where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Regulation (EU) No 722/2012.

2. The manufacturer shall undertake to keep available for the competent national authorities documentation that indicates its manufacturing site or sites and allows an understanding to be formed of the design, manufacture and performance of the device, including the expected performance, so as to allow assessment of conformity with the requirements of this Regulation.

3. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which are manufactured in accordance with the documentation referred to in Section 2.

4. The statement referred to in the introductory part of Section 1 shall be kept for a period of at least 10 years after the device has been placed on the market. In the case of implantable devices, the period shall be at least 15 years.

   Section 8 of Annex IX shall apply.

5. The manufacturer shall review and document experience gained in the post-production phase, including from PMCF as referred to in Part B of Annex XIV, and implement appropriate means to apply any necessary corrective action, In that context, it shall report in accordance with Article 87(1) to the competent authorities any serious incidents or field safety corrective actions or both as soon as it learns of them.

ANNEX XIV

CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

PART A

CLINICAL EVALUATION

1. To plan, continuously conduct and document a clinical evaluation, manufacturers shall:

   (a) establish and update a clinical evaluation plan, which shall include at least:

   — an identification of the general safety and performance requirements that require support from relevant clinical data;

   — a specification of the intended purpose of the device;

   — a clear specification of intended target groups with clear indications and contra-indications;

   — a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;

   — a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;

   — an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;

   — an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are to be addressed; and

   — a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Annex with an indication of milestones and a description of potential acceptance criteria;

   (b) identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review;

   (c) appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;

   (d) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues; and

   (e) analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.

2. The clinical evaluation shall be thorough and objective, and take into account both favourable and unfavourable data. Its depth and extent shall be proportionate and appropriate to the nature, classification, intended purpose and risks of the device in question, as well as to the manufacturer's claims in respect of the device.

3. A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

   — Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;

   — Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

— Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

4. The results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a clinical evaluation report which shall support the assessment of the conformity of the device.

The clinical evidence together with non-clinical data generated from non-clinical testing methods and other relevant documentation shall allow the manufacturer to demonstrate conformity with the general safety and performance requirements and shall be part of the technical documentation for the device in question.

Both favourable and unfavourable data considered in the clinical evaluation shall be included in the technical documentation.

PART B

POST-MARKET CLINICAL FOLLOW-UP

5. PMCF shall be understood to be a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of this Annex and shall be addressed in the manufacturer's post-market surveillance plan. When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

6. PMCF shall be performed pursuant to a documented method laid down in a PMCF plan.

6.1. The PMCF plan shall specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of:

(a) confirming the safety and performance of the device throughout its expected lifetime,

(b) identifying previously unknown side-effects and monitoring the identified side-effects and contraindications,

(c) identifying and analysing emergent risks on the basis of factual evidence,

(d) ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I, and

(e) identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

6.2. The PMCF plan shall include at least:

(a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;

(b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;

(c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);

(d) a reference to the relevant parts of the clinical evaluation report referred to in Section 4 and to the risk management referred to in Section 3 of Annex I;

(e) the specific objectives to be addressed by the PMCF;

(f) an evaluation of the clinical data relating to equivalent or similar devices;

(g) reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and

(h) a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer.

7. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation.

8. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 61 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

ANNEX XV

CLINICAL INVESTIGATIONS

CHAPTER I

GENERAL REQUIREMENTS

1. Ethical principles

Each step in the clinical investigation, from the initial consideration of the need for and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles.

2. Methods

2.1. Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims regarding the safety, performance and aspects relating to benefit-risk of devices as referred to in Article 62(1); the clinical investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions. The rationale for the design and chosen statistical methodology shall be presented as further described in Section 3.6 of Chapter II of this Annex.

2.2. The procedures used to perform the clinical investigation shall be appropriate to the device under investigation.

2.3. The research methodologies used to perform the clinical investigation shall be appropriate to the device under investigation.

2.4. Clinical investigations shall be performed in accordance with the clinical investigation plan by a sufficient number of intended users and in a clinical environment that is representative of the intended normal conditions of use of the device in the target patient population. Clinical investigations shall be in line with the clinical evaluation plan as referred to in Part A of Annex XIV.

2.5. All the appropriate technical and functional features of the device, in particular those involving safety and performance, and their expected clinical outcomes shall be appropriately addressed in the investigational design. A list of the technical and functional features of the device and the related expected clinical outcomes shall be provided.

2.6. The endpoints of the clinical investigation shall address the intended purpose, clinical benefits, performance and safety of the device. The endpoints shall be determined and assessed using scientifically valid methodologies. The primary endpoint shall be appropriate to the device and clinically relevant.

2.7. Investigators shall have access to the technical and clinical data regarding the device. Personnel involved in the conduct of an investigation shall be adequately instructed and trained in the proper use of the investigational device, and as regards the clinical investigation plan and good clinical practice. This training shall be verified and where necessary arranged by the sponsor and documented appropriately.

2.8. The clinical investigation report, signed by the investigator, shall contain a critical evaluation of all the data collected during the clinical investigation, and shall include any negative findings.

CHAPTER II

DOCUMENTATION REGARDING THE APPLICATION FOR CLINICAL INVESTIGATION

For investigational devices covered by Article 62, the sponsor shall draw up and submit the application in accordance with Article 70 accompanied by the following documents:

1. Application form

The application form shall be duly filled in, containing information regarding:

1.1. name, address and contact details of the sponsor and, if applicable, name, address and contact details of its contact person or legal representative in accordance with Article 62(2) established in the Union;

1.2. if different from those in Section 1.1, name, address and contact details of the manufacturer of the device intended for clinical investigation and, if applicable, of its authorised representative;

1.3. title of the clinical investigation;

1.4. status of the clinical investigation application (i.e. first submission, resubmission, significant amendment);

1.5. details and/or reference to the clinical evaluation plan;

1.6. If the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or in the case of significant amendment, reference to the original application. The sponsor shall identify all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews;

1.7. if the application is submitted in parallel with an application for a clinical trial in accordance with Regulation (EU) No 536/2014, reference to the official registration number of the clinical trial;

1.8. identification of the Member States and third countries in which the clinical investigation is to be conducted as part of a multicentre or multinational study at the time of application;

1.9. a brief description of the investigational device, its classification and other information necessary for the identification of the device and device type;

1.10. information as to whether the device incorporates a medicinal substance, including a human blood or plasma derivative or whether it is manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives;

1.11. summary of the clinical investigation plan including the objective or objectives of the clinical investigation, the number and gender of subjects, criteria for subject selection, whether there are subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation;

1.12. if applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device;

1.13. evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical investigation in accordance with the clinical investigation plan;

1.14. details of the anticipated start date and duration of the investigation;

1.15. details to identify the notified body, if already involved at the stage of application for a clinical investigation;

1.16. confirmation that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application; and

1.17. the statement referred to in Section 4.1.

2. Investigator's Brochure

The investigator's brochure (IB) shall contain the clinical and non-clinical information on the investigational device that is relevant for the investigation and available at the time of application. Any updates to the IB or other relevant information that is newly available shall be brought to the attention of the investigators in a timely manner. The IB shall be clearly identified and contain in particular the following information:

2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule pursuant to Annex VIII, design and manufacturing of the device and reference to previous and similar generations of the device.

2.2. Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements, as well as, to the extent that such information is available, information to be placed on the label, and instructions for use to be provided with the device when placed on the market. In addition, information relating to any relevant training required.

2.3. Pre-clinical evaluation based on relevant pre-clinical testing and experimental data, in particular regarding in-design calculations, *in vitro* tests, *ex vivo* tests, animal tests, mechanical or electrical tests, reliability tests, sterilisation validation, software verification and validation, performance tests, evaluation of biocompatibility and biological safety, as applicable.

2.4. Existing clinical data, in particular:

— from relevant scientific literature available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of the device and/or of equivalent or similar devices;

— other relevant clinical data available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance, clinical benefit and safety-related issues and any corrective actions taken.

2.5. Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contraindications and warnings.

2.6. In the case of devices that incorporate a medicinal substance, including a human blood or plasma derivative or devices manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives, detailed information on the medicinal substance or on the tissues, cells or their derivatives, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the substance or tissues, cells or their derivatives, as well as evidence for the added value of incorporation of such constituents in relation to the clinical benefit and/or safety of the device.

2.7. A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and CS applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking.

2.8. A detailed description of the clinical procedures and diagnostic tests used in the course of the clinical investigation and in particular information on any deviation from normal clinical practice.

3. Clinical Investigation Plan

The clinical investigation plan (CIP) shall set out the rationale, objectives, design methodology, monitoring, conduct, record-keeping and the method of analysis for the clinical investigation. It shall contain in particular the information as laid down in this Annex. If part of this information is submitted in a separate document, it shall be referenced in the CIP.

3.1. General

3.1.1. Single identification number of the clinical investigation, as referred to in Article 70(1).

3.1.2. Identification of the sponsor — name, address and contact details of the sponsor and, where applicable, the name, address and contact details of the sponsor's contact person or legal representative in accordance with Article 62(2) established in the Union.

3.1.3. Information on the principal investigator at each investigational site, the coordinating investigator for the investigation, the address details for each investigational site and the emergency contact details for the principal investigator at each site. The roles, responsibilities and qualifications of the various kinds of investigators shall be specified in the CIP.

3.1.4. A brief description of how the clinical investigation is financed and a brief description of the agreement between the sponsor and the site.

3.1.5. Overall synopsis of the clinical investigation, in an official Union language determined by the Member State concerned.

3.2. Identification and description of the device, including its intended purpose, its manufacturer, its traceability, the target population, materials coming into contact with the human body, the medical or surgical procedures involved in its use and the necessary training and experience for its use, background literature review, the current state of the art in clinical care in the relevant field of application and the proposed benefits of the new device.

3.3. Risks and clinical benefits of the device to be examined, with justification of the corresponding expected clinical outcomes in the clinical investigation plan.

3.4. Description of the relevance of the clinical investigation in the context of the state of the art of clinical practice.

3.5. Objectives and hypotheses of the clinical investigation.

3.6. Design of the clinical investigation with evidence of its scientific robustness and validity.

3.6.1. General information such as type of investigation with rationale for choosing it, for its endpoints and for its variables as set out in the clinical evaluation plan.

3.6.2. Information on the investigational device, on any comparator and on any other device or medication to be used in the clinical investigation.

3.6.3. Information on subjects, selection criteria, size of investigation population, representativeness of investigation population in relation to target population and, if applicable, information on vulnerable subjects involved such as children, pregnant women, immuno-compromised or, elderly subjects.

3.6.4. Details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors.

3.6.5. Description of the clinical procedures and diagnostic methods relating to the clinical investigation and in particular highlighting any deviation from normal clinical practice.

3.6.6. Monitoring plan.

3.7. Statistical considerations, with justification, including a power calculation for the sample size, if applicable.

3.8. Data management.

3.9. Information about any amendments to the CIP.

3.10. Policy regarding follow-up and management of any deviations from the CIP at the investigational site and clear prohibition of use of waivers from the CIP.

3.11. Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical investigation and the return of unused, expired or malfunctioning devices.

3.12. Statement of compliance with the recognised ethical principles for medical research involving humans, and the principles of good clinical practice in the field of clinical investigations of devices, as well as with the applicable regulatory requirements.

3.13. Description of the Informed consent process.

3.14. Safety reporting, including definitions of adverse events and serious adverse events, device deficiencies, procedures and timelines for reporting.

3.15. Criteria and procedures for follow-up of subjects following the end, temporary halt or early termination of an investigation, for follow-up of subjects who have withdrawn their consent and procedures for subjects lost to follow-up. Such procedures shall for implantable devices, cover as a minimum traceability.

3.16. A description of the arrangements for taking care of the subjects after their participation in the clinical investigation has ended, where such additional care is necessary because of the subjects' participation in the clinical investigation and where it differs from that normally expected for the medical condition in question.

3.17. Policy as regards the establishment of the clinical investigation report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 1 of Chapter I.

3.18. List of the technical and functional features of the device, with specific mention of those covered by the investigation.

3.19. Bibliography.

4. Other information

4.1. A signed statement by the natural or legal person responsible for the manufacture of the investigational device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

4.2. Where applicable according to national law, copy of the opinion or opinions of the ethics committee or committees concerned. Where according to national law the opinion or opinions of the ethics committee or committees is not required at the time of the submission of the application, a copy of the opinion or opinions shall be submitted as soon as available.

4.3. Proof of insurance cover or indemnification of subjects in case of injury, pursuant to Article 69 and the corresponding national law.

4.4. Documents to be used to obtain informed consent, including the patient information sheet and the informed consent document.

4.5. Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:

— organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;

— a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects; and

— a description of measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects.

4.6. Full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports, shall, upon request, be submitted to the competent authority reviewing an application.

CHAPTER III

OTHER OBLIGATIONS OF THE SPONSOR

1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter II of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the investigational device, that obligation may be fulfilled by that person on behalf of the sponsor.

2. The Sponsor shall have an agreement in place to ensure that any serious adverse events or any other event as referred to in Article 80(2) are reported by the investigator or investigators to the sponsor in a timely manner.

3. The documentation mentioned in this Annex shall be kept for a period of at least 10 years after the clinical investigation with the device in question has ended, or, in the event that the device is subsequently placed on the market, at least 10 years after the last device has been placed on the market. In the case of implantable devices, the period shall be at least 15 years.

   Each Member State shall require that this documentation is kept at the disposal of the competent authorities for the period referred to in the first subparagraph in case the sponsor, or its contact person or legal representative as referred to in Article 62(2) established within its territory, goes bankrupt or ceases its activity prior to the end of this period.

4. The Sponsor shall appoint a monitor that is independent from the investigational site to ensure that the investigation is conducted in accordance with the CIP, the principles of good clinical practice and this Regulation.

5. The Sponsor shall complete the follow-up of investigation subjects.

6. The Sponsor shall provide evidence that the investigation is being conducted in line with good clinical practice, for instance through internal or external inspection.

7. The Sponsor shall prepare a clinical investigation report which includes at least the following:

   — Cover/introductory page or pages indicating the title of the investigation, the investigational device, the single identification number, the CIP number and the details with signatures of the coordinating investigators and the principal investigators from each investigational site.

   — Details of the author and date of the report.

   — A summary of the investigation covering the title, purpose of the investigation, description of the investigation, investigational design and methods used, the results of the investigation and conclusion of the investigation. The completion date of the investigation, and in particular details of early termination, temporary halts or suspensions of investigations.

   — Investigational device description, in particular clearly defined intended purpose.

   — A summary of the clinical investigation plan covering objectives, design, ethical aspects, monitoring and quality measures, selection criteria, target patient populations, sample size, treatment schedules, follow-up duration, concomitant treatments, statistical plan, including hypothesis, sample size calculation and analysis methods, as well as a justification.

   — Results of the clinical investigation covering, with rationale and justification, subject demographics, analysis of results related to chosen endpoints, details of subgroup analysis, as well as compliance with the CIP, and covering follow-up of missing data and of patients withdrawing from the clinical investigation, or lost to follow-up.

   — Summary of serious adverse events, adverse device effects, device deficiencies and any relevant corrective actions.

   — Discussion and overall conclusions covering safety and performance results, assessment of risks and clinical benefits, discussion of clinical relevance in accordance with clinical state of the art, any specific precautions for specific patient populations, implications for the investigational device, limitations of the investigation.

ANNEX XVI

LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)

1. Contact lenses or other items intended to be introduced into or onto the eye.

2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.

3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.

4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.

6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

ANNEX XVII

CORRELATION TABLE

Council Directive 90/385/EEC	Council Directive 93/42/EEC	This Regulation
Article 1(1)	Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)	Article 2
Article 1(3)	Article 1(3) first subparagraph	Article 1(9) first subparagraph
—	Article 1(3) second subparagraph	Article 1(9) second subparagraph
Article 1(4) and (4a)	Article 1(4) and (4a)	Article 1(8) first subparagraph
Article 1(5)	Article 1(7)	Article 1(11)
Article 1(6)	Article 1(5)	Article 1(6)
—	Article 1(6)	—
—	Article 1(8)	Article 1(13)
Article 2	Article 2	Article 5(1)
Article 3 first paragraph	Article 3 first paragraph	Article 5(2)
Article 3 second paragraph	Article 3 second paragraph	Article 1(12)
Article 4(1)	Article 4(1)	Article 24
Article 4(2)	Article 4(2)	Article 21(1) and (2)
Article 4(3)	Article 4(3)	Article 21(3)
Article 4(4)	Article 4(4)	Article 10(11)
Article 4(5)(a)	Article 4(5) first subparagraph	Article 20(6)
Article 4(5)(b)	Article 4(5) second subparagraph	—
Article 5(1)	Article 5(1)	Article 8(1)
Article 5(2)	Article 5(2)	Article 8(2)
Article 6(1)	Articles 5(3) and 6	—
Article 6(2)	Article 7(1)	Article 114
Article 7	Article 8	Articles 94 to 97
—	Article 9	Article 51
Article 8(1)	Article 10(1)	Articles 87(1) and 89 (2)
Article 8(2)	Article 10(2)	Article 87(10) and Article 87(11) first subparagraph
Article 8(3)	Article 10(3)	Article 89(7)
Article 8(4)	Article 10(4)	Article 91
Article 9(1)	Article 11(1)	Article 52(3)
—	Article 11(2)	Article 52(6)
—	Article 11(3)	Article 52(4) and (5)
—	Article 11(4)	—
—	Article 11(5)	Article 52(7)

Council Directive 90/385/EEC	Council Directive 93/42/EEC	This Regulation
Article 9(2)	Article 11 (6)	Article 52(8)
Article 9(3)	Article 11(8)	Article 11(3)
Article 9(4)	Article 11(12)	Article 52(12)
Article 9(5)	Article 11(7)	—
Article 9(6)	Article 11(9)	Article 53(1)
Article 9(7)	Article 11(10)	Article 53(4)
Article 9(8)	Article 11(11)	Article 56(2)
Article 9(9)	Article 11(13)	Article 59
Article 9(10)	Article 11(14)	Article 4(5) and Article 122 third paragraph
—	Article 12	Article 22
—	Article 12a	Article 17
Article 9a(1) first indent	Article 13(1)(c)	—
Article 9a(1) second indent	Article 13(1)(d)	Article 4(1)
—	Article 13(1)(a)	Article 51(3)(a) and Article 51(6)
—	Article 13(1)(b)	Article 51(3)(b) and Article 51(6)
Article 10	Article 15	Articles 62 to 82
Article 10a(1), second sentence of Article 10a(2) and Article 10a(3)	Article 14(1), second sentence of Article 14(2) and Article 14(3)	Articles 29(4), 30 and 31
Article 10a(2), first sentence	Article 14(2) first sentence	Article 11(1)
Article 10b	Article 14a	Articles 33 and 34
Article 10c	Article 14b	Article 98
Article 11(1)	Article 16(1)	Articles 42 and 43
Article 11(2)	Article 16(2)	Article 36
Article 11(3)	Article 16(3)	Article 46(4)
Article 11(4)	Article 16(4)	—
Article 11(5)	Article 16(5)	Article 56(5)
Article 11(6)	Article 16(6)	Article 56(4)
Article 11(7)	Article 16(7)	Articles 38(2) and 44(2)
Article 12	Article 17	Article 20
Article 13	Article 18	Articles 94 to 97
Article 14	Article 19	Article 99
Article 15	Article 20	Article 109
Article 15a	Article 20a	Article 102
Article 16	Article 22	—
Article 17	Article 23	—
—	Article 21	—

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Directive 98/79/EC of the European Parliament and of the Council ([3]) constitutes the Union regulatory framework for *in vitro* diagnostic medical devices. However, a fundamental revision of that Directive is needed to establish a robust, transparent, predictable and sustainable regulatory framework for *in vitro* diagnostic medical devices which ensures a high level of safety and health whilst supporting innovation.

(2) This Regulation aims to ensure the smooth functioning of the internal market as regards *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of *in vitro* diagnostic medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for *in vitro* diagnostic medical devices by ensuring, among other things, that data generated in performance studies are reliable and robust and that the safety of subjects participating in performance studies is protected.

(3) This Regulation does not seek to harmonise rules relating to the further making available on the market of *in vitro* diagnostic medical devices after they have already been put into service, such as in the context of second-hand sales.

(4) Key elements of the existing regulatory approach, such as the supervision of notified bodies, risk classification, conformity assessment procedures, performance evaluation and performance studies, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices should be introduced, to improve health and safety.

(5) To the extent possible, guidance developed for *in vitro* diagnostic medical devices at international level, in particular in the context of the Global Harmonization Task Force and its follow-up initiative, the International Medical Devices Regulators Forum, should be taken into account to promote the global convergence of

([1]) Opinion of 14 February 2013 (OJ C 133, 9.5.2013, p. 52).
([2]) Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 7 March 2017 (not yet published in the Official Journal).
([3]) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical evidence.

(6) There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned.

(7) The scope of application of this Regulation should be clearly delimited from other legislation concerning products, such as medical devices, general laboratory products and products for research use only.

(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. In order to ensure consistent qualification decisions in that regard across all Member States, particularly with regard to borderline cases, the Commission should be allowed to, on its own initiative or at the duly substantiated request of a Member State, having consulted the Medical Device Coordination Group ('MDCG'), decide on a case-by-case basis whether or not a specific product, category or group of products falls within the scope of this Regulation. When deliberating on the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products or food products, the Commission should ensure an appropriate level of consultation of the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority, as relevant.

(9) It appears that it is possible that divergent national rules regarding the provision of information and counselling in relation to genetic testing might only have an impact on the smooth functioning of the internal market to a limited extent. Therefore, it is appropriate to lay down only limited requirements in this regard in this Regulation, having regard to the need to ensure constant respect of the principles of proportionality and subsidiarity.

(10) It should be made clear that all tests that provide information on the predisposition to a medical condition or a disease, such as genetic tests, and tests that provide information to predict treatment response or reactions, such as companion diagnostics, are *in vitro* diagnostic medical devices.

(11) Companion diagnostics are essential for defining patients' eligibility for specific treatment with a medicinal product through the quantitative or qualitative determination of specific markers identifying subjects at a higher risk of developing an adverse reaction to the medicinal product in question or identifying patients in the population for whom the therapeutic product has been adequately studied, and found safe and effective. Such biomarker or biomarkers can be present in healthy subjects and/or in patients.

(12) Devices that are used with a view to monitoring treatment with a medicinal product in order to ensure that the concentration of relevant substances in the human body is within the therapeutic window are not considered to be companion diagnostics.

(13) The requirement to reduce risks as far as possible should be fulfilled taking into account the generally acknowledged state of the art in the field of medicine.

(14) Safety aspects addressed by Directive 2014/30/EU of the European Parliament and of the Council ([1]) are an integral part of the general safety and performance requirements laid down in this Regulation for devices. Consequently, this Regulation should be considered a *lex specialis* in relation to that Directive.

(15) This Regulation should include requirements regarding the design and manufacture of devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom ([2]) which pursues other objectives.

(16) This Regulation should include requirements for devices' safety and performance characteristics which are developed in such a way as to prevent occupational injuries, including protection from radiation.

([1]) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79).

([2]) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

(17) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of an *in vitro* diagnostic medical device, qualifies as an *in vitro* diagnostic medical device, while software for general purposes, even when used in a healthcare setting, or software intended for well-being purposes is not an *in vitro* diagnostic medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

(18) The definitions in this Regulation regarding the devices themselves, the making available of devices, economic operators, users and specific processes, the conformity assessment, clinical evidence, post-market surveillance, vigilance and market surveillance, standards and other technical specifications, should be aligned with well-established practice in the field at Union and international level in order to enhance legal certainty.

(19) It should be made clear that it is essential that devices offered to persons in the Union by means of information society services within the meaning of Directive (EU) 2015/1535 of the European Parliament and of the Council [1] and devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union comply with the requirements of this Regulation, where the product in question is placed on the market or the service is provided in the Union.

(20) To recognise the important role of standardisation in the field of *in vitro* diagnostic medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council [2] should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality and risk management, laid down in this Regulation.

(21) Directive 98/79/EC allows the Commission to adopt common technical specifications for specific categories of *in vitro* diagnostic medical devices. In areas where no harmonised standards exist or where they are insufficient, the Commission should be empowered to lay down common specifications which provide a means of complying with the general safety and performance requirements and the requirements for performance studies and performance evaluation and/or post-market follow-up, laid down in this Regulation.

(22) Common specifications ('CS') should be developed after consulting the relevant stakeholders and taking account of the European and international standards.

(23) The rules applicable to devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council [3] and Decision No 768/2008/EC of the European Parliament and of the Council [4].

(24) The rules on Union market surveillance and control of products entering the Union market laid down in Regulation (EC) No 765/2008 apply to devices covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

(25) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, building on the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the various parts of this Regulation, to enhance understanding of the requirements laid down in this Regulation and thus to improve regulatory compliance by the relevant operators.

(26) For the purpose of this Regulation, the activities of distributors should be deemed to include acquisition, holding and supplying of devices.

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[1] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

[2] Regulation (EU) No 1025/2012 of 25 October 2012 of the European Parliament and of the Council on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

[3] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

[4] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(27) Several of the obligations on manufacturers, such as performance evaluation or vigilance reporting, that were set out only in the Annexes to Directive 98/79/EC, should be incorporated into the enacting provisions of this Regulation to facilitate its application.

(28) To ensure the highest level of health protection, the rules governing *in vitro* diagnostic medical devices, manufactured and used within a single health institution only, should be clarified and strengthened. That use should be understood to include measurement and delivery of results.

(29) Health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, on a non-industrial scale, the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent device available on the market. In that context, it is appropriate to provide that certain rules of this Regulation, as regards devices manufactured and used only within health institutions, including hospitals as well as institutions, such as laboratories and public health institutes that support the health care system and/or address patient needs, but which do not treat or care for patients directly, should not apply, since the aims of this Regulation would still be met in a proportionate manner. It should be noted that the concept of 'health institution' does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres. As a result, the exemption applicable to health institutions does not apply to such establishments.

(30) In view of the fact that natural or legal persons can claim compensation for damage caused by a defective device in accordance with applicable Union and national law, it is appropriate to require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability under Council Directive 85/374/EEC ([1]). Such measures should be proportionate to the risk class, type of device and the size of the enterprise. In this context, it is also appropriate to lay down rules concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

(31) To ensure that devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of the devices they manufacture is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance system in place which should be proportionate to the risk class and the type of the device in question. In addition, in order to minimize risks or prevent incidents related to devices, manufacturers should establish a system for risk management and a system for reporting incidents and field safety corrective actions.

(32) The risk management system should be carefully aligned with and reflected in the performance evaluation process for the device, including the clinical risks to be addressed as part of performance studies, performance evaluation and post-market performance follow-up. The risk management and performance evaluation processes should be inter-dependent and should be regularly updated.

(33) It should be ensured that supervision and control of the manufacture of devices, as well as post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification.

(34) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union. Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations. The liability of the authorised representative provided for in this Regulation is without prejudice to the provisions of Directive 85/374/EEC, and accordingly the authorised representative should be jointly and severally liable with the importer and the manufacturer. The tasks of an authorised representative should be defined in a written mandate. Considering the role of authorised representatives, the minimum requirements they should meet should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's person responsible for regulatory compliance.

([1]) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

(35) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of a device.

(36) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 TFEU subject to the limitations arising from the need for protection of health and safety and from the need for protection of intellectual property rights provided for under Article 36 TFEU. Application of the principle of parallel trade is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging, should therefore be specified in this Regulation, taking into account the case-law of the Court of Justice ([1]) in other relevant sectors and existing good practice in the field of *in vitro* diagnostic medical devices.

(37) Devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation. However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.

(38) The traceability of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly enhance the effectiveness of the post-market safety-related activities for devices, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against falsified devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.

(39) The UDI system should apply to all devices placed on the market except devices for performance studies, and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the UDI system to become functional in time for the application of this Regulation, detailed rules should be laid down in this Regulation and in Regulation (EU) 2017/745 of the European Parliament and of the Council ([2]).

(40) Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

(41) One key aspect in fulfilling the objectives of this Regulation is the creation of a European database on medical devices (Eudamed) that should integrate different electronic systems to collate and process information regarding devices on the market and the relevant economic operators, certain aspects of conformity assessment, notified bodies, certificates, performance studies, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to avoid multiple reporting requirements, to enhance coordination between Member States and to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission. Within the internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices set up by Commission Decision 2010/227/EU ([3]).

(42) To facilitate the functioning of Eudamed, an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. Furthermore, that nomenclature should be available, where reasonably practicable, free of charge also to other stakeholders.

([1]) Judgment of 28 July 2011 in Orifarm and Paranova, joined cases C-400/09 and C-207/10, ECLI:EU:C:2011:519.
([2]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (see page 1 of this Official Journal).
([3]) Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices (OJ L 102, 23.4.2010, p. 45).

(43) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on performance studies should serve as a tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and to report serious adverse events, device deficiencies and related updates. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of the evaluation of such incidents and events by competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

(44) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC of the European Parliament and of the Council ([1]) applies to the processing of personal data carried out in the Member States, under the supervision of the Member States' competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001 of the European Parliament and of the Council ([2]) applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.

(45) For class C and D devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the performance evaluation in a document that should be publicly available.

(46) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

(47) Notified bodies' assessments of manufacturers' technical documentation, in particular documentation on performance evaluation, should be critically evaluated by the authority responsible for notified bodies. That evaluation should be part of the risk-based approach to the oversight and monitoring activities of notified bodies and should be based on sampling of the relevant documentation.

(48) The position of notified bodies vis-à-vis manufacturers should be strengthened, including with regard to their right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on devices to ensure continuous compliance by manufacturers after receipt of the original certification.

(49) To increase transparency with regard to the oversight of notified bodies by national authorities, the authorities responsible for notified bodies should publish information on the national measures governing the assessment, designation and monitoring of notified bodies. In accordance with good administrative practice, this information should be kept up to date by those authorities in particular to reflect relevant, significant or substantive changes to the procedures in question.

(50) The Member State in which a notified body is established should be responsible for enforcing the requirements of this Regulation with regard to that notified body.

(51) In view, in particular, of the responsibility of Member States for the organisation and delivery of health services and medical care, they should be allowed to lay down additional requirements on notified bodies designated for the conformity assessment of devices and established on their territory as far as issues that are not regulated in this Regulation are concerned. Any such additional requirements laid down should not affect more specific horizontal Union legislation on notified bodies and equal treatment of notified bodies.

(52) For class D devices, competent authorities should be informed about certificates granted by notified bodies and be given the right to scrutinise the assessment conducted by notified bodies.

([1]) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

([2]) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(53) For class D devices for which no CS exist it is appropriate to provide that where it is the first certification for that specific type of device and there is no similar device on the market having the same intended purpose and based on similar technology, notified bodies should, in addition to the laboratory testing of the performance claimed by the manufacturer and the compliance of the device by the EU reference laboratories, be obliged to request expert panels to scrutinise their performance evaluation assessment reports. The consultation of expert panels in relation to the performance evaluation should lead to a harmonised evaluation of high-risk *in vitro* diagnostic medical devices by sharing expertise on performance aspects and developing CS on categories of devices that have undergone that consultation process.

(54) To enhance patient safety and to take due account of technological progress, the current classification system for devices set out in Directive 98/79/EC should be fundamentally changed, in line with international practice, and the corresponding conformity assessment procedures should be accordingly adapted.

(55) It is necessary, in particular for the purpose of the conformity assessment procedures, to classify devices in four risk classes and to establish a set of robust risk-based classification rules, in line with international practice.

(56) The conformity assessment procedure for class A devices should be carried out, as a general rule, under the sole responsibility of manufacturers, since such devices pose a low risk to patients. For class B, class C and class D devices, an appropriate level of involvement of a notified body should be compulsory.

(57) The conformity assessment procedures for devices should be further strengthened and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

(58) It is appropriate that certificates of free sale contain information that makes it possible to use Eudamed in order to obtain information on the device, in particular with regard to whether it is on the market, withdrawn from the market or recalled, and on any certificate on its conformity.

(59) It is necessary to clarify the requirements regarding batch release verification for the highest risk devices.

(60) EU reference laboratories should be enabled to verify by laboratory testing the performance claimed by the manufacturer and the compliance of devices presenting the highest risk with the applicable CS, when such CS are available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.

(61) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical evidence. It is necessary to clarify the requirements for the demonstration of the clinical evidence, that is based on data on scientific validity, and the analytical performance and clinical performance of the device. To allow for a structured and transparent process, generating reliable and robust data, sourcing and assessment of available scientific information and data generated in performance studies should be based on a performance evaluation plan.

(62) As a general rule, clinical evidence should be sourced from performance studies that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the performance study.

(63) It is necessary to ensure that the clinical evidence of devices is updated throughout their lifecycle. Such updating entails the planned monitoring of scientific developments and changes in medical practice by the manufacturer. Relevant new information should then trigger a reassessment of the clinical evidence of the device thus ensuring safety and performance through a continuous process of performance evaluation.

(64) It should be recognised that the concept of clinical benefit for *in vitro* diagnostic medical devices is fundamentally different from that which applies in the case of pharmaceuticals or of therapeutic medical devices, since the benefit of *in vitro* diagnostic medical devices lies in providing accurate medical information on patients, where appropriate, assessed against medical information obtained through the use of other diagnostic options and technologies, whereas the final clinical outcome for the patient is dependent on further diagnostic and/or therapeutic options which could be available.

(65) Where specific devices have no analytical or clinical performance or specific performance requirements are not applicable, it is appropriate to justify in the performance evaluation plan, and related reports, omissions relating to such requirements.

(66) The rules on performance studies should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects, so as to make it easier for the results of performance studies conducted in the Union to be accepted as documentation outside the Union and to make it easier for the results of performance studies conducted outside the Union in accordance with international guidelines to be accepted within the Union. In addition, the rules should be in line with the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

(67) It should be left to the Member State where a performance study is to be conducted to determine the appropriate authority to be involved in the assessment of the application to conduct a performance study and to organise the involvement of ethics committees within the timelines for the authorisation of that performance study as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. In that context, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available.

(68) An electronic system should be set up at Union level to ensure that every interventional clinical performance study and other performance study involving risks for the subjects of the studies is recorded and reported in a publicly accessible database. To protect the right to protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union ('the Charter'), no personal data of subjects participating in a performance study should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on performance studies should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

(69) Where an interventional clinical performance study or another performance study involving risks for the subjects is to be conducted in more than one Member State, the sponsor should have the possibility of submitting a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety-related aspects of the device for performance study and of the scientific design of that performance study, the procedure for the assessment of such single application should be coordinated between the Member States under the direction of a coordinating Member State. Such coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a performance study, including informed consent. For an initial period of seven years from the date of application of this Regulation, Member States should be able to participate on a voluntary basis in the coordinated assessment. After that period, all Member States should be obliged to participate in the coordinated assessment. The Commission, based on the experience gained from the voluntary coordination between Member States, should draw up a report on the application of the relevant provisions regarding the coordinated assessment procedure. In the event that the findings of the report are negative, the Commission should submit a proposal to extend the period of participation on a voluntary basis in the coordinated assessment procedure.

(70) Sponsors should report certain adverse events and device deficiencies that occur during interventional clinical performance studies and other performance studies involving risks for the subjects to the Member States in which those studies are being conducted. Member States should have the possibility of terminating or suspending the studies or revoking the authorisation for those studies, if considered necessary to ensure a high level of protection of the subjects participating in such studies. Such information should be communicated to the other Member States.

(71) The sponsor of a performance study should submit a summary of results of the performance study that is easily understandable for the intended user together with the performance study report, where applicable, within the timelines laid down in this Regulation. Where it is not possible to submit the summary of the results within the defined timelines for scientific reasons, the sponsor should justify this and specify when the results will be submitted.

(72) With exemption of some general requirements, this Regulation should only cover performance studies intended to gather scientific data for the purpose of demonstrating conformity of devices.

(73) It is necessary to clarify that performance studies using left-over specimens need not be authorised. Nevertheless, the general requirements and other additional requirements with regard to data protection and the requirements applicable to procedures that are performed in accordance with national law such as ethical review should continue to apply to all performance studies, including when using left-over specimens.

(74) The principles of replacement, reduction and refinement in the area of animal experimentation laid down in the Directive 2010/63/EU of the European Parliament and the Council [1] should be observed. In particular, the unnecessary duplication of tests and studies should be avoided.

(75) Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities. To that end, manufacturers should establish a comprehensive post-market surveillance system, set up under their quality management system and based on a post-market surveillance plan. Relevant data and information gathered through post-market surveillance, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as those relating to risk assessment and performance evaluation, and should also serve the purposes of transparency.

(76) In order to better protect health and safety regarding devices on the market, the electronic system on vigilance for devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

(77) Member States should take appropriate measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents. Healthcare professionals, users and patients should be encouraged and enabled to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers of any suspected serious incident and, where a manufacturer confirms that such an incident might have occurred, the authorities concerned should ensure that appropriate follow-up action is taken in order to minimise recurrence of such incidents.

(78) The evaluation of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State, with the objective of sharing resources and ensuring consistency regarding the corrective action.

(79) In the context of the investigation of incidents, the competent authorities should take into account, where appropriate, the information provided by and views of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.

(80) The reporting of serious adverse events or device deficiencies during interventional clinical performance studies and other performance studies involving risks for the subjects, and the reporting of serious incidents occurring after a device has been placed on the market should be clearly distinguished to avoid double reporting.

(81) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

(82) Any statistically significant increase in the number or severity of incidents that are not serious or in expected erroneous results that could have a significant impact on the benefit-risk analysis and which could lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.

(83) An expert committee, the MDCG, composed of persons designated by the Member States based on their role and expertise in the field of medical devices including *in vitro* diagnostic medical devices, should be established in

[1] Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010. p. 33).

accordance with the conditions and modalities defined in Regulation (EU) 2017/745 to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) 2017/745, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. The MDCG should be able to establish subgroups in order to have access to necessary in-depth technical expertise in the field of medical devices including *in vitro* diagnostic medical devices. When establishing subgroups, appropriate consideration should be given to the possibility of involving existing groups at Union level in the field of medical devices.

(84) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is essential for ensuring a uniform high level of health and safety protection within the internal market, in particular in the areas of performance studies and vigilance. The principle of coordinated exchange and assessment should also apply across other authority activities described in this Regulation, such as the designation of notified bodies and should be encouraged in the area of market surveillance of devices. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level.

(85) The Commission should provide scientific, technical and corresponding logistical support to coordinating national authorities and ensure that the regulatory system for devices is effectively and uniformly implemented at Union level based on sound scientific evidence.

(86) The Union and, where appropriate, the Member States should actively participate in international regulatory cooperation in the field of devices to facilitate the exchange of safety-related information regarding devices and foster the further development of international regulatory guidelines that promote the adoption in other jurisdictions of regulations that lead to a level of health and safety protection equivalent to that set by this Regulation.

(87) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement.

(88) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should, in order to ensure transparency, inform the Commission and the other Member States before they decide on the level and structure of such fees. In order to further ensure transparency, the structure and level of the fees should be publicly available on request.

(89) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

(90) The power to adopt delegated acts in accordance with Article 290 TFEU should be delegated to the Commission in order to amend certain non-essential provisions of this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law Making [1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with preparation of delegated acts.

(91) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council [2].

[1] OJ L 123, 12.5.2016, p. 1.
[2] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(92) The advisory procedure should be used for implementing acts that set out the form and presentation of the data elements of manufacturers' summaries of safety and performance, and that establish the model for certificates of free sale, given that such implementing acts are of a procedural nature and do not directly have an impact on health and safety at Union level.

(93) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures, imperative grounds of urgency so require.

(94) In order to enable it to designate issuing entities and EU reference laboratories, implementing powers should be conferred on the Commission.

(95) To allow economic operators, especially SMEs, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation and to ensure its proper application, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements that are to be made. However, certain parts of the Regulation that directly affect Member States and the Commission should be implemented as soon as possible. It is also particularly important that, by the date of application of this Regulation, a sufficient number of notified bodies be designated in accordance with the new requirements so as to avoid any shortage of devices on the market. Nonetheless, it is necessary that any designation of a notified body in accordance with the requirements of this Regulation prior to the date of its application be without prejudice to the validity of the designation of those notified bodies under Directive 98/79/EC and to their capacity to continue issuing valid certificates under that Directive until the date of application of this Regulation.

(96) In order to ensure a smooth transition to the new rules for registration of devices and of certificates, the obligation to submit the relevant information to the electronic systems set up at Union level pursuant to this Regulation should, in the event that the corresponding IT systems are developed according to plan, only become fully effective from 18 months after the date of application of this Regulation. During this transitional period, certain provisions of Directive 98/79/EC should remain in force. However, in order to avoid multiple registrations, economic operators and notified bodies who register in the relevant electronic systems set up at Union level pursuant to this Regulation should be considered to be in compliance with the registration requirements adopted by the Member States pursuant to those provisions.

(97) In order to provide for a smooth introduction of the UDI system, the moment of application of the obligation to place the UDI carrier on the label of the device should vary from one to five years after the date of application of this Regulation depending upon the class of the device concerned.

(98) Directive 98/79/EC should be repealed to ensure that only one set of rules applies to the placing of *in vitro* diagnostic medical devices on the market and the related aspects covered by this Regulation. Manufacturers' obligations as regards the making available of documentation regarding devices they placed on the market and manufacturers' and Member States' obligations as regards vigilance activities for devices placed on the market pursuant to that Directive should however continue to apply. While it should be left to Member States to decide how to organise vigilance activities, it is desirable for them to have the possibility of reporting adverse incidents related to devices placed on the market pursuant to that Directive using the same tools as those for reporting on devices placed on the market pursuant to this Regulation. However, Decision 2010/227/EU adopted in implementation of that Directive and Council Directives 90/385/EEC ([1]) and 93/42/EEC ([2]) should also be repealed as from the date when Eudamed becomes fully functional.

(99) The requirements of this Regulation should be applicable to all devices placed on the market or put into service from the date of application of this Regulation. However, in order to provide for a smooth transition it should be possible, for a limited period of time from that date, for devices to be placed on the market or put into service by virtue of a valid certificate issued pursuant to Directive 98/79/EC.

(100) The European Data Protection Supervisor has given an opinion ([3]) pursuant to Article 28(2) of Regulation (EC) No 45/2001.

([1]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17)
([2]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1)
([3]) OJ C 358, 7.12.2013, p. 10.

(101) Since the objectives of this Regulation, namely to ensure the smooth functioning of the internal market as regards medical devices and to ensure high standards of quality and safety for *in vitro* diagnostic medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

INTRODUCTORY PROVISIONS

Section 1

Scope and definitions

Article 1

Subject matter and scope

1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of *in vitro* diagnostic medical devices for human use and accessories for such devices in the Union. This Regulation also applies to performance studies concerning such *in vitro* diagnostic medical devices and accessories conducted in the Union.

2. For the purposes of this Regulation, *in vitro* diagnostic medical devices and accessories for *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'.

3. This Regulation does not apply to:

(a) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;

(b) invasive sampling products or products which are directly applied to the human body for the purpose of obtaining a specimen;

(c) internationally certified reference materials;

(d) materials used for external quality assessment schemes.

4. Any device which, when placed on the market or put into service, incorporates, as an integral part, a medical device as defined in point 1 of Article 2 of Regulation (EU) 2017/745 shall be governed by that Regulation. The requirements of this Regulation shall apply to the *in vitro* diagnostic medical device part.

5. This Regulation is specific Union legislation within the meaning of Article 2(3) of Directive 2014/30/EU.

6. Devices which are also machinery within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council [1] shall, where a hazard relevant under that Directive exists, also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation.

7. This Regulation shall not affect the application of Directive 2013/59/Euratom.

8. This Regulation shall not affect the right of a Member State to restrict the use of any specific type of device in relation to aspects not covered by this Regulation.

[1] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery (OJ L 157, 9.6.2006, p. 24).

9. This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or use certain devices or that their use be accompanied by specific professional counselling.

10. Nothing in this Regulation shall restrict the freedom of the press or the freedom of expression in the media in so far as those freedoms are guaranteed in the Union and in the Member States, in particular under Article 11 of the Charter of Fundamental Rights of the European Union.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means 'medical device' as defined in point (1) of Article 2 of Regulation (EU) 2017/745;

(2) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

(a) concerning a physiological or pathological process or state;

(b) concerning congenital physical or mental impairments;

(c) concerning the predisposition to a medical condition or a disease;

(d) to determine the safety and compatibility with potential recipients;

(e) to predict treatment response or reactions;

(f) to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices;

(3) 'specimen receptacle' means a device, whether of a vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination;

(4) 'accessory for an *in vitro* diagnostic medical device' means an article which, whilst not being itself an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the *in vitro* diagnostic medical device(s) in terms of its/their intended purpose(s);

(5) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services;

(6) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional;

(7) 'companion diagnostic' means a device which is essential for the safe and effective use of a corresponding medicinal product to:

(a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or

(b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product;

(8) 'generic device group' means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(9) 'single-use device' means a device that is intended to be used during a single procedure;

(10) 'falsified device' means any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;

(11) 'kit' means a set of components that are packaged together and intended to be used to perform a specific *in vitro* diagnostic examination, or a part thereof;

(12) 'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation;

(13) 'label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

(14) 'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;

(15) 'Unique Device Identifier' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

(16) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;

(17) 'benefit-risk determination' means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

(18) 'compatibility' is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:

(a) perform without losing or compromising the ability to perform as intended, and/or

(b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or

(c) be used together without conflict/interference or adverse reaction;

(19) 'interoperability' is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:

(a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or

(b) communicate with each other, and/or

(c) work together as intended;

(20) 'making available on the market' means any supply of a device, other than a device for performance study, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(21) 'placing on the market' means the first making available of a device, other than a device for performance study, on the Union market;

(22) 'putting into service' means the stage at which a device, other than a device for performance study, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

(23) 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trade mark;

(24) 'fully refurbishing', for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

(25) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(26) 'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market;

(27) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

(28) 'economic operator' means a manufacturer, an authorised representative, an importer or a distributor;

(29) 'health institution' means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

(30) 'user' means any healthcare professional or lay person who uses a device;

(31) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

(32) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

(33) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

(34) 'notified body' means a conformity assessment body designated in accordance with this Regulation;

(35) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

(36) 'clinical evidence' means clinical data and performance evaluation results, pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer;

(37) 'clinical benefit' means the positive impact of a device related to its function, such as that of screening, monitoring, diagnosis or aid to diagnosis of patients, or a positive impact on patient management or public health;

(38) 'scientific validity of an analyte' means the association of an analyte with a clinical condition or a physiological state;

(39) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting that intended purpose;

(40) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyte;

(41) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user;

(42) 'performance study' means a study undertaken to establish or confirm the analytical or clinical performance of a device;

(43) 'performance study plan' means a document that describes the rationale, objectives, design methodology, monitoring, statistical considerations, organisation and conduct of a performance study;

(44) 'performance evaluation' means an assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device;

(45) 'device for performance study' means a device intended by the manufacturer to be used in a performance study.

A device intended to be used for research purposes, without any medical objective, shall not be deemed to be a device for performance study;

(46) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;

(47) 'subject' means an individual who participates in a performance study and whose specimen(s) undergo *in vitro* examination by a device for performance study and/or by a device used for control purposes;

(48) 'investigator' means an individual responsible for the conduct of a performance study at a performance study site;

(49) 'diagnostic specificity' means the ability of a device to recognise the absence of a target marker associated with a particular disease or condition;

(50) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;

(51) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;

(52) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;

(53) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;

(54) 'likelihood ratio' means the likelihood of a given result arising in an individual with the target clinical condition or physiological state compared to the likelihood of the same result arising in an individual without that clinical condition or physiological state;

(55) 'calibrator' means a measurement reference material used in the calibration of a device;

(56) 'control material' means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device;

(57) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the performance study;

(58) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular performance study, after having been informed of all aspects of the performance study that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the performance study;

(59) 'ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;

(60) 'adverse event' means any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a performance study, whether or not related to the device for performance study;

(61) 'serious adverse event' means any adverse event that led to any of the following:

(a) a patient management decision resulting in death or an imminent life-threatening situation for the individual being tested, or in the death of the individual's offspring,

(b) death,

(c) serious deterioration in the health of the individual being tested or the recipient of tested donations or materials, that resulted in any of the following:

(i) life-threatening illness or injury,

(ii) permanent impairment of a body structure or a body function,

(iii) hospitalisation or prolongation of patient hospitalisation,

(iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

(v) chronic disease,

(d) foetal distress, foetal death or a congenital physical or mental impairment or birth defect;

(62) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of a device for performance study, including malfunction, use errors or inadequacy in information supplied by the manufacturer;

(63) 'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

(64) 'market surveillance' means the activities carried out and measures taken by public authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

(65) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;

(66) 'withdrawal' means any measure aimed at preventing a device in the supply chain from being further made available on the market;

(67) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any harm as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device;

(68) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person,

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

(c) a serious public health threat;

(69) 'serious public health threat' means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time;

(70) 'corrective action' means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;

(71) 'field safety corrective action' means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

(72) 'field safety notice' means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action;

(73) 'harmonised standard' means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012;

(74) 'common specifications' (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.

Section 2

Regulatory status of products and counselling

Article 3

Regulatory status of products

1. Upon a duly substantiated request of a Member State, the Commission shall, after consulting the Medical Device Coordination Group established under Article 103 of Regulation (EU) 2017/745 (MDCG), by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of '*in vitro* diagnostic medical device' or 'accessory for an *in vitro* diagnostic medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3) of this Regulation.

2. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

3. The Commission shall ensure that Member States share expertise in the fields of *in vitro* diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products, in order to determine the appropriate regulatory status of a product, or category or group of products.

4. When deliberating on the possible regulatory status as a device of products involving medicinal products, human tissues and cells, biocides or food products, the Commission shall ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency and the European Food Safety Authority, as relevant.

Article 4

Genetic information, counselling and informed consent

1. Member States shall ensure that where a genetic test is used on individuals, in the context of healthcare as defined in point (a) of Article 3 of Directive 2011/24/EU of the European Parliament and of the Council ([1]) and for the medical purposes of diagnostics, improvement of treatment, predictive or prenatal testing, the individual being tested or, where applicable, his or her legally designated representative is provided with relevant information on the nature, the significance and the implications of the genetic test, as appropriate.

2. In the context of the obligations referred to in paragraph 1, Member States shall, in particular, ensure that there is appropriate access to counselling in the case of the use of genetic tests that provide information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable according to the state of science and technology.

3. Paragraph 2 shall not apply in cases where a diagnosis of a medical condition and/or a disease which the individual being tested is already known to have is confirmed by a genetic test or in cases where a companion diagnostic is used.

4. Nothing in this Article shall prevent Member States from adopting or maintaining measures at national level which are more protective of patients, more specific or which deal with informed consent.

CHAPTER II

MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, CE MARKING, FREE MOVEMENT

Article 5

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

([1]) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. Demonstration of conformity with the general safety and performance requirements shall include a performance evaluation in accordance with Article 56.

4. Devices that are manufactured and used within health institutions, with the exception of devices for performance studies, shall be considered as having been put into service.

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

(a) the devices are not transferred to another legal entity;

(b) manufacture and use of the devices occur under appropriate quality management systems;

(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation;

(d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;

(e) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

(f) the health institution draws up a declaration which it shall make publicly available, including:

(i) the name and address of the manufacturing health institution,

(ii) the details necessary to identify the devices,

(iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor;

(g) as regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met. Member States may apply this provision also to class A, B or C devices in accordance with the rules set out in Annex VIII;

(h) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (g); and

(i) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.

6. In order to ensure the uniform application of Annex I, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 6

Distance sales

1. A device offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation.

2. Without prejudice to national law regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.

3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.

4. A Member State may, on grounds of protection of public health, require a provider of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to cease its activity.

Article 7

Claims

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

(a) ascribing functions and properties to the device which the device does not have;

(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;

(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

Article 8

Use of harmonised standards

1. Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

The first subparagraph shall also apply to system or process requirements to be fulfilled in accordance with this Regulation by economic operators or sponsors, including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up ('PMPF').

References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the *Official Journal of the European Union*.

2. References in this Regulation to harmonised standards shall also include the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, provided that references to those monographs have been published in the *Official Journal of the European Union*.

Article 9

Common specifications

1. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the performance evaluation and PMPF set out in Annex XIII or the requirements regarding performance studies set out in Annex XIII. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

2. Devices that are in conformity with the CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CS or the relevant parts of those CS.

3. Manufacturers shall comply with the CS referred to in paragraph 1 unless they can duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto.

Article 10

General obligations of manufacturers

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

3. Manufacturers shall conduct a performance evaluation in accordance with the requirements set out in Article 56 and Annex XIII, including a PMPF.

4. Manufacturers shall draw up and keep up to date the technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.

The Commission is empowered to adopt delegated acts in accordance with Article 108 amending, in the light of technical progress, the Annexes II and III.

5. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance study, shall draw up an EU declaration of conformity in accordance with Article 17, and affix the CE marking of conformity in accordance with Article 18.

6. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 24 and with the registration obligations referred to in Article 26 and 28.

7. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 51, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market.

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available.

8. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a product is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than devices for performance study, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.

The quality management system shall address at least the following aspects:

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(c) responsibility of the management;

(d) resource management, including selection and control of suppliers and sub-contractors;

(e) risk management as set out in Section 3 of Annex I;

(f) performance evaluation, in accordance with Article 56 and Annex XIII, including PMPF;

(g) product realisation, including planning, design, development, production and service provision;

(h) verification of the UDI assignments made in accordance with Article 24(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 26;

(i) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 78;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) management of corrective and preventive actions and verification of their effectiveness;

(m) processes for monitoring and measurement of output, data analysis and product improvement.

9. Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 78.

10. Manufacturers shall ensure that the device is accompanied by the information set out in Section 20 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

The information supplied in accordance with Section 20 of Annex I with devices for self-testing or near-patient testing shall be easily understandable and provided in the official Union language(s) determined by the Member State in which the device is made available to the user or patient.

11. Manufacturers that consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly.

Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 51, in particular, of the non-compliance and of any corrective action taken.

12. Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 82 and 83.

13. Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable, grant access to the device. Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may, in order to ensure the protection of public health and patient safety, take all appropriate measures to prohibit or restrict the device's being made available on its national market, to withdraw the device from that market or to recall it until the manufacturer cooperates or provides complete and correct information.

If a competent authority considers or has reason to believe that a device has caused damage, it shall, upon request, facilitate the provision of the information and documentation referred to in the first subparagraph to the potentially injured patient or user and, as appropriate, the patient's or user's successor in title, the patient's or user's health insurance company or other third parties affected by the damage caused to the patient or user, without prejudice to data protection rules and, unless there is an overriding public interest in disclosure, without prejudice to the protection of intellectual property rights.

The competent authority need not comply with the obligation laid down in the third subparagraph where disclosure of the information and documentation referred to in the first subparagraph is ordinarily dealt with in the context of legal proceedings.

14. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 27(1).

15. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

Article 11

Authorised representative

1. Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative.

2. The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.

3. The authorised representative shall perform the tasks specified in the mandate agreed between it and the manufacturer. The authorised representative shall provide a copy of the mandate to the competent authority, upon request.

The mandate shall require, and the manufacturer shall enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:

(a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 51, at the disposal of competent authorities for the period referred to in Article 10(7);

(c) comply with the registration obligations laid down in Article 28 and verify that the manufacturer has complied with the registration obligations laid down in Article 26;

(d) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

(e) forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

(f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(h) terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

4. The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (5), (6), (8), (9), (10) and (11).

5. Without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

6. An authorised representative who terminates its mandate on the grounds referred to in point (h) of paragraph 3 shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

7. Any reference in this Regulation to the competent authority of the Member State in which the manufacturer has its registered place of business shall be understood as a reference to the competent authority of the Member State in which the authorised representative, designated by a manufacturer referred to in paragraph 1, has its registered place of business.

Article 12

Change of authorised representative

The detailed arrangements for a change of authorised representative shall be clearly defined in an agreement between the manufacturer, where practicable the outgoing authorised representative, and the incoming authorised representative. That agreement shall address at least the following aspects:

(a) the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative;

(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative.

Article 13

General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.

2. In order to place a device on the market, importers shall verify that:

(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) a manufacturer is identified and that an authorised representative in accordance with Article 11 has been designated by the manufacturer;

(c) the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;

(d) where applicable, a UDI has been assigned by the manufacturer in accordance with Article 24.

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. Where the importer considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which the importer is established.

3. Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall verify that the device is registered in the electronic system in accordance with Article 26. Importers shall add their details to the registration in accordance with Article 28.

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.

6. Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it, is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 51 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.

8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.

9. Importers shall, for the period referred to in Article 10(7), keep a copy of the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 51.

10. Importers shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.

Article 14

General obligations of distributors

1. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2. Before making a device available on the market, distributors shall verify that all of the following requirements are met:

(a) the device has been CE marked and the EU declaration of conformity of the device has been drawn up;

(b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(10);

(c) for imported devices, the importer has complied with the requirements set out in Article 13(3);

(d) that, where applicable, a UDI has been assigned by the manufacturer.

In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.

3. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

4. Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

5. Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

6. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

Article 15

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of *in vitro* diagnostic medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC [1] shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.

3. The person responsible for regulatory compliance shall at least be responsible for ensuring that:

(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

[1] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;

(c) the post-market surveillance obligations are complied with in accordance with Article 10(9);

(d) the reporting obligations referred to in Articles 82 to 86 are fulfilled;

(e) in the case of devices for performance studies intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects, the statement referred to in Section 4.1 of Annex XIV is issued.

4. If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1, 2 and 3, their respective areas of responsibility shall be stipulated in writing.

5. The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation.

6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

Article 16

Cases in which obligations of manufacturers apply to importers, distributors or other persons

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:

(a) makes available on the market a device under its own name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;

(b) changes the intended purpose of a device already placed on the market or put into service;

(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in point (23) of Article 2, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

(a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 20 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;

(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.

Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, *inter alia*, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.

4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities referred to in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.

Article 17

EU declaration of conformity

1. The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device. The declaration shall contain all the information required for identification of the Union legislation to which the declaration relates.

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. The Commission is empowered to adopt delegated acts in accordance with Article 108 amending the minimum content of the EU declaration of conformity set out in Annex IV in the light of technical progress.

Article 18

CE marking of conformity

1. Devices, other than devices for performance studies, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex V.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 48. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

6. Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.

Article 19

Devices for special purposes

1. Member States shall not create obstacles to devices for performance study being supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 57 to 76, and in the implementing acts adopted pursuant to Article 77.

2. The devices referred to in paragraph 1 shall not bear the CE marking, with the exception of the devices referred to in Article 70.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create obstacles to the showing of devices which do not comply with this Regulation, provided that a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with this Regulation.

Article 20

Parts and components

1. Any natural or legal person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available for the competent authorities of the Member States.

2. An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in this Regulation.

Article 21

Free movement

Except where otherwise provided for in this Regulation, Member States shall not refuse, prohibit or restrict the making available on the market or putting into service within their territory of devices which comply with the requirements of this Regulation.

CHAPTER III

IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES

Article 22

Identification within the supply chain

1. Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.

2. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(7):

(a) any economic operator to whom they have directly supplied a device;

(b) any economic operator who has directly supplied them with a device;

(c) any health institution or healthcare professional to which they have directly supplied a device.

Article 23

Medical devices nomenclature

To facilitate the functioning of the European database on medical devices (Eudamed) as referred to in Article 33 of Regulation (EU) 2017/745, the Commission shall ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

Article 24

Unique Device Identification system

1. The Unique Device Identification system ('UDI system') described in Part C of Annex VI shall allow the identification and facilitate the traceability of devices, other than devices for performance studies, and shall consist of the following:

(a) production of a UDI that comprises the following:

  (i) a UDI device identifier ('UDI-DI') specific to a manufacturer and a device, providing access to the information laid down in Part B of Annex VI;

  (ii) a UDI production identifier ('UDI-PI') that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Annex VI;

(b) placing of the UDI on the label of the device or on its packaging;

(c) storage of the UDI by economic operators, health institutions and healthcare professionals, in accordance with the conditions laid down in paragraphs 8 and 9 respectively;

(d) establishment of an electronic system for Unique Device Identification ('UDI database') in accordance with Article 28 of Regulation (EU) 2017/745.

2. The Commission shall, by means of implementing acts, designate one or several entities to operate a system for assignment of UDIs pursuant to this Regulation ('issuing entity'). That entity or those entities shall satisfy all of the following criteria:

(a) the entity is an organisation with legal personality;

(b) its system for the assignment of UDIs is adequate to identify a device throughout its distribution and use in accordance with the requirements of this Regulation;

(c) its system for the assignment of UDIs conforms to the relevant international standards;

(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions;

(e) the entity undertakes to do the following:

  (i) operate its system for the assignment of UDIs for at least 10 years after its designation;

  (ii) make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;

  (iii) remain in compliance with the criteria for designation and the terms of designation.

When designating issuing entities, the Commission shall endeavour to ensure that UDI carriers, as defined in Part C of Annex VI, are universally readable regardless of the system used by the issuing entity, with a view to minimising financial and administrative burdens for economic operators, health institutions and healthcare professionals.

3. Before placing a device, other than a device for performance study, on the market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging, a UDI created in compliance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2.

Before a device, other than a device for performance study, is placed on the market the manufacturer must ensure that the information referred to in Part B of Annex V of the device in question are correctly submitted and transferred to the UDI database referred to in Article 25.

4. UDI carriers shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers.

5. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 82.

6. The Basic UDI-DI, as defined in Part C of Annex VI of the device shall appear on the EU declaration of conformity referred to in Article 17.

7. As part of the technical documentation referred to in Annex II, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned.

8. Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 11.

9. Member States shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

Member States shall encourage, and may require, health care professionals to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied with.

10. The Commission is empowered to adopt delegated acts in accordance with Article 108:

(a) amending the list of information set out in Part B of Annex VI in the light of technical progress; and

(b) amending Annex VI in the light of international developments and technical progress in the field of Unique Device Identification.

11. The Commission may, by means of implementing acts, specify the detailed arrangements and the procedural aspects for the UDI system with a view to ensuring its harmonised application in relation to any of the following:

(a) determining the devices, categories or groups of devices to which the obligation laid down in paragraph 8 is to apply;

(b) specifying the data to be included in the UDI-PI of specific devices or device groups.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

12. When adopting the measures referred to in paragraph 11, the Commission shall take into account all of the following:

(a) confidentiality and data protection as referred to in Articles 102 and 103 respectively;

(b) the risk-based approach;

(c) the cost-effectiveness of the measures;

(d) the convergence of UDI systems developed at international level;

(e) the need to avoid duplications in the UDI system;

(f) the needs of the health care systems of the Member States, and where possible, compatibility with other medical device identification systems that are used by stakeholders.

Article 25

UDI database

The Commission, after consulting the MDCG, shall set up and manage a UDI database in accordance with the conditions and detailed arrangements provided for in Article 28 of Regulation (EU) 2017/745.

Article 26

Registration of devices

1. Before placing a device on the market, the manufacturer shall, in accordance with the rules of the issuing entity referred to in Article 24(2), assign a Basic UDI-DI as defined in Part C of Annex VI to the device and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

2. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), the second subparagraph of Article 48(7), Article 48(8) and the second subparagraph of Article 48(9), the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment.

For the devices referred to in the first subparagraph, the notified body shall include a reference to the Basic UDI-DI on the certificate issued in accordance with point (a) of Section 4 of Annex XII and confirm in Eudamed that the information referred to in Section 2.2 of Part A of Annex VI is correct. After the issuing of the relevant certificate and before placing the device on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

3. Before placing a device on the market, the manufacturer shall enter or, if already provided, verify in Eudamed the information referred to in Section 2 of Part A of Annex VI, with the exception of Section 2.2 thereof, and thereafter shall keep the information updated.

Article 27

Electronic system for registration of economic operators

1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 28(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be provided to that electronic system by the economic operators are laid down in Section 1 of Part A of Annex VI.

2. Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory.

3. Within two weeks of placing a device on the market, importers shall verify that the manufacturer or authorised representative has provided to the electronic system the information referred to in paragraph 1.

Where applicable, importers shall inform the relevant authorised representative or manufacturer if the information referred to in paragraph 1 is not included or is incorrect. Importers shall add their details to the relevant entry/entries.

Article 28

Registration of manufacturers, authorised representatives and importers

1. Before placing a device on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 30 the information referred to in Section 1 of Part A of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 48, the information referred to in Section 1 of Part A of Annex VI shall be provided to that electronic system before applying to the notified body.

2. After having verified the data entered pursuant to paragraph 1, the competent authority shall obtain a single registration number ('SRN') from the electronic system referred to in Article 27 and issue it to the manufacturer, the authorised representative or the importer.

3. The manufacturer shall use the SRN when applying to a notified body for conformity assessment and for accessing Eudamed in order to fulfil its obligations under Article 26.

4. Within one week of any change occurring in relation to the information referred to in paragraph 1 of this Article, the economic operator shall update the data in the electronic system referred to in Article 27.

5. Not later than one year after submission of the information in accordance with paragraph 1, and every second year thereafter, the economic operator shall confirm the accuracy of the data. In the event of a failure to do so within six months of those deadlines, any Member State may take appropriate corrective measures within its territory until that economic operator complies with that obligation.

6. Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in Section 1 of Part A of Annex VI.

7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 27 shall be accessible to the public.

8. The competent authority may use the data to charge the manufacturer, the authorised representative or the importer a fee pursuant to Article 104.

Article 29

Summary of safety and performance

1. For class C and D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance.

The summary of safety and performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.

The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary is available.

2. The summary of safety and performance shall include at least the following aspects:

(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN;

(b) the intended purpose of the device and any indications, contra-indications and target populations;

(c) a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device;

(d) reference to any harmonised standards and CS applied;

(e) the summary of the performance evaluation as referred to in Annex XIII, and relevant information on the PMPF;

(f) the metrological traceability of assigned values;

(g) suggested profile and training for users;

(h) information on any residual risks and any undesirable effects, warnings and precautions.

3. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 107(2).

Article 30

European database on medical devices

1. The Commission, after consulting the MDCG, shall set up, maintain and manage the European database on medical devices ('Eudamed') in accordance with the conditions and detailed arrangements established by Articles 33 and 34 of Regulation (EU) 2017/745.

2. Eudamed shall include the following electronic systems:

(a) the electronic system for registration of devices referred to in Article 26;

(b) the UDI database referred to in Article 25;

(c) the electronic system on registration of economic operators referred to in Article 27;

(d) the electronic system on notified bodies and on certificates referred to in Article 52;

(e) the electronic system on performance studies referred to in Article 69,

(f) the electronic system on vigilance and post-market surveillance referred to in Article 87;

(g) the electronic system on market surveillance referred to in Article 95.

CHAPTER IV

NOTIFIED BODIES

Article 31

Authorities responsible for notified bodies

1. Any Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall appoint an authority (the 'authority responsible for notified bodies'), which may consist of separate constituent entities under national law and shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.

2. The authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.

3. The authority responsible for notified bodies shall be organised in a manner such that each decision relating to designation or notification is taken by personnel different from those who carried out the assessment.

4. The authority responsible for notified bodies shall not perform any activities that notified bodies perform on a commercial or competitive basis.

5. The authority responsible for notified bodies shall safeguard the confidential aspects of the information it obtains. However, it shall exchange information on notified bodies with other Member States, the Commission and, when required, with other regulatory authorities.

6. The authority responsible for notified bodies shall have a sufficient number of competent personnel permanently available for the proper performance of its tasks.

Where the authority responsible for notified bodies is a different authority from the national competent authority for *in vitro* diagnostic medical devices, it shall ensure that the national authority responsible for *in vitro* diagnostic medical devices is consulted on relevant matters.

7. Member States shall make publicly available general information on their measures governing the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on such tasks.

8. The authority responsible for notified bodies shall participate in peer-review activities provided for in Article 44.

Article 32

Requirements relating to notified bodies

1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil those tasks. In particular, notified bodies shall comply with Annex VII.

In order to meet the requirements referred to in the first subparagraph, notified bodies shall have permanent availability of sufficient administrative, technical and scientific personnel in accordance with Section 3.1.1 of Annex VII, and personnel with relevant clinical expertise in accordance with Section 3.2.4 of Annex VII, where possible employed by the notified body itself.

The personnel referred to in Sections 3.2.3 and 3.2.7 of Annex VII shall be employed by the notified body itself and shall not be external experts or subcontractors.

2. Notified bodies shall make available and submit upon request all relevant documentation, including the manufacturer's documentation, to the authority responsible for notified bodies to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.

3. In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt implementing acts, to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 33

Subsidiaries and subcontracting

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the applicable requirements set out in Annex VII and shall inform the authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Notified bodies shall make publicly available a list of their subsidiaries.

4. Conformity assessment activities may be subcontracted or carried out by a subsidiary provided that the legal or natural person that applied for conformity assessment has been informed accordingly.

5. Notified bodies shall keep at the disposal of the authority responsible for notified bodies all relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

Article 34

Application by conformity assessment bodies for designation

1. Conformity assessment bodies shall submit an application for designation to the authority responsible for notified bodies.

2. The application shall specify the conformity assessment activities as defined in this Regulation, and the types of devices for which the body is applying to be designated, and shall be supported by documentation demonstrating compliance with Annex VII.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VII, a valid accreditation certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted and shall be taken into consideration during the assessment described in Article 35. However, the applicant shall make available all the documentation referred to in the first subparagraph to demonstrate compliance with those requirements upon request.

3. The notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VII.

Article 35

Assessment of the application

1. The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 34 is complete and shall request the applicant to provide any missing information. Once the application is complete that national authority shall send it to the Commission.

The authority responsible for notified bodies shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.

2. The authority responsible for notified bodies shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the MDCG.

3. Within 14 days of the submission referred to in paragraph 2 of this Article, the Commission, in conjunction with the MDCG, shall appoint a joint assessment team made up of three experts, unless the specific circumstances require a different number of experts, chosen from the list referred to in Article 36. One of the experts shall be a representative of the Commission who shall coordinate the activities of the joint assessment team. The other two experts shall come from Member States other than the one in which the applicant conformity assessment body is established.

The joint assessment team shall be comprised of competent experts who are competent to assess the conformity assessment activities and the types of devices which are the subject of the application or, in particular when the assessment procedure is initiated in accordance with Article 43(3) to ensure that the specific concern can be appropriately assessed.

4. Within 90 days of its appointment, the joint assessment team shall review the documentation submitted with the application in accordance with Article 34. The joint assessment team may provide feedback to, or require clarification from, the authority responsible for notified bodies on the application and on the planned on-site assessment.

The authority responsible for notified bodies together with the joint assessment team shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, to be involved in the conformity assessment process.

The on-site assessment of the applicant body shall be led by the authority responsible for notified bodies.

5. Findings regarding non-compliance of an applicant conformity assessment body with the requirements set out in Annex VII shall be raised during the assessment process and discussed between the authority responsible for notified bodies and the joint assessment team with a view to reaching consensus and resolving any diverging opinions, with respect to the assessment of the application.

At the end of the on-site assessment, the authority responsible for notified bodies shall list for the applicant conformity assessment body the non-compliances resulting from the assessment and summarise of the assessment by the joint assessment team.

Within a specified timeframe, the applicant conformity assessment body shall submit to the national authority a corrective and preventive action plan to address the non-compliances.

6. The joint assessment team shall document any remaining diverging opinions with respect to the assessment within 30 days of completion of the on-site assessment and send them to the authority responsible for notified bodies.

7. The authority responsible for notified bodies shall, following receipt of a corrective and preventive action plan from the applicant body, assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

The authority responsible for notified bodies shall, having confirmed the corrective and preventive action plan, forward it and its opinion thereon to the joint assessment team. The joint assessment team may request of the authority responsible for notified bodies further clarification and modifications.

The authority responsible for notified bodies shall draw up its final assessment report which shall include:

— the result of the assessment,

— confirmation that the corrective and preventive actions have been appropriately addressed and, where required, implemented,

— any remaining diverging opinion with the joint assessment team, and, where applicable,

— the recommended scope of designation.

8. The authority responsible for notified bodies shall submit its final assessment report and, if applicable, the draft designation to the Commission, the MDCG and the joint assessment team.

9. The joint assessment team shall provide a final opinion regarding the assessment report prepared by the authority responsible for notified bodies and, if applicable, the draft designation within 21 days of receipt of those documents to the Commission which shall immediately submit that final opinion to the MDCG. Within 42 days of receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft designation, which the authority responsible for notified bodies shall duly take into consideration for its decision on the designation of the notified body.

10. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements specifying procedures and reports for the application for designation referred to in Article 34 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 36

Nomination of experts for joint assessment of applications for notification

1. The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of *in vitro* diagnostic medical devices to participate in the activities referred to in Articles 35 and 44.

2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1 of this Article, together with information on their specific field of competence and expertise. That list shall be made available to Member States competent authorities through the electronic system referred to in Article 52.

Article 37

Language requirements

All documents required pursuant to Articles 34 and 35 shall be drawn up in a language or languages which shall be determined by the Member State concerned.

Member States, in applying the first paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documentation concerned.

The Commission shall provide translations of the documentation pursuant to Articles 34 and 35, or parts thereof into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team appointed in accordance with Article 35(3).

Article 38

Designation and notification procedure

1. Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 35 was completed and which comply with Annex VII.

2. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool within the database of notified bodies developed and managed by the Commission (NANDO).

3. The notification shall clearly specify, using the codes referred to in paragraph 13 of this Article, the scope of the designation indicating the conformity assessment activities as defined in this Regulation, and the types of devices which the notified body is authorised to assess and, without prejudice to Article 40, any conditions associated with the designation.

4. The notification shall be accompanied by the final assessment report of the authority responsible for notified bodies, the final opinion of the joint assessment team referred to in Article 35(9) and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.

5. The notifying Member State shall, without prejudice to Article 40, inform the Commission and the other Member States of any conditions associated with the designation and provide documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VII.

6. Within 28 days of the notification referred to in paragraph 2, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the authority responsible for notified bodies. Where no objection is raised, the Commission shall publish in NANDO the notification within 42 days of its having been notified as referred to in paragraph 2.

7. When a Member State or the Commission raises objections in accordance with paragraph 6, the Commission shall bring the matter before the MDCG within 10 days of the expiry of the period referred to in paragraph 6. After consulting the parties involved, the MDCG shall give its opinion at the latest within 40 days of the matter having been brought before it. Where the MDCG is of the opinion that the notification can be accepted, the Commission shall publish in NANDO the notification within 14 days.

8. Where the MDCG, after having been consulted in accordance with paragraph 7, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.

9. Where the notifying Member State decides to uphold its decision to designate the conformity assessment body, having given its reasons in accordance with paragraph 8, the Commission shall publish in NANDO the notification within 14 days of being informed thereof.

10. When publishing the notification in NANDO, the Commission shall add to the electronic system referred to in Article 52 the information relating to the notification of the notified body along with the documents mentioned in paragraph 4 of this Article and the opinion and response referred to in paragraphs 7 and 8 of this Article.

11. The designation shall become valid the day after the notification is published in NANDO. The published notification shall state the scope of lawful conformity assessment activity of the notified body.

12. The conformity assessment body concerned may perform the activities of a notified body only after the designation has become valid in accordance with paragraph 11.

13 The Commission shall by 26 November 2017, by means of implementing acts, draw up a list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3). The Commission, after consulting the MDCG, may update this list based, inter alia, on information arising from the coordination activities described in Article 44.

Article 39

Identification number and list of notified bodies

1. The Commission shall assign an identification number to each notified body for which the notification becomes valid in accordance with Article 38(11). It shall assign a single identification number even when the body is notified under several Union acts. If they are successfully designated in accordance with this Regulation, bodies notified pursuant to Directive 98/79/EC shall retain the identification number assigned to them pursuant to that Directive.

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the conformity assessment activities as defined in this Regulation and the types of devices for which they have been notified, accessible to the public in NANDO. It shall also make this list available on the electronic system referred to in Article 52. The Commission shall ensure that the list is kept up to date.

Article 40

Monitoring and re-assessment of notified bodies

1. Notified bodies shall, without delay, and at the latest within 15 days, inform the authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VII or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.

2. The authorities responsible for notified bodies shall monitor the notified bodies established on their territory and their subsidiaries and subcontractors to ensure ongoing compliance with the requirements and the fulfilment of its obligations set out in this Regulation. Notified bodies shall, upon request by their authority responsible for notified bodies, supply all relevant information and documents, required to enable the authority, the Commission and other Member States to verify compliance.

3. Where the Commission or the authority of a Member State submits a request to a notified body established on the territory of another Member State relating to a conformity assessment carried out by that notified body, it shall send a copy of that request to the authority responsible for notified bodies of that other Member State. The notified body concerned shall respond without delay and within 15 days at the latest to the request. The authority responsible for notified bodies of the Member State in which the body is established shall ensure that requests submitted by authorities of any other Member State or by the Commission are resolved by the notified body unless there is a legitimate reason for not doing so in which case the matter may be referred to the MDCG.

4. At least once a year, the authorities responsible for notified bodies shall re-assess whether the notified bodies established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in Annex VII. That review shall include an on-site audit of each notified body and, where necessary, of its subsidiaries and subcontractors.

The authority responsible for notified bodies shall conduct its monitoring and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. That plan shall provide a reasoned schedule for the frequency of assessment of the notified body and, in particular, associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.

5. The monitoring of notified bodies by the authority responsible for notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, as that personnel in the process of conducting quality management system assessments at a manufacturer's facility.

6. The monitoring of notified bodies conducted by the authority responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance to help guide its activities.

The authority responsible for notified bodies shall provide for a systematic follow-up of complaints and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

7. The authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance.

8. The authority responsible for notified bodies shall review the assessments by notified bodies of manufacturers' technical documentation, in particular the performance evaluation documentation as further outlined in Article 41.

9. The authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VII and shall monitor the timely implementation of corrective and preventive actions.

10. Three years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VII shall be conducted by the authority responsible for notified bodies of the Member State in which the body is established and by a joint assessment team appointed for the purpose of the procedure described in Articles 34 and 35.

11. The Commission is empowered to adopt delegated acts in accordance with Article 108 in order to amend paragraph 10 of this Article to modify the frequency at which the complete re-assessment referred to in that paragraph is to be carried out.

12. The Member States shall report to the Commission and to the MDCG, at least once a year, on their monitoring and on-site assessment activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. The report shall provide details of the outcome of those activities, including activities pursuant to paragraph 7, and shall be treated as confidential by the MDCG and the Commission; however, it shall contain a summary which shall be made publicly available.

The summary of the report shall be uploaded to the electronic system referred to in Article 52.

Article 41

Review of notified body assessment of technical documentation and performance evaluation documentation

1. The authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies, shall review an appropriate number of notified body assessments of manufacturers' technical documentation, in particular the performance evaluation documentation to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. The reviews by the authority responsible for notified bodies shall be conducted both off-site and on-site.

2. The sampling of files to be reviewed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body, in particular high-risk devices, and be appropriately justified and documented in a sampling plan, which shall be made available by the authority responsible for notified bodies to the MDCG upon request.

3. The authority responsible for notified bodies shall review whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such checking shall include the technical documentation and performance evaluation documentation of the manufacturer upon which the notified body has based its assessment. Such reviews shall be conducted utilising CS.

4. Those reviews shall also form part of the re-assessment of notified bodies in accordance with Article 40(10) and the joint assessment activities referred to in Article 43(3). The reviews shall be conducted utilising appropriate expertise.

5. Based on the reports of the reviews and assessments by the authority responsible for notified bodies or joint assessment teams, on input from the market surveillance, vigilance and post-market surveillance activities described in Chapter VII, or on the continuous monitoring of technical progress, or on the identification of concerns and emerging issues concerning the safety and performance of devices, the MDCG may recommend that the sampling carried out under this Article cover a greater or lesser proportion of the technical documentation and performance evaluation documentation assessed by a notified body.

6. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements, associated documents for, and coordination of, the review of assessments of technical documentation and performance evaluation documentation, as referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 42

Changes to designations and notifications

1. The authority responsible for notified bodies shall notify the Commission and the other Member States of any relevant changes to the designation of a notified body.

The procedures described in Article 35 and in Article 38 shall apply to extensions of the scope of the designation.

For changes to the designation other than extensions of its scope, the procedures laid down in the following paragraphs shall apply.

2. The Commission shall immediately publish the amended notification in NANDO. The Commission shall immediately enter information on the changes to the designation of the notified body in the electronic system referred to in Article 52.

3. Where a notified body decides to cease its conformity assessment activities it shall inform the authority responsible for notified bodies and the manufacturers concerned as soon as possible and in the case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of the notified body's activities on condition that another notified body has confirmed in writing that it will assume responsibilities for the devices covered by those certificates. The new notified body shall complete a full assessment of the devices affected by the end of that period before issuing new certificates for those devices. Where the notified body has ceased its activity, the authority responsible for notified bodies shall withdraw the designation.

4. Where a authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VII, or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period.

The authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a designation.

5. Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the manufacturers concerned at the latest within 10 days.

6. In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall take appropriate steps to ensure that the files of the notified body concerned are kept and make them available to authorities in other Member States responsible for notified bodies and to authorities responsible for market surveillance at their request.

7 In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall:

(a) assess the impact on the certificates issued by the notified body;

(b) submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the designation;

(c) require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued to ensure the safety of devices on the market;

(d) enter in the electronic system referred to in Article 52 information in relation to certificates of which it has required their suspension or withdrawal;

(e) inform the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer has its registered place of business through the electronic system referred to in Article 52 of the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.

8. With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in the following circumstances:

(a) the authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue in relation to certificates affected by the suspension or restriction and the authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction; or

(b) the authority responsible for notified bodies has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor, and remain responsible for, existing certificates issued for the period of the suspension or restriction. In the event that the authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide, to the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business, within three months of the suspension or restriction, a written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.

9. With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:

(a) where the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business has confirmed that there is no safety issue associated with the devices in question; and

(b) another notified body has confirmed in writing that it will assume immediate responsibilities for those devices and will have completed assessment of them within twelve months of the withdrawal of the designation.

In the circumstances referred to in the first subparagraph, the national competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business may extend the provisional validity of the certificates for further periods of three months, which altogether shall not exceed twelve months.

The authority or the notified body assuming the functions of the notified body affected by the change of designation shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

Article 43

Challenge to the competence of notified bodies

1. The Commission, in conjunction with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in Annex VII or the obligations to which they are subject. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.

2. The notifying Member State shall provide the Commission, on request, with all information regarding the designation of the notified body concerned.

3. The Commission, in conjunction with the MDCG, may initiate, as applicable, the assessment procedure described in Article 35(3) and (5) where there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VII and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles of Article 35. Alternatively, depending on the severity of the issue, the Commission, in conjunction with the MDCG, may request that the authority responsible for notified bodies allow the participation of up to two experts from the list established pursuant to Article 36 in an on-site assessment as part of the planned monitoring and assessment activities in accordance with Article 40 and as outlined in the annual assessment plan described in Article 40(4) therein.

4. Where the Commission ascertains that a notified body no longer meets the requirements for its designation, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the designation if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the designation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3). It shall notify the Member State concerned of its decision and update NANDO and the electronic system referred to in Article 52.

5. The Commission shall ensure that all confidential information obtained in the course of its investigations is treated accordingly.

Article 44

Peer review and exchange of experience between authorities responsible for notified bodies

1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the authorities responsible for notified bodies. Such exchange shall cover elements including:

(a) development of best practice documents relating to the activities of the authorities responsible for notified bodies;

(b) development of guidance documents for notified bodies in relation to the implementation of this Regulation;

(c) training and qualification of the experts referred to in Article 36;

(d) monitoring of trends relating to changes to notified body designations and notifications, and trends in certificate withdrawals and transfers between notified bodies;

(e) monitoring of the application and applicability of scope codes referred to in Article 38(13);

(f) development of a mechanism for peer reviews between authorities and the Commission;

(g) methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies.

2. The authorities responsible for notified bodies shall participate in a peer review every third year through the mechanism developed pursuant to paragraph 1 of this Article. Such reviews shall normally be conducted in parallel with the on-site joint assessments described in Article 35. Alternatively, a national authority may make the choice of having such reviews take place as part of its monitoring activities referred to in Article 40.

3. The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism.

4. The Commission shall compile an annual summary report of the peer review activities, which shall be made publicly available.

5. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements and related documents for the peer review mechanisms and training and qualification as referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 45

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies, as referred to in Article 49 of Regulation (EU) 2017/745.

The bodies notified under this Regulation shall participate in the work of that group.

Article 46

List of standard fees

Notified bodies shall establish lists of their standard fees for the conformity assessment activities that they carry out and shall make those lists publicly available.

CHAPTER V

CLASSIFICATION AND CONFORMITY ASSESSMENT

Section 1

Classification

Article 47

Classification of devices

1. Devices shall be divided into classes A, B, C and D, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

2. Any dispute between the manufacturer and the notified body concerned, arising from the application of Annex VIII, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in the last indent of point (b) of the second paragraph of Section 2.2. of Annex IX has its registered place of business. Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

3. At the request of a Member State, the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:

(a) application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;

(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII.

4. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.

5. In order to ensure the uniform application of Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

6. The implementing acts referred to in paragraphs 3, 4 and 5 of this Article shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Section 2

Conformity assessment

Article 48

Conformity assessment procedures

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

2. Prior to putting into service a device that is not placed on the market, with the exception of in-house devices manufactured pursuant to Article 5(5), manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

3. Manufacturers of class D devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I, II except for Section 5, and in Chapter III of Annex IX.

In addition to the procedures referred to in the first subparagraph, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for technical documentation assessment set out in Section 5.1 of Annex IX.

In addition to the procedures referred to in the first and second subparagraphs, for companion diagnostics, the notified body shall consult a competent authority designated by the Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council ([1]) or the EMA, as applicable, in accordance with the procedure set out in Section 5.2 of Annex IX.

4. Manufacturers of class D devices, other than devices for performance study, may, instead of the conformity assessment procedure applicable pursuant to paragraph 3, choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI.

For companion diagnostics, the notified body shall in particular consult a competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, as applicable, in accordance with the procedure set out in point (k) of Section 3 of Annex X.

5. In particular, and without prejudice to any of the obligations pursuant to the other procedures referred to in paragraphs 3 and 4, for devices for which one or more EU reference laboratories have been designated in accordance with Article 100, the notified body performing the conformity assessment shall request one of the EU reference laboratories to verify by laboratory testing the performance claimed by the manufacturer and the compliance of the device with the applicable CS, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 4.9 of Annex IX and in point (j) of Section 3 of Annex X. Laboratory tests performed by an EU reference laboratory shall in particular focus on analytical and diagnostic sensitivity using the best available reference materials.

6. In addition to the procedure applicable pursuant to paragraphs 3 and 4, where no CS are available for class D devices and where it is also the first certification for that type of device, the notified body shall consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 on the performance evaluation report of the manufacturer. To that end, the notified body shall provide the performance evaluation report of the manufacturer to the expert panel within five days of receiving it from the manufacturer. The relevant experts shall, under the supervision of the Commission, provide their views, in accordance with Section 4.9 of Annex IX or point (j) of Section 3 of Annex X, as applicable, to the notified body within the deadline for delivery of the scientific opinion by the EU reference laboratory as specified therein.

7. Manufacturers of class C devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex of at least one representative device per generic device group.

In addition to the procedures referred to in the first subparagraph, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for technical documentation assessment set out in Section 5.1 of Annex IX.

In addition to the procedures referred to in the first and second subparagraphs, for companion diagnostics the notified body shall for every device follow the procedure for technical documentation assessment laid down in Section 5.2 of Annex IX, and shall apply the procedure for technical documentation assessment laid down in Sections 4.1 to 4.8 of Annex IX and shall consult the competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, as applicable, in accordance with the procedure set out in Section 5.2 of Annex IX.

([1]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

8. Manufacturers of class C devices, other than devices for performance study, may, instead of the conformity assessment procedure pursuant to paragraph 7, choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI except its Section 5.

For companion diagnostics the notified body shall in particular for every device consult a competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, as applicable, in accordance with the procedure set out in point (k) of Section 3 of Annex X.

9. Manufacturers of class B devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex for at least one representative device per category of devices.

In addition to the procedures referred to in the first subparagraph, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for assessment of the technical documentation set out in Section 5.1 of Annex IX.

10. Manufacturers of class A devices, other than devices for performance study, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 17, after drawing up the technical documentation set out in Annexes II and III.

However, if those devices are placed on the market in sterile condition, the manufacturer shall apply the procedures set out in Annex IX or in Annex XI. Involvement of the notified body shall be limited to the aspects relating to establishing, securing and maintaining sterile conditions.

11. Devices for performance studies shall be subject to the requirements set out in Articles 57 to 77.

12. The Member State in which the notified body is established may require that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 10 be made available in an official Union language(s) determined by that Member State. In the absence of such requirement, those documents shall be available in any official Union language acceptable to the notified body.

13. The Commission may, by means of implementing acts, specify the detailed arrangements and procedural aspects with a view to ensuring the harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects:

(a) the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in third paragraph of Section 2.3. and in Section 3.5 of Annex IX, in the case of class C devices;

(b) the minimum frequency of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the frequency of samples of the manufactured devices or batches of class D devices to be sent to an EU reference laboratory designated under Article 100 in accordance with Section 4.12 of Annex IX and Section 5.1 of Annex XI; or

(d) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of technical documentation and type examination in accordance with Sections 3.4 and 4.3 of Annex IX and points (f) and (g) of Section 3. of Annex X.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 49

Involvement of notified bodies in conformity assessment procedures

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned. The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

2. The notified body concerned shall, by means of the electronic system referred to in Article 52, inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment.

3. When applying to a notified body under paragraph 1, manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body and provide information about any previous application for the same conformity assessment that has been refused by another notified body.

4. The notified body may require any information or data from the manufacturer, which is necessary in order to properly conduct the chosen conformity assessment procedure.

5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

Article 50

Mechanism for scrutiny of conformity assessments of class D devices

1. A notified body shall notify the competent authority of certificates it has granted for class D devices, with the exception of applications to supplement or renew existing certificates. Such notification shall take place through the electronic system referred to in Article 52 and shall include the instructions for use referred to in Section 20.4 of Annex I, the summary of safety and performance referred to in Article 29, the assessment report by the notified body, and, where applicable, the laboratory tests and the scientific opinion by the EU reference laboratory pursuant to the second subparagraph of Article 48(3), and where applicable the views expressed in accordance with Article 48(4) by the experts referred to in Article 106 of Regulation (EU) 2017/745. In the case of divergent views between the notified body and the experts, a full justification shall also be included.

2. A competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures in accordance with Article 40, 41, 42, 43 or 89 and, where deemed necessary, take appropriate measures in accordance with to Articles 90 and 92.

3. The MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device.

Article 51

Certificates of conformity

1. The certificates issued by the notified bodies in accordance with Annexes IX, X and XI shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates shall be as set out in Annex XII.

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

3. Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or users or require manufacturers to undertake specific PMPF studies pursuant to Part B of Annex XIII.

4. Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

5. The notified body shall enter in the electronic system referred to in Article 52 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public.

6. In the light of technical progress, the Commission is empowered to adopt delegated acts in accordance with Article 108 amending the minimum content of the certificates set out in Annex XII.

Article 52

Electronic system on notified bodies and on certificates of conformity

For the purposes of this Regulation, the following information shall be collated and processed pursuant to Article 57 of Regulation (EU) 2017/745 in the electronic system set up in accordance with that Article:

(a) the list of subsidiaries referred to in Article 33(2);

(b) the list of experts referred to in Article 36(2);

(c) the information relating to the notification referred to in Article 38(10) and the amended notifications referred to in Article 42(2);

(d) the list of notified bodies referred to in Article 39(2);

(e) the summary of the report referred to in Article 40(12);

(f) the notifications for conformity assessments and certificates referred to in Article 50(1);

(g) withdrawal or refusals of applications for the certificates as referred to in Article 49(2) and Section 4.3 of Annex VII;

(h) the information regarding certificates referred to in Article 51(5);

(i) the summary of safety and performance referred to in Article 29.

Article 53

Voluntary change of notified body

1. In cases where a manufacturer terminates its contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the detailed arrangements for the change of notified body shall be clearly defined in an agreement between the manufacturer, the incoming notified body and, where practicable the outgoing notified body. That agreement shall cover at least the following aspects:

(a) the date on which the certificates issued by the outgoing notified body become invalid;

(b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the date after which the conformity assessment tasks of the outgoing notified body is assigned to the incoming notified body;

(e) the last serial number or lot number for which the outgoing notified body is responsible.

2. The outgoing notified body shall withdraw the certificates it has issued for the device concerned on the date on which they become invalid.

Article 54

Derogation from the conformity assessment procedures

1. By way of derogation from Article 48, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the procedures referred to in that Article have not been carried out but use of which is in the interest of public health or patient safety or health.

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

3. Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(4).

Article 55

Certificate of free sale

1. For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the CE-marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall set out the Basic UDI-DI of the device as provided to the UDI database under Article 26. Where a notified body has issued a certificate pursuant to Article 51, the certificate of free sale shall set out the unique number identifying the certificate issued by the notified body, as referred to in Section 3 of Chapter II of Annex XII.

2. The Commission may, by means of implementing acts, establish a model for certificates of free sale, taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 107(2).

CHAPTER VI

CLINICAL EVIDENCE, PERFORMANCE EVALUATION AND PERFORMANCE STUDIES

Article 56

Performance evaluation and clinical evidence

1. Confirmation of conformity with relevant general safety and performance requirements set out in Annex I, in particular those concerning the performance characteristics referred to in Chapter I and Section 9 of Annex I, under the normal conditions of the intended use of the device, and the evaluation of the interference(s) and cross-reaction(s) and of the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I, shall be based on scientific validity, analytical and clinical performance data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

To that end, manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XIII.

2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer and be based on a continuous process of performance evaluation, following a performance evaluation plan.

3. A performance evaluation shall follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with this Article and with Part A of Annex XIII:

(a) scientific validity;

(b) analytical performance;

(c) clinical performance.

The data and conclusions drawn from the assessment of those elements shall constitute the clinical evidence for the device. The clinical evidence shall be such as to scientifically demonstrate, by reference to the state of the art in medicine, that the intended clinical benefit(s) will be achieved and that the device is safe. The clinical evidence derived from the performance evaluation shall provide scientifically valid assurance, that the relevant general safety and performance requirements set out in Annex I, are fulfilled, under normal conditions of use.

4. Clinical performance studies in accordance with Section 2 of Part A of Annex XIII shall be carried out unless it is duly justified to rely on other sources of clinical performance data.

5. The scientific validity data, the analytical performance data and the clinical performance data, their assessment and the clinical evidence derived therefrom, shall be documented in the performance evaluation report referred to in Section 1.3.2 of Part A of Annex XIII. The performance evaluation report shall be part of the technical documentation, referred to in Annex II, relating to the device concerned.

6. The performance evaluation and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's PMPF plan in accordance with Part B of Annex XIII and the post-market surveillance plan referred to in Article 79.

The performance evaluation report for class C and D devices shall be updated when necessary, but at least annually, with the data referred to in the first subparagraph. The summary of safety and performance referred to in Article 29(1) shall be updated as soon as possible, where necessary.

7. Where necessary to ensure the uniform application of Annex XIII, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 57

General requirements regarding performance studies

1. The manufacturer shall ensure that a device for performance study complies with the general safety and performance requirements set out in Annex I apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.

2. Where appropriate, performance studies shall be performed in circumstances similar to the normal conditions of use of the device.

3. Performance studies shall be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects participating in such performance studies are protected and prevail over all other interests and the data generated are scientifically valid, reliable and robust.

Performance studies, including performance studies that use left-over samples, shall be conducted in accordance with applicable law on data protection.

Article 58

Additional requirements for certain performance studies

1. Any performance study:

(a) in which surgically invasive sample-taking is done only for the purpose of the performance study;

(b) that is an interventional clinical performance study as defined in point (46) of Article 2; or

(c) where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies,

shall, in addition to meeting the requirements set out in Article 57 and Annex XIII, be designed, authorised, conducted, recorded and reported in accordance with this Article and Articles 59 to 77 and Annex XIV.

2. Performance studies involving companion diagnostics shall be subject to the same requirements as the performance studies listed in paragraph 1. This does not apply to performance studies involving companion diagnostics using only left-over samples. Such studies shall however be notified to the competent authority.

3. Performance studies shall be subject to scientific and ethical review. The ethical review shall be performed by an ethics committee in accordance with national law. Member States shall ensure that the procedures for review by ethics committees are compatible with the procedures set out in this Regulation for the assessment of the application for authorisation of a performance study. At least one lay person shall participate in the ethical review.

4. Where the sponsor of a performance study is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication with that legal representative shall be deemed to be a communication with the sponsor.

Member States may choose not to apply the first subparagraph to performance studies to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that performance study who shall be the addressee for all communications with the sponsor provided for in this Regulation.

5. A performance study as referred to in paragraph 1 may be conducted only where all of the following conditions are met:

(a) the performance study is the subject of an authorisation by the Member State(s) in which the performance study is to be conducted, in accordance with this Regulation, unless otherwise stated;

(b) an ethics committee, set up in accordance with national law, has not issued a negative opinion in relation to the performance study, which is valid for that entire Member State under its national law;

(c) the sponsor or its legal representative or a contact person pursuant to paragraph 4 is established in the Union;

(d) vulnerable populations and subjects are appropriately protected in accordance with Articles 59 to 64;

(e) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;

(f) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent, in accordance with Article 59;

(g) the subject or, where the subject is not able to give informed consent, his or her legally designated representative, has been provided with the contact details of an entity where further information can be received in case of need;

(h) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;

(i) the performance study has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the degree of distress are specifically defined in the performance study plan and constantly monitored;

(j) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, any other person entitled by national law to provide the relevant patient care under performance study conditions;

(k) no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the performance study;

(l) where appropriate, biological safety testing reflecting the latest scientific knowledge or any other test deemed necessary in the light of the device's intended purpose has been conducted;

(m) in the case of clinical performance studies, the analytical performance has been demonstrated, taking into consideration the state of the art;

(n) in the case of interventional clinical performance studies, the analytical performance and scientific validity has been demonstrated, taking into consideration the state of the art. Where, for companion diagnostics, the scientific validity is not established, the scientific rationale for the use of the biomarker shall be provided;

(o) the technical safety of the device with regard to its use has been proven, taking into consideration the state of the art as well as provisions in the field of occupational safety and accident prevention;

(p) the requirements of Annex XIV are fulfilled.

6. Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the performance study at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

7. The investigator shall be a person exercising a profession which is recognised in the Member State concerned, as qualifying for the role of investigator on account of having the necessary scientific knowledge and experience in patient care or laboratory medicine. Other personnel involved in conducting a performance study shall be suitably qualified, by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.

8. Where appropriate, the facilities where the performance study involving subjects is to be conducted shall be suitable for the performance study and shall be similar to the facilities where the device is intended to be used.

Article 59

Informed consent

1. Informed consent shall be written, dated and signed by the person performing the interview referred to in point (c) of paragraph 2, and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 2. Where the subject is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. In that case, the witness shall sign and date the informed consent document. The subject or, where the subject is not able to give informed consent, his or her legally designated representative shall be provided with a copy of the document or the record, as appropriate, by which informed consent has been given. The informed consent shall be documented. Adequate time shall be given for the subject or his or her legally designated representative to consider his or her decision to participate in the performance study.

2. Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:

(a) enable the subject or his or her legally designated representative to understand:

(i) the nature, objectives, benefits, implications, risks and inconveniences of the performance study;

(ii) the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate in and the right to withdraw from the performance study at any time without any resulting detriment and without having to provide any justification;

(iii) the conditions under which the performance study is to be conducted, including the expected duration of the subject's participation in the performance study; and

(iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the performance study is discontinued;

(b) be kept comprehensive, concise, clear, relevant, and understandable to the subject or his or her legally designated representative;

(c) be provided in a prior interview with a member of the investigating team who is appropriately qualified under national law; and

(d) include information about the applicable damage compensation system referred to in Article 65;

(e) include the Union-wide unique single identification number for the performance study referred to in Article 66(1) and information about the availability of the performance study results in accordance with paragraph 6 of this Article.

3. The information referred to in paragraph 2 shall be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.

4. In the interview referred to in point (c) of paragraph 2, special attention shall be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information.

5. In the interview referred to in point (c) of paragraph 2, it shall be verified that the subject has understood the information.

6. The subject shall be informed that a report of the performance study and a summary presented in terms understandable to the intended user will be made available pursuant to Article 73(5) in the electronic system on performance studies referred to in Article 69, irrespective of the outcome of the performance study, and shall be informed, to the extent possible, when they have become available.

7. This Regulation is without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a performance study.

Article 60

Performance studies on incapacitated subjects

1. In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a performance study may be conducted only where, in addition to the conditions set out in Article 58(5), all of the following conditions are met:

(a) the informed consent of their legally designated representative has been obtained;

(b) the incapacitated subjects have received the information referred to in Article 59(2) in a way that is adequate in view of their capacity to understand it;

(c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in Article 59(2) to refuse participation in, or to withdraw from, the performance study at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the performance study;

(e) the performance study is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in performance studies on persons able to give informed consent, or by other research methods;

(f) the performance study relates directly to a medical condition from which the subject suffers;

(g) there are scientific grounds for expecting that participation in the performance study will produce:

(i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved; or

(ii) some benefit for the population represented by the incapacitated subject concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the incapacitated subject concerned in comparison with the standard treatment of the incapacitated subject's condition.

2. The subject shall as far as possible take part in the informed consent procedure.

3. Point (g)(ii) of paragraph 1 shall be without prejudice to more stringent national rules prohibiting the conduct of those performance studies on incapacitated subjects, where there are no scientific grounds to expect that participation in the performance study will produce a direct benefit to the subject outweighing the risks and burdens involved.

Article 61

Performance studies on minors

1. A performance study on minors may be conducted only where, in addition to the conditions set out in Article 58 (5), all of the following conditions are met:

(a) the informed consent of their legally designated representative has been obtained;

(b) the minors have received the information referred to in Article 59(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;

(c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 59(2) to refuse participation in, or to withdraw from, the performance study at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the performance study;

(e) the performance study is intended to investigate treatments for a medical condition that only occurs in minors or the performance study is essential with respect to minors to validate data obtained in performance studies on persons able to give informed consent or by other research methods;

(f) the performance study either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;

(g) there are scientific grounds for expecting that participation in the performance study will produce:

(i) a direct benefit to the minor subject outweighing the risks and burdens involved; or

(ii) some benefit for the population represented by the minor concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition;

(h) the minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity;

(i) if during a performance study the minor reaches the age of legal competence to give informed consent as defined in the national law, his or her express informed consent shall be obtained before that subject can continue to participate in the performance study.

2. Point (g)(ii) of paragraph 1 shall be without prejudice to more stringent national rules prohibiting the conduct of those performance studies on minors, where there are no scientific grounds to expect that participation in the performance study will produce a direct benefit to the subject outweighing the risks and burdens involved.

Article 62

Performance studies on pregnant or breastfeeding women

A performance study on pregnant or breastfeeding women may be conducted only where, in addition to the conditions set out in Article 58(5), all of the following conditions are met:

(a) the performance study has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;

(b) if such a performance study has no direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, it can be conducted only if:

(i) a performance study of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;

(ii) the performance study contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction or other embryos, foetuses or children; and

(iii) the performance study poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth;

(c) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child;

(d) no incentives or financial inducements are given to subjects, except for compensation for expenses and loss of earnings directly related to the participation in the performance study.

Article 63

Additional national measures

Member States may maintain additional measures regarding persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in performance studies, or persons in residential care institutions.

Article 64

Performance studies in emergency situations

1. By way of derogation from point (f) of Article 58(5), from points (a) and (b) of Article 60(1) and from points (a) and (b) of Article 61(1), informed consent to participate in a performance study may be obtained, and information on the performance studies may be given, after the decision to include the subject in the performance study, provided that that decision is taken at the time of the first intervention on the subject, in accordance with the clinical performance study plan for that performance study and that all of the following conditions are fulfilled:

(a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the performance study;

(b) there are scientific grounds to expect that participation of the subject in the performance study will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;

(c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;

(d) the investigator certifies that he or she is not aware of any objections to participate in the performance study previously expressed by the subject;

(e) the performance study relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the performance study is of such a nature that it may be conducted exclusively in emergency situations;

(f) the performance study poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

2. Following an intervention pursuant to paragraph 1 of this Article, informed consent in accordance with Article 59 shall be sought to continue the participation of the subject in the performance study, and information on the performance study shall be given, in accordance with the following requirements:

(a) regarding incapacitated subjects and minors, the informed consent shall be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in Article 59(2) shall be given as soon as possible to the subject and to his or her legally designated representative;

(b) regarding other subjects, the informed consent shall be sought by the investigator without undue delay from the subject or his or her legally designated representative, whichever can be done sooner, and the information referred to in Article 59(2) shall be given as soon as possible to the subject or his or her legally designated representative, as applicable.

For the purposes of point (b) where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the performance study shall be obtained from the subject as soon as he or she is capable of giving informed consent.

3. If the subject or, where applicable, his or her legally designated representative does not give consent, he or she shall be informed of the right to object to the use of data obtained from the performance study.

Article 65

Damage compensation

1. Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a performance study conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.

2. The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State in which the performance study is conducted.

Article 66

Application for performance studies

1. The sponsor of a performance study referred to in Article 58(1) and (2) shall enter and submit an application to the Member State(s) in which the performance study is to be conducted (referred to for the purposes of this Article as 'Member State concerned') accompanied by the documentation referred to in Sections 2 and 3 of Annex XIII and in Annex XIV.

The application shall be submitted by means of the electronic system referred to in Article 69, which shall generate a Union-wide unique single identification number for the performance study which shall be used for all relevant communication in relation to that performance study. Within 10 days of receiving the application, the Member State concerned shall notify the sponsor as to whether the performance study falls within the scope of this Regulation and as to whether the application dossier is complete in accordance with Chapter I of Annex XIV.

2. Within one week of any change occurring in relation to the documentation referred to in Chapter I of Annex XIV, the sponsor shall update the relevant data in the electronic system referred to in Article 69 and make that change to the documentation clearly identifiable. The Member State concerned shall be notified of the update by means of that electronic system.

3. Where the Member State concerned finds that the performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a time limit of maximum 10 days for the sponsor to comment or to complete the application by means of the electronic system referred to in Article 69. The Member State concerned may extend this period by a maximum of 20 days where appropriate.

Where the sponsor has not provided comments nor completed the application within the time limit referred to in the first subparagraph, the application shall be deemed to have lapsed. Where the sponsor considers that the application falls under the scope of this Regulation and/or is complete but the Member State concerned does not agree, the application shall be considered to have been rejected. The Member State concerned shall provide for an appeal procedure in respect of such refusal.

The Member State concerned shall notify the sponsor within five days of receipt of the comments or of the requested additional information, whether the performance study is considered as falling within the scope of this Regulation and the application is complete.

4. The Member State concerned may also extend the period referred to in paragraphs 1 and 3 each by a further five days.

5. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 1 or 3 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the periods referred to in paragraphs 1, 3 and 4 respectively.

6. During the period when the application is being assessed the Member State may request additional information from the sponsor. The expiry of the deadline pursuant to the point (b) of paragraph 7 shall be suspended from the date of the first request until such time as the additional information has been received.

7. The sponsor may start the performance study in the following circumstances:

(a) in the case of performance studies carried out pursuant to point (a) of Article 58(1) and where the specimen collection does not represent a major clinical risk to the subject of the study, unless otherwise stated by national law, immediately after the validation date of application described in paragraph 5 of this Article, provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the performance study;

(b) in the case of performance studies carried out pursuant to points (b) and (c) of Article 58(1) and Article 58(2) or performance studies other than those referred to in point (a) of this paragraph, as soon as the Member State concerned has notified the sponsor of its authorisation and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the performance study. The Member State shall notify the sponsor of the authorisation within 45 days of the validation date of the application referred to in paragraph 5. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.

8. The Commission is empowered to adopt delegated acts in accordance with Article 108 amending, in the light of technical progress and global regulatory developments, the requirements laid down in Chapter I of Annex XIV.

9. In order to assure the uniform application of the requirements laid down in Chapter I of Annex XIV, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 67

Assessment by Member States

1. Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of natural or legal persons financing the performance study, as well as free of any other undue influence.

2. Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience.

3. Member States shall assess whether the performance study is designed in such a way that potential remaining risks to subjects or third persons, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall, while taking into account applicable CS or harmonised standards, examine in particular:

(a) the demonstration of compliance of the device(s) for performance study with the applicable general safety and performance requirements, apart from the aspects covered by the performance study, and whether, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, in case of performance studies, the evaluation of the analytical performance, and in case of interventional clinical performance studies, the evaluation of the analytical performance, clinical performance and scientific validity, taking into consideration the state of the art;

(b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, whether the risk-minimisation solutions provide a level of protection that is equivalent to that provided by harmonised standards;

(c) whether the measures planned for the safe installation, putting into service and maintenance of the device for performance study are adequate;

(d) the reliability and robustness of the data generated in the performance study, taking account of statistical approaches, design of the performance study and methodological aspects, including sample size, comparator and endpoints;

(e) whether the requirements of Annex XIV are met.

4. Member States shall refuse the authorisation of the performance study if:

(a) the application dossier submitted pursuant to Article 66(3) remains incomplete;

(b) the device or the submitted documents, especially the performance study plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the performance study, in particular, is not suitable for providing evidence for the safety, performance characteristics or benefit of the device on subjects or patients;

(c) the requirements of Article 58 are not met; or

(d) any assessment under paragraph 3 is negative.

Member States shall provide for an appeal procedure in respect of a refusal pursuant to the first subparagraph.

Article 68

Conduct of a performance study

1. The sponsor and the investigator shall ensure that the performance study is conducted in accordance with the approved performance study plan.

2. In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the performance study is in compliance with the requirements of this Regulation, the sponsor shall ensure adequate monitoring of the conduct of a performance study. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the performance study including the following:

(a) the objective and methodology of the performance study; and

(b) the degree of deviation of the intervention from normal clinical practice.

3. All performance study information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.

4. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves transmission over a network.

5. Member States shall inspect, at an appropriate level, performance study site(s) to check that performance studies are conducted in accordance with the requirements of this Regulation and with the approved investigation plan.

6. The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the study.

Article 69

Electronic system on performance studies

1. The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system:

(a) to create the single identification numbers for performance studies referred to in Article 66(1);

(b) to be used as an entry point for the submission of all applications or notifications for performance studies referred to in Articles 66, 70, 71 and 74 and for all other submission of data, or processing of data in this context;

(c) for the exchange of information relating to performance studies in accordance with this Regulation between the Member States and between them and the Commission including the exchange of information referred to in to Articles 72 and 74;

(d) for information to be provided by the sponsor in accordance with Article 73, including the performance study report and its summary as required in paragraph 5 of that Article;

(e) for reporting on serious adverse events and device deficiencies, and related updates referred to in Article 76.

2. When setting up the electronic system referred to in paragraph 1 of this Article, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article 81 of Regulation (EU) No 536/2014 of the European Parliament and of the Council [1] as concerns performance studies of companion diagnostics.

3. The information referred to in point (c) of paragraph 1 shall only be accessible to the Member States and the Commission. The information referred to in the other points of that paragraph shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:

(a) protection of personal data in accordance with Regulation (EC) No 45/2001;

(b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure;

(c) effective supervision of the conduct of the performance study by the Member State(s) concerned.

4. No personal data of subjects shall be publicly available.

5. The user interface of the electronic system referred to in paragraph 1 shall be available in all official languages of the Union.

Article 70

Performance studies regarding devices bearing the CE marking

1. Where a performance study is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 18(1) ('PMPF study'), and where the performance study would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 69. The sponsor shall include the documentation referred to in Section 2 of Part A of Annex XIII and in Annex XIV. Points (b) to (l) and (p) of Article 58(5), and Articles 71, 72 and 73 Article 76(5) and the relevant provisions of Annexes XIII and XIV shall apply to PMPF studies.

2. Where a performance study is to be conducted to assess, outside the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 18(1), Articles 58 to 77 shall apply.

[1] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Article 71

Substantial modifications to performance studies

1. If a sponsor intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the study, it shall notify, within one week, by means of the electronic system referred to in Article 69, the Member State(s) in which the performance study is being or is to be conducted of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation referred to in Annex XIV as part of the notification. Changes to the relevant documentation shall be clearly identifiable.

2. The Member State shall assess any substantial modification to the performance study in accordance with the procedure laid down in Article 67.

3. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 38 days after the notification referred to in paragraph 1, unless:

(a) the Member State in which the performance study is being or is to be conducted has notified the sponsor of its refusal based on the grounds referred to in Article 67(4) or on considerations of public health, of subject and user safety or health, or of public policy; or

(b) an ethics committee in that Member State has issued a negative opinion in relation to the substantial modification to the performance study, which, in accordance with national law, is valid for that entire Member State.

4. The Member State(s) concerned may extend the period referred to in paragraph 3 by a further seven days, for the purpose of consulting with experts.

Article 72

Corrective measures to be taken by Member States and information exchange between Member States on performance studies

1. Where a Member State in which a performance study is being or is to be conducted has grounds for considering that the requirements set out in this Regulation are not met, it may take at least any of the following measures on its territory:

(a) revoke the authorisation for the performance study;

(b) suspend or terminate the performance study;

(c) require the sponsor to modify any aspect of the performance study.

2. Before the Member State concerned takes any of the measures referred to in paragraph 1 it shall, except where immediate action is required, ask the sponsor or the investigator or both for their opinion. That opinion shall be delivered within seven days.

3. Where a Member State has taken a measure referred to in paragraph 1 of this Article, or has refused a performance study, or has been notified by the sponsor of the early termination of a performance study on safety grounds, that Member State shall communicate the corresponding decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 69.

4. Where an application is withdrawn by the sponsor prior to a decision by a Member State, that information shall be made available through the electronic system referred to in Article 69 to all Member States and the Commission.

Article 73

Information from the sponsor at the end of a performance study or in the event of a temporary halt or early termination

1. If the sponsor has temporarily halted a performance study or has terminated a performance study early, it shall inform within 15 days the Member States in which that performance study has been temporarily halted or terminated early, through the electronic system referred to in Article 69, of the temporary halt or early termination. In the event that the sponsor has temporarily halted or terminated early the performance study on safety grounds, it shall inform all Member States in which that performance study is being conducted thereof within 24 hours.

2. The end of a performance study shall be deemed to coincide with the last visit of the last subject unless another point in time for such end is set out in the performance study plan.

3. The sponsor shall notify each Member State in which that performance study was being conducted of the end of that performance study in that Member State. That notification shall be made within 15 days of the end of the performance study in relation to that Member State.

4. If a study is conducted in more than one Member State, the sponsor shall notify all Member States in which that performance study was conducted of the end of the performance study in all Member States. That notification shall be made within 15 days of that end of the performance study.

5. Irrespective of the outcome of the performance study, within one year of the end of the performance study or within three months of the early termination or temporary halt, the sponsor shall submit to the Member States in which a performance study was conducted a performance study report as referred to in Section 2.3.3. of Part A of Annex XIII.

The performance study report shall be accompanied by a summary presented in terms that are easily understandable to the intended user. Both the report and summary shall be submitted by the sponsor by means of the electronic system referred to in Article 69.

Where, for scientific reasons, it is not possible to submit the performance study report within one year of the end of the study, it shall be submitted as soon as it is available. In such case, the clinical performance study plan referred to in Section 2.3.2. of Part A of Annex XIII shall specify when the results of the performance study are going to be available, together with a justification.

6. The Commission shall issue guidelines regarding the content and structure of the summary of the performance study report.

In addition, the Commission may issue guidelines for the formatting and sharing of raw data, for cases where the sponsor decides to share raw data on a voluntary basis. Those guidelines may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of performance studies.

7. The summary and the performance study report referred to in paragraph 5 of this Article shall become publicly accessible through the electronic system referred to in Article 69, at the latest when the device is registered in accordance with Article 26 and before it is placed on the market. In cases of early termination or temporary halt, the summary and the report shall become publicly accessible immediately after submission.

If the device is not registered in accordance with Article 26 within one year of the summary and the performance study report having been entered into the electronic system pursuant to paragraph 5 of this Article, they shall become publicly accessible at that point in time.

Article 74

Coordinated assessment procedure for performance studies

1. By means of the electronic system referred to in Article 69, the sponsor of a performance study to be conducted in more than one Member State may submit, for the purpose of Article 66, a single application that, upon receipt, is transmitted electronically to all Member States in which the performance study is to be conducted.

2. The sponsor shall propose in the single application referred to in paragraph 1 that one of the Member States in which the performance study is to be conducted acts as coordinating Member State. The Member States in which the performance study is to be conducted shall, within six days of submission of the application, agree on one of them taking the role of the coordinating Member State. If they do not agree on a coordinating Member State, the coordinating Member State proposed by the sponsor shall assume that role.

3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation referred to in Chapter I of Annex XIV.

However, the completeness of the documentation referred to in Sections 1.13, 4.2, 4.3 and 4.4 of Chapter I of Annex XIV and point (c) of Section 2.3.2. of Part A of Annex XIII shall be assessed separately by each Member State concerned in accordance with Article 66(1) to (5).

4. With regard to documentation other than that referred to in the second subparagraph of paragraph 3, the coordinating Member State shall:

(a) within six days of receipt of the single application, notify the sponsor that it is the coordinating Member State ('notification date');

(b) for the purpose of the validation of the application, take into account any considerations submitted within seven days of the notification date by any Member State concerned;

(c) within 10 days of the notification date, assess whether the performance study falls within the scope of this Regulation and whether the application is complete and shall notify the sponsor accordingly. Article 66(1) and (3) to (5) shall apply to the coordinating Member State in relation to that assessment;

(d) establish the results of its assessment in a draft assessment report to be transmitted within 26 days of the validation date to the Member States concerned. By day 38 after the validation date, the other Member States concerned shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State which shall take due account of those comments and proposals in its finalisation of the final assessment report, to be transmitted within 45 days of the validation date to the sponsor and the other Member States concerned.

The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with Article 66(7).

5. As regards the assessment of the documentation referred to in the second subparagraph of paragraph 3, each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed 12 days from the receipt of the request. The expiry of the last deadline pursuant to point (d) of paragraph 4 shall be suspended from the date of the request until such time as the additional information has been received.

6. For class C and D devices, the coordinating Member State may also extend the periods referred to in paragraph 4 by a further 50 days, for the purpose of consulting with experts.

7. The Commission may, by means of implementing acts, further specify the procedures and timescales for coordinated assessments to be taken into account by Member States concerned when deciding on the sponsor's application. Such implementing acts may also set out the procedures and timescales for coordinated assessment in the case of substantial modifications pursuant to paragraph 12 of this Article and in the case of reporting of adverse events pursuant to Article 76(4) and in the case of performance studies involving companion diagnostics, where the medicinal products are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) No 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

8. Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the conduct of the performance study is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of all Member State(s) concerned.

Notwithstanding the first subparagraph, a Member State concerned may only disagree with the conclusion of the coordinating Member State concerning the area of coordinated assessment on the following grounds:

(a) when it considers that participation in the performance study would lead to a subject receiving treatment inferior to that received in normal clinical practice in that Member State concerned;

(b) infringement of national law; or

(c) considerations as regards subject safety and data reliability and robustness submitted under point (d) of paragraph 4.

Where one of the Member States concerned disagrees with the conclusion on the basis of the second subparagraph of this paragraph, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 69 to the Commission, to all other Member States concerned, and to the sponsor.

9. Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the performance study is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.

10. A Member State concerned shall refuse to authorise a performance study if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 8, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.13, 4.2, 4.3 and 4.4 of Chapter I of Annex XIV are not complied with, or where an ethics committee has issued a negative opinion in relation to that performance study which is valid in accordance with national law for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

11. Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 69 as to whether the performance study is authorised, whether it is authorised subject to conditions, or whether authorisation has been refused. Notification shall be done by way of one single decision within five days of the transmission, pursuant to point (d) of paragraph 4 of this Article, by the coordinating Member State of the final assessment report. Where an authorisation of a performance study is subject to conditions, those conditions may only be such that, by their nature, they cannot be fulfilled at the time of that authorisation.

12. Any substantial modifications as referred to in Article 71 shall be notified to the Member States concerned by means of the electronic system referred to in Article 69. Any assessment as to whether there are grounds for disagreement as referred to in the second subparagraph of paragraph 8 of this Article shall be carried out under the direction of the coordinating Member State, except for substantial modifications concerning sections 1.13, 4.2, 4.3 and 4.4 of Chapter I of Annex XIV and point (c) of Section 2.3.2 of Part A of Annex XIII, which shall be assessed separately by each Member State concerned.

13. The Commission shall provide administrative support to the coordinating Member State in the accomplishment of its tasks under this Chapter.

14. The procedure set out in this Article shall, until 27 May 2029, be applied only by those of the Member States in which the performance studies are to be conducted which have agreed to apply it. After 27 May 2029, all Member States shall be required to apply that procedure.

Article 75

Review of the coordinated assessment procedure

By 27 May 2028, the Commission shall submit to the European Parliament and to the Council a report on the experience gained from the application of Article 74 and, if necessary, propose a review of Article 74(14) and point (g) of Article 113(3).

Article 76

Recording and reporting of adverse events that occur during performance studies

1. The sponsor shall fully record all of the following:

(a) any adverse event of a type identified in the performance study plan as being critical to the evaluation of the results of that performance study;

(b) any serious adverse event;

(c) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(d) any new findings in relation to any event referred to in points (a) to (c).

2. The sponsor shall report without delay to all Member States in which a performance study is being conducted all of the following by means of the electronic system referred to in Article 69:

(a) any serious adverse event that has a causal relationship with the device, the comparator or the study procedure or where such causal relationship is reasonably possible;

(b) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(c) any new findings in relation to any event referred to in points (a) and (b).

The period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report.

Upon request by any Member State in which the performance study is being conducted, the sponsor shall provide all information referred to in paragraph 1.

3. The sponsor shall also report to the Member States in which the performance study is being conducted any event referred to in paragraph 2 of this Article that occurred in third countries in which a performance study is performed under the same clinical performance study plan as the one applying to a performance study covered by this Regulation by means of the electronic system referred to in Article 69.

4. In the case of a performance study for which the sponsor has used the single application referred to in Article 74, the sponsor shall report any event as referred to in paragraph 2 of this Article by means of the electronic system referred to in Article 69. Upon receipt, this report shall be transmitted electronically to all Member States in which the performance study is being conducted.

Under the direction of the coordinating Member State referred to in Article 74(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether to modify, suspend or terminate the performance study or whether to revoke the authorisation for that performance study.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of PMPF studies referred to in Article 70(1), the provisions on vigilance laid down in Articles 82 to 85 and in the implementing acts adopted pursuant to Article 86 shall apply instead of this Article.

6. Notwithstanding paragraph 5, this Article shall apply where a causal relationship between the serious adverse event and the preceding performance study has been established.

Article 77

Implementing acts

The Commission may, by means of implementing acts, establish the detailed arrangements and procedural aspects necessary for the implementation of this Chapter, as regards the following:

(a) harmonised electronic forms for the application for performance studies and their assessment as referred to in Articles 66 and 74, taking into account specific categories or groups of devices;

(b) the functioning of the electronic system referred to in Article 69;

(c) harmonised electronic forms for the notification of PMPF studies as referred to in Article 70(1), and of substantial modifications as referred to in Article 71;

(d) the exchange of information between Member States as referred to in Article 72;

(e) harmonised electronic forms for the reporting of serious adverse events and device deficiencies as referred to in Article 76;

(f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 76;

(g) uniform application of the requirements regarding the clinical evidence/data needed to demonstrate compliance with the general safety and performance requirements set out in Annex I.

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

CHAPTER VII

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

Section 1

Post-market surveillance

Article 78

Post-market surveillance system of the manufacturer

1. For each device manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(8).

2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

(a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

(b) to update the design and manufacturing information, the instructions for use and the labelling;

(c) to update the performance evaluation;

(d) to update the summary of safety and performance referred to in Article 29;

(e) for the identification of needs for preventive, corrective or field safety corrective action;

(f) for the identification of options to improve the usability, performance and safety of the device;

(g) when relevant, to contribute to the post-market surveillance of other devices; and

(h) to detect and report trends in accordance with Article 83.

The technical documentation shall be updated accordingly.

4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 82.

Article 79

Post-market surveillance plan

The post-market surveillance system referred to in Article 78 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1 of Annex III. The post-market surveillance plan shall be part of the technical documentation specified in Annex II.

Article 80

Post-market surveillance report

Manufacturers of class A and B devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the notified body and the competent authority upon request.

Article 81

Periodic safety update report

1. Manufacturers of class C and class D devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79 together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) the conclusions of the benefit-risk determination;

(b) the main findings of the PMPF; and

(c) the volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of class C and D devices shall update the PSUR at least annually. That PSUR shall be part of the technical documentation as specified in Annexes II and III.

2. Manufacturers of class D devices shall submit PSUR by means of the electronic system referred to in Article 87 to the notified body involved in the conformity assessment of such devices in accordance with Article 48. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSUR and the evaluation by the notified body shall be made available to competent authorities through that electronic system.

3. For class C devices, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

Section 2

Vigilance

Article 82

Reporting of serious incidents and field safety corrective actions

1. Manufacturers of devices, made available on the Union market, other than devices for performance study, shall report, to the relevant competent authorities, in accordance with Articles 87(5) and (7), the following:

(a) any serious incident involving devices made available on the Union market, except expected erroneous results which are clearly documented and quantified in the product information and in the technical documentation and are subject to trend reporting pursuant to Article 83;

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 87.

2. As a general rule, the period for the reporting referred to in paragraph 1 shall take account of the severity of the serious incident.

3. Manufacturers shall report any serious incident as referred to in point (a) immediately after they have established a causal relationship between that incident and their device or that such causal relationship is reasonably possible, and not later than 15 days after they become aware of the incident.

4. Notwithstanding paragraph 3, in the event of a serious public health threat the report referred to in paragraph 1 shall be provided immediately, and not later than 2 days after the manufacturer becomes aware of that threat.

5. Notwithstanding paragraph 3, in the event of death or an unanticipated serious deterioration in a person's state of health the report shall be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

6. Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

7. If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with paragraphs 2 to 5.

8. Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field safety corrective action referred to in point (b) of paragraph 1, in advance of the field safety corrective action being undertaken.

9. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 84(9), in consultation with the competent authorities referred to in points (a) and (b) of Article 87(8), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 87(8), the manufacturer may provide periodic summary reports following agreement with that competent authority.

10. The Member States shall take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents referred to in point (a) of paragraph 1.

The competent authorities shall record centrally at national level reports they receive from healthcare professionals, users and patients.

11. Where a competent authority of a Member State obtains such reports on suspected serious incidents referred to in point (a) of paragraph 1 from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide a report in accordance with paragraphs 1 to 5 of this Article on that serious incident to the competent authority of the Member State in which that serious incident occurred and shall take the appropriate follow-up action in accordance with Article 84.

Where the manufacturer of the device concerned considers that the incident is not a serious incident or is to be treated as an increase in expected erroneous results, which will be covered by trend reporting in accordance with to Article 83, it shall provide an explanatory statement. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with paragraphs 1 to 5 of this Article and require it to ensure that appropriate follow-up action is taken in accordance with Article 84.

Article 83

Trend reporting

1. Manufacturers shall report by means of the electronic system referred to in Article 87 any statistically significant increase in the frequency or severity of incidents that are not serious incidents that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons or of any significant increase in expected erroneous results established in comparison to the stated performance of the device as referred to in points (a) and (b) of Section 9.1 of Annex I and specified in the technical documentation and product information.

The manufacturer shall specify how to manage the incidents referred to in the first subparagraph and the methodology used for determining any statistically significant increase in the frequency or severity of such events or change in performance, as well as the observation period, in the post-market surveillance plan referred to in Article 79.

2. The competent authorities may conduct their own assessments on the trend reports referred to in paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. Each competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such assessment and of the adoption of such measures.

Article 84

Analysis of serious incidents and field safety corrective actions

1. Following the reporting of a serious incident pursuant to Article 82(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include risk assessment of the incident and field safety corrective action taking into account the criteria as referred to in paragraph 3 of this Article as appropriate.

The manufacturer shall co-operate with the competent authorities and where relevant with the notified body concerned during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 82 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer, and, where relevant, the notified body concerned.

3. In the context of the evaluation referred to in paragraph 2, the competent authority shall evaluate the risks arising from the reported serious incident and evaluate any field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm, the severity of that harm, the clinical benefit of the device, intended and potential users, and the population affected. The competent authority shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety contained in Annex I.

Upon request by the national competent authority, manufacturers shall provide for all documents necessary for the risk assessment.

4. The competent authority shall monitor the manufacturer's investigation of a serious incident. Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.

5. The manufacturer shall provide a final report to the competent authority setting out its findings from the investigation by means of the electronic system referred to in Article 87. The report shall set out conclusions and where relevant indicate corrective actions to be taken.

6. In the case of companion diagnostic, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall, depending on whether the relevant competent authority of the Member State that authorised the medicinal products or the EMA was consulted by the notified body in accordance with the procedures set out in Section 5.2 of Annex IX and Section 3.11 of Annex X, inform that national competent authority or the EMA, as appropriate.

7. After carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority shall, through the electronic system referred to in Article 87, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying serious incidents and the outcome of its assessment.

8. The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The field safety notice shall be edited in an official Union language or languages determined by the Member State in which the field safety corrective action is taken. Except in cases of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in the cases referred to in paragraph 9, to the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

The field safety notice shall allow the correct identification of the device or devices involved, in particular by including the relevant UDIs, and the correct identification, in particular by including the SRN, if already issued, of the manufacturer that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons and shall clearly indicate all the actions to be taken by users.

The manufacturer shall enter the field safety notice in the electronic system referred to in Article 87 through which that notice shall be accessible to the public.

9. The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 in the following cases:

(a) where there is concern regarding a particular serious incident or cluster of serious incidents relating to the same device or type of device of the same manufacturer in more than one Member State;

(b) where the appropriateness of a field safety corrective action that is proposed by a manufacturer in more than one Member State is in question.

That coordinated procedure shall cover the following:

— designation of a coordinating competent authority on a case by case basis, when required;

— defining the coordinated assessment process, including the tasks and responsibilities of the coordinating competent authority and the involvement of other competent authorities.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the competent authority of the Member State in which the manufacturer has its registered place of business.

The coordinating competent authority shall, through the electronic system referred to in Article 87, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

10. The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.

11. The Commission shall provide administrative support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

Article 85

Analysis of vigilance data

The Commission shall, in collaboration with the Member States, put in place systems and processes to actively monitor the data available in the electronic system referred to in Article 87, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, which shall then take the necessary corrective actions.

Article 86

Implementing acts

The Commission may, by means of implementing acts, and after consultation of the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 80 to 85 and 87 as regards the following:

(a) the typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision of periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 80, 81, 82, 83 and 84 respectively;

(c) standard structured forms for electronic and non-electronic reporting, including a minimum data set for reporting of suspected serious incidents by healthcare professionals, users and patients;

(d) timelines for the reporting of field safety corrective actions, and for the provision by manufacturers of periodic summary reports and trend reports, taking into account the severity of the incident to be reported as referred to in Article 82;

(e) harmonised forms for the exchange of information between competent authorities as referred to in Article 84;

(f) procedures for the designation of a coordinating competent authority; the coordinated evaluation process, including tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 87

Electronic system on vigilance and post-market surveillance

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 82(1) and Article 84(5);

(b) the periodic summary reports by manufacturers referred to in Article 82(9);

(c) the reports by manufacturers on trends referred to in Article 83;

(d) the PSURs referred to in Article 81;

(e) the field safety notices by manufacturers referred to in Article 84(8);

(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 84(7) and (9).

That electronic system shall include relevant links to the UDI database.

2. The information referred to in paragraph 1 of this Article shall be made available through the electronic system to the competent authorities of the Member States and to the Commission. The notified bodies shall also have access to that information to the extent that it relates to devices for which they issued a certificate in accordance with Article 49.

3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system referred to in paragraph 1.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the electronic system referred to in paragraph 1 at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents referred to in point (a) of Article 82(1), shall be automatically transmitted, upon receipt, via the electronic system referred to in paragraph 1 of this Article, to the competent authority of the Member State in which the incident occurred.

6. The trend reports referred to in Article 83(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the Member States in which the incidents occurred.

7. The reports on field safety corrective actions referred to in point (b) of Article 82(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the following Member States:

(a) the Member State in which the field safety corrective action is being or is to be undertaken;

(b) the Member State in which the manufacturer has its registered place of business.

8. The periodic summary reports referred to in Article 82(9) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authority of:

(a) the Member State or Member States participating in the coordination procedure in accordance with Article 84(9) and which have agreed on the periodic summary report;

(b) the Member State in which the manufacturer has its registered place of business.

9. The information referred to in paragraphs 5 to 8 of this Article shall be automatically transmitted, upon receipt, through the electronic system referred to in paragraph 1 of this Article, to the notified body that issued the certificate for the device in question in accordance with Article 51.

Section 3

Market surveillance

Article 88

Market surveillance activities

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

2. The competent authorities shall draw up annual surveillance activity plans and allocate a sufficient number of material and competent human resources in order to carry out those activities taking into account the European market surveillance programme developed by the MDCG pursuant to Article 99 and local circumstances.

3. In order to fulfil the obligations laid down in paragraph 1, the competent authorities:

(a) may require economic operators to, *inter alia*, make available the documentation and information necessary for the purpose of carrying out the authorities' activities and, where justified, to provide the necessary samples of devices or access to devices free of charge; and

(b) shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.

4. The competent authorities shall prepare an annual summary of the results of their surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 95.

5. The competent authorities may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk or falsified devices where they deem it necessary to do so in the interests of the protection of public health.

6. Following each inspection carried out for the purposes referred to in paragraph 1, the competent authority shall draw up a report on the findings of the inspection that concern compliance with the legal and technical requirements applicable under this Regulation. The report shall set out any corrective actions needed.

7. The competent authority which carried out the inspection shall communicate the content of the report referred to in paragraph 6 of this Article to the economic operator that has been the subject of the inspection. Before adopting the final report, the competent authority shall give that economic operator the opportunity to submit comments. That final inspection report shall be entered in the electronic system provided for in Article 95.

8. The Member States shall review and assess the functioning of their market surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. Each Member State shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 95.

9. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States.

Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.

10. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.

11. Where appropriate, the competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

Article 89

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe that a device:

(a) may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health; or

(b) otherwise does not comply with the requirements laid down in this Regulation,

they shall carry out an evaluation of the device concerned covering all requirements laid down in this Regulation relating to the risk presented by the device or to any other non-compliance of the device.

The relevant economic operators shall cooperate with the competent authorities.

Article 90

Procedure for dealing with devices presenting an unacceptable risk to health and safety

1. Where, having performed an evaluation pursuant to Article 89, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, its authorised representative and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Regulation relating to the risk presented by the device and, in a manner that is proportionate to the nature of the risk, to restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator.

2. The competent authorities shall, without delay, notify the Commission, the other Member States and, where a certificate has been issued in accordance with Article 51 for the device concerned, the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 95.

3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken throughout the Union in respect of all the devices concerned that they have made available on the market.

4. Where the economic operator as referred to in paragraph 1 does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it.

The competent authorities shall notify the Commission, the other Member States and the notified body referred to in paragraph 2 of this Article, without delay, of those measures, by means of the electronic system referred to in Article 95.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.

6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 95, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned.

In the event of disagreement with the notified national measure, they shall, without delay, inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 95.

7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified. In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market are taken without delay in respect of the device concerned.

Article 91

Procedure for evaluating national measures at Union level

1. Where, within two months of receipt of the notification referred to in Article 90(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall, after consulting the competent authorities concerned and, where necessary, the economic operators concerned, evaluate that national measure. On the basis of the results of that evaluation, the Commission may decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

2. Where the Commission considers the national measure to be justified as referred to in paragraph 1 of this Article, the second subparagraph of Article 90(7) shall apply. If the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure.

Where the Commission does not adopt a decision pursuant to paragraph 1 of this Article within eight months of receipt of the notification referred to in Article 90(4), the national measure shall be considered to be justified.

3. Where a Member State or the Commission considers that the risk to health and safety emanating from a device cannot be mitigated satisfactorily by means of measures taken by the Member State or Member States concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 92

Other non-compliance

1. Where, having performed an evaluation pursuant to Article 89, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 of this Article, the Member State concerned shall without delay take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article 95.

3. In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 93

Preventive health protection measures

1. Where a Member State, after having performed an evaluation, which indicates a potential risk related to a device or a specific category or group of devices considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, it may take any necessary and justified measures.

2. The Member State referred to in paragraph 1 shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 95.

3. The Commission, in consultation with the MDCG and, where necessary, the economic operators concerned, shall assess the national measures taken. The Commission may decide, by means of implementing acts, whether the national measures are justified or not. In the absence of a Commission decision within six months of their notification, the national measures shall be considered to be justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

4. Where the assessment referred to in paragraph 3 of this Article demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission may adopt implementing acts) to take the necessary and duly justified measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 94

Good administrative practice

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 90 to 93 shall state the exact grounds on which it is based. Where such a measure is addressed to a specific economic operator, the competent authority shall notify without delay the economic operator concerned of that measure, and shall at the same time inform that economic operator of the remedies available under the law or the administrative practice of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general applicability, it shall be appropriately published.

2. Except in cases where immediate action is necessary for reasons of unacceptable risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time that is clearly defined before any measure is adopted.

Where action has been taken without the economic operator having had the opportunity to make submissions as referred to in the first subparagraph, it shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that it has taken effective corrective action and that the device is in compliance with the requirements of this Regulation.

4. Where a measure adopted pursuant to Articles 90 to 93 concerns a device for which a notified body has been involved in the conformity assessment, the competent authorities shall by means of the electronic system referred to in Article 95 inform the relevant notified body and the authority responsible for the notified body of the measure taken.

Article 95

Electronic system on market surveillance

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:

(a) summaries of the results of the surveillance activities referred to in Article 88(4);

(b) the final inspection report as referred to in Article 88(7);

(c) information in relation to devices presenting an unacceptable risk to health and safety as referred to in Article 90(2), (4) and (6);

(d) information in relation to non-compliance of products as referred to in Article 92(2);

(e) information in relation to the preventive health protection measures referred to in Article 93(2);

(f) summaries of the results of the reviews and assessments of the market surveillance activities of the Member States referred to in Article 88(8).

2. The information referred to in paragraph 1 of this Article shall be immediately transmitted through the electronic system to all competent authorities concerned and, where applicable, to the notified body that issued a certificate in accordance with Article 51 for the device concerned and be accessible to the Member States and to the Commission.

3. Information exchanged between Member States shall not be made public where to do so might impair market surveillance activities and co-operation between Member States.

CHAPTER VIII

COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EU REFERENCE LABORATORIES AND DEVICE REGISTERS

Article 96

Competent authorities

The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.

Article 97

Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.

2. Member States shall with the support of the Commission participate, where appropriate, in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

Article 98

Medical Device Coordination Group

The Medical Device Coordination Group (MDCG) established in accordance with the conditions and detailed arrangements referred to in Article 103 and 107 of Regulation (EU) 2017/745 shall carry out, with the support of the Commission as provided in Article 104 of Regulation (EU) 2017/745, the tasks conferred on it under this Regulation as well as those under Regulation (EU) 2017/745.

Article 99

Tasks of the MDCG

Under this Regulation, the MDCG shall have the following tasks:

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 45;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of performance evaluations by manufacturers, assessment by notified bodies and vigilance activities;

(d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation and Regulation (EU) 2017/745 are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation;

(e) to contribute to the development of device standards and of CS;

(f) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, performance studies, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 88;

(g) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;

(h) to contribute to harmonised administrative practice with regard to devices in the Member States.

Article 100

The European Union reference laboratories

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories (the 'EU reference laboratories'), that satisfy the criteria set out in paragraph 4. The Commission shall only designate the EU reference laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.

2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:

(a) to verify the performance claimed by the manufacturer and the compliance of class D devices with the applicable CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the third subparagraph of Article 48(3);

(b) to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 4.12 of Annex IX and in Section 5.1 of Annex XI;

(c) to provide scientific and technical assistance to the Commission, the MDCG, the Member States and notified bodies in relation to the implementation of this Regulation;

(d) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;

(e) to set up and manage a network of national reference laboratories after consulting with the national authorities and publish a list of the participating national reference laboratories and their respective tasks;

(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;

(g) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;

(h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;

(i) to contribute to the development of CS and of international standards;

(j) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation and publish them by electronic means having considered national provisions on confidentiality.

3. At the request of a Member State, the Commission may also designate the EU reference laboratories where that Member State wishes to have recourse to such laboratories to ensure the verification of the performance claimed by the manufacturer and the compliance of class C devices with the applicable CS when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.

4. The EU reference laboratories shall satisfy the following criteria:

(a) have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the *in vitro* diagnostic medical devices for which they are designated;

(b) possess the necessary equipment and reference material to carry out the tasks assigned to them;

(c) have the necessary knowledge of international standards and best practices;

(d) have an appropriate administrative organisation and structure;

(e) ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks;

(f) act in the public interest and in an independent manner;

(g) ensure that their staff do not have financial or other interests in the *in vitro* diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the *in vitro* diagnostic medical device industry and update this declaration whenever a relevant change occurs.

5. The EU reference laboratories shall form a network in order to coordinate and harmonise their working methods as regards testing and assessment. That coordination and harmonisation shall involve:

(a) applying coordinated methods, procedures and processes;

(b) agreeing on the use of same reference materials and common test samples and seroconversion panels;

(c) establishing common assessment and interpretation criteria;

(d) using common testing protocols and assessing the test results using standardised and coordinated evaluation methods;

(e) using standardised and coordinated test reports;

(f) developing, applying and maintaining a peer review system;

(g) organizing regular quality assessment tests (including mutual checks on the quality and comparability of test results);

(h) agreeing on joint guidelines, instructions, procedural instructions or standard operational procedures;

(i) coordinating the introduction of testing methods for new technologies and according to new or amended CS;

(j) reassessing the state of the art on the basis of comparative test results or by further studies, as requested by a Member State or by the Commission.

6. The EU reference laboratories may be granted a Union financial contribution.

The Commission may adopt, by means of implementing acts, the detailed arrangements and the amount of a Union financial contribution to the EU reference laboratories, taking into account the objectives of health and safety protection, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

7. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out the requested task according to predetermined and transparent terms and conditions.

8. The Commission shall specify by means of implementing acts:

(a) detailed rules to facilitate the application of paragraph 2 of this Article and detailed rules to ensure compliance with the criteria referred to in paragraph 4 of this Article.

(b) the structure and the level of the fees referred to in paragraph 7 of this Article which may be levied by an EU reference laboratory for providing scientific opinions in response to consultations by notified bodies and Member States in accordance with this Regulation, taking into account the objectives of human health and safety protection, support of innovation and cost-effectiveness.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

9. The EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If those controls find that an EU reference laboratory is not complying with the requirements for which it has been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the restriction, suspension or withdrawal of the designation.

10. The provisions in Article 107(1) of Regulation (EU) 2017/745 shall apply to the staff of the EU reference laboratories.

Article 101

Device registers and databanks

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices setting common principles to collect comparable information. Such registers and databanks shall contribute to the independent evaluation of the long-term safety and performance of devices.

CHAPTER IX

CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES

Article 102

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

(a) personal data in accordance with Article 103;

(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights unless disclosure is in the public interest;

(c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.

2. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission shall not be disclosed without the prior agreement of the originating authority.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 103

Data protection

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

Article 104

Levying of fees

1. This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.

2. Member States shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. The structure and level of fees shall be made publicly available on request.

Article 105

Funding of activities related to designation and monitoring of notified bodies

The costs associated with joint assessment activities shall be covered by the Commission. The Commission shall, by means of implementing acts, lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 106

Penalties

The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify the Commission of those rules and of those measures by 25 February 2022 and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER X

FINAL PROVISIONS

Article 107

Committee procedure

1. The Commission shall be assisted by the Committee on Medical Devices established by Article 114 of Regulation (EU) 2017/745. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or 5 thereof, as appropriate, shall apply.

Article 108

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 10(4), 17(4), 24(10), 51(6) and 66(8) shall be conferred on the Commission for a period of five years from 25 May 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 10(4), 17(4), 24(10), 51(6) and 66(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 10(4), 17(4), 24(10), 51(6) and 66(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Article 109

Separate delegated acts for different delegated powers

The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.

Article 110

Transitional provisions

1. From 26 May 2022, any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.

2. Certificates issued by notified bodies in accordance with Directive 98/79/EC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex VI to Directive 98/79/EC which shall become void at the latest on 27 May 2024.

Certificates issued by notified bodies in accordance with Directive 98/79/EC from 25 May 2017 shall become void by 27 May 2024.

3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 98/79/EC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with that Directive, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply and replace the corresponding requirements in that Directive.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all applicable requirements relating to the devices it has certified.

4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 and devices placed on the market 26 May 2022 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.

5. By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before 26 May 2022.

6. By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2022. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2022.

7. As regards devices subject to the procedures laid down in Article 48(3) and (4), paragraph 5 of this Article applies provided that the necessary appointments to the MDCG and expert panels and of EU reference laboratories have been made.

8. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to in point (f) of Article 113(3) and ending 18 months later, comply with Article 27(3) and Article 28(1) and Article 51(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Decision 2010/227/EU.

9. Authorisations granted by the competent authorities of the Member States in accordance with Article 9(12) of Directive 98/79/EC shall keep the validity indicated in the authorisation.

10. Until the Commission has designated, pursuant to Article 24(2), issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities.

Article 111

Evaluation

By 27 May 2027, the Commission shall assess the application of this Regulation and produce an evaluation report on the progress towards achievement of the objectives contained herein including an assessment of the resources required to implement this Regulation. Special attention shall be given to the traceability of devices through the storage, pursuant to Article 24, of the UDI by economic operators, health institutions and health professionals. The evaluation shall also include a review on the functioning of Article 4.

Article 112

Repeal

Without prejudice to Articles 110 (3) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and the obligations of manufacturers as regards the making available of documentation, under Directive 98/79/EC, that Directive is repealed with effect from 26 May 2022 with the exception of:

(a) Article 11, point (c) of Article 12(1) and Article 12(2) and (3) of Directive 98/79/EC, and the obligations relating to vigilance and performance studies provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation; and

(b) Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, and the obligations relating to registration of devices and economic operators, and certificate notifications provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation.

As regards the devices referred to in Article 110(3) and (4) of this Regulation, Directive 98/79/EC shall continue to apply until 27 May 2025 to the extent necessary for the application of those paragraphs.

Decision 2010/227/EU adopted in implementation of Directives 90/385/EEC, 93/42/EEC and 98/79/EC shall be repealed with effect from the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation.

References to the repealed Directive shall be understood as references to this Regulation and shall be read in accordance with the correlation table laid down in Annex XV.

Article 113

Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from 26 May 2022.

3. By way of derogation from paragraph 2:

(a) Article 27(3) and Article 51(5) shall apply from 27 November 2023;

(b) Articles 31 to 46 and Article 96 shall apply from 26 November 2017. However, from that date until 26 May 2022 the obligations on notified bodies pursuant to Articles 31 to 46 shall apply only to those bodies which submit an application for designation in accordance with Article 34;

(c) Article 97 shall apply from 26 May 2018;

(d) Article 100 shall apply from 25 November 2020;

(e) for class D devices, Article 24(4) shall apply from 26 May 2023. For class B and class C devices Article 24(4) shall apply from 26 May 2025. For class A devices Article 24(4) shall apply from 26 May 2027;

(f) without prejudice to the obligations on the Commission pursuant to Article 34 of Regulation (EU) 2017/745, where, due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 34(1) of that Regulation, Eudamed is not fully functional on 26 May 2022, the obligations and requirements that relate to Eudamed shall apply from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3) of that Regulation. The provisions referred to in the preceding sentence are:

— Article 26,

— Article 28,

— Article 29,

— the second sentence of Article 36(2),

— Article 38(10),

— Article 39(2),

— the second subparagraph of Article 40(12),

— points (d) and (e) of Article 42(7),

— Article 49(2),

— Article 50(1),

— Articles 66 to 73,

— paragraphs 1 to 13 of Article 74,

— Articles 75 to 77,

— Article 81(2),

— Articles 82 and 83,

— Article 84(5) and (7) and the third subparagraph of Article 84(8),

— Article 85,

— Article 88(4), (7) and (8),

— Article 90(2) and (4),

— the last sentence of Article 92(2),

— Article 94(4),

— the second sentence of the first subparagraph of Article 110(3).

Until Eudamed is fully functional the corresponding provisions of Directive 98/79/EC shall continue to apply for the purpose of meeting the obligations laid down in the provisions listed in the first paragraph of this point regarding exchange of information including, and in particular, information regarding performance studies, vigilance reporting, registration of devices and economic operators, and certificate notifications.

(g) The procedure set out in Article 74 shall, apply from 26 May 2027 without prejudice to Article 74(14).

(h) Article 110(10) shall apply from 26 May 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 5 April 2017.

For the European Parliament	*For the Council*
The President	*The President*
A. TAJANI	I. BORG

ANNEXES

I General safety and performance requirements

II Technical documentation

III Technical documentation on post-market surveillance

IV EU declaration of conformity

V CE marking of conformity

VI Information to be submitted upon the registration of devices and economic operators in accordance with Articles 26(3) and 28, core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 25 and 26 and the UDI system

VII Requirements to be met by notified bodies

VIII Classification rules

IX Conformity assessment based on a quality management system and on assessment of technical documentation

X Conformity assessment based on type examination

XI Conformity assessment based on production quality assurance

XII Certificates issued by a notified body

XIII Performance evaluation, performance studies and post-market performance follow-up

XIV Interventional clinical performance studies and certain other performance studies

XV Correlation table

ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

CHAPTER I

GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

3. Manufacturers shall establish, implement, document and maintain a risk management system.

   Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

   (a) establish and document a risk management plan for each device;

   (b) identify and analyse the known and foreseeable hazards associated with each device;

   (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;

   (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;

   (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, the benefit-risk ratio and risk acceptability; and

   (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:

   (a) eliminate or reduce risks as far as possible through safe design and manufacture;

   (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and

   (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

   Manufacturers shall inform users of any residual risks.

5. In eliminating or reducing risks related to use error, the manufacturer shall:

   (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

   (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

6. The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

8. All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal conditions of use.

CHAPTER II

REQUIREMENTS REGARDING PERFORMANCE, DESIGN AND MANUFACTURE

9. Performance characteristics

9.1. Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable:

(a) the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and

(b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.

9.2. The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.

9.3. Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.

9.4. The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions:

(a) for devices for self-testing, performances obtained by laypersons;

(b) for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).

10. Chemical, physical and biological properties

10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled.

Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.

10.2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.

10.3. Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([1]), and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]).

10.4. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.

11. Infection and microbial contamination

11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons. The design shall:

(a) allow easy and safe handling;

(b) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use;

and, where necessary

(c) prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.

11.2. Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.

11.3. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.

11.4. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.

11.5. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

11.6. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.

12. Devices incorporating materials of biological origin

Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person.

([1]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([2]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).

In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.

13. Construction of devices and interaction with their environment

13.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.

13.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

(a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;

(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;

(c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

(d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;

(e) the risks of accidental ingress of substances into the device;

(f) the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended;

(g) the risks of any foreseeable interference with other devices.

13.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.

13.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.

13.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

13.6. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.

13.7 The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

14. Devices with a measuring function

14.1. Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended purpose of the device.

14.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC ([1]).

15. Protection against radiation

15.1. Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.

15.2. When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be:

(a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and

(b) fitted with visual displays and/or audible warnings of such emissions.

15.3. The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.

16. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

16.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

16.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

16.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).

16.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

17. Devices connected to or equipped with an energy source

17.1. For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.

17.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.

17.3. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.

17.4. Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.

([1]) Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).

17.5. Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

18. Protection against mechanical and thermal risks

18.1. Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.

18.2. Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.

18.3. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.

Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.

18.4. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

18.5. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

18.6. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.

18.7. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

18.8. Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

19. Protection against the risks posed by devices intended for self-testing or near-patient testing

19.1. Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.

19.2. Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to:

(a) ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and

(b) reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.

19.3. Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user:

(a) can verify that, at the time of use, the device will perform as intended by the manufacturer; and

(b) be warned if the device has failed to provide a valid result.

CHAPTER III

REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE

20. Label and instructions for use

20.1. General requirements regarding the information supplied by the manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.

(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes.

(d) Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.

(e) Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.

(f) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.

(g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.

(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

(i) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.

(j) The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information, as appropriate, is already made available in the instructions for use.

20.2. Information on the label

The label shall bear all of the following particulars:

(a) the name or trade name of the device;

(b) the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;

(c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;

(d) if the manufacturer has its registered place of business outside the Union, the name of its authorised representative and the address of the registered place of business of the authorised representative;

(e) an indication that the device is an *in vitro* diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;

(f) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;

(g) the UDI carrier as referred to in Article 24 and Part C of Annex VI;

(h) an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;

(i) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;

(j) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;

(k) an indication of any special storage and/or handling condition that applies;

(l) where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;

(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;

(n) if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their accessibility (or availability), and where applicable the website address where they can be consulted;

(o) where applicable, any particular operating instructions;

(p) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;

(q) if the device is intended for self-testing or near-patient testing, an indication of that fact;

(r) where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;

(s) where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;

(t) the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. As far as practicable and appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;

(u) the label for devices for self-testing shall bear the following particulars:

(i) the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);

(ii) the need for additional materials for the test to function properly;

(iii) contact details for further advice and assistance.

The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.

20.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging'):

The following particulars shall appear on the sterile packaging:

(a) an indication permitting the sterile packaging to be recognised as such,

(b) a declaration that the device is in a sterile condition,

(c) the method of sterilisation,

(d) the name and address of the manufacturer,

(e) a description of the device,

(f) the month and year of manufacture,

(g) an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order,

(h) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.

20.4. Information in the instructions for use

20.4.1. The instructions for use shall contain all of the following particulars:

(a) the name or trade name of the device;

(b) the details strictly necessary for the user to uniquely identify the device;

(c) the device's intended purpose:

(i) what is detected and/or measured;

(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);

(iii) the specific information that is intended to be provided in the context of:

— a physiological or pathological state;

— congenital physical or mental impairments;

— the predisposition to a medical condition or a disease;

— the determination of the safety and compatibility with potential recipients;

— the prediction of treatment response or reactions;

— the definition or monitoring of therapeutic measures;

(iv) whether it is automated or not;

(v) whether it is qualitative, semi-quantitative or quantitative;

(vi) the type of specimen(s) required;

(vii) where applicable, the testing population; and

(viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.

(d) an indication that the device is an *in vitro* diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;

(e) the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);

(f) the test principle;

(g) a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);

(h) a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;

(i) a list of materials provided and a list of special materials required but not provided;

(j) for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment:

— information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or

— information on any known restrictions to combinations of devices and equipment.

(k) an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;

(l) in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;

(m) if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;

(n) information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate:

(i) warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,

(ii) warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,

(iii) warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,

(iv) precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,

(v) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union,

(vi) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilisation. Information shall be provided to identify when the device should no longer be reused, such as signs of material degradation or the maximum number of allowable reuses;

(o) any warnings and/or precautions related to potentially infectious material that is included in the device;

(p) where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on radiation safety, or particular qualifications of the intended user;

(q) conditions for collection, handling, and preparation of the specimen;

(r) details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final assembly, calibration, etc., for the device to be used as intended by the manufacturer;

(s) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

— details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;

— identification of any consumable components and how to replace them;

— information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;

— methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.

(t) where applicable, recommendations for quality control procedures;

(u) the metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;

(v) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant figures and units of measure;

(w) analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;

(x) clinical performance characteristics as defined in Section 9.1 of this Annex;

(y) the mathematical approach upon which the calculation of the analytical result is made;

(z) where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;

(aa) where relevant, reference intervals in normal and affected populations;

(ab) information on interfering substances or limitations (*e.g.* visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;

(ac) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:

(i) infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;

(ii) environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);

(iii) physical hazards such as explosion.

(ad) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;

(ae) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;

(af) a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established;

(ag) where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation;

(ah) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

20.4.2 In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles:

(a) details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;

(b) specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;

(c) the device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;

(d) the results shall be expressed and presented in a way that is readily understood by the intended user;

(e) information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;

(f) the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice such as national helplines, websites;

(g) for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.

ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

(a) product or trade name and a general description of the device including its intended purpose and intended users;

(b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;

(c) the intended purpose of the device which may include information on:

(i) what is to be detected and/or measured;

(ii) its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic;

(iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;

(iv) whether it is automated or not;

(v) whether it is qualitative, semi-quantitative or quantitative;

(vi) the type of specimen(s) required;

(vii) where applicable, the testing population;

(viii) the intended user;

(ix) in addition, for companion diagnostics, the relevant target population and the associated medicinal product(s).

(d) the description of the principle of the assay method or the principles of operation of the instrument;

(e) the rationale for the qualification of the product as a device;

(f) the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;

(g) the description of the components and where appropriate, the description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers;

and where applicable:

(h) the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use;

(i) for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays;

(j) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;

(k) a description of any software to be used with the device;

(l) a description or complete list of the various configurations/variants of the device that are intended to be made available on the market;

(m) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with the device.

1.2. Reference to previous and similar generations of the device

(a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;

(b) an overview of identified similar devices available on the Union or international markets, where such devices exist.

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

A complete set of

(a) the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in the case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold;

(b) the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.

3. DESIGN AND MANUFACTURING INFORMATION

3.1. Design information

Information to allow the design stages applied to the device to be understood shall include:

(a) a description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device;

(b) for instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software;

(c) for instruments and software, an overview of the entire system;

(d) for software, a description of the data interpretation methodology, namely the algorithm;

(e) for devices intended for self-testing or near-patient testing, a description of the design aspects that make them suitable for self-testing or near-patient testing.

3.2. Manufacturing information

(a) information to allow the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device to be understood. More detailed information shall be provided for the audit of the quality management system or other applicable conformity assessment procedures;

(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall also include:

(a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;

(b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;

(c) the harmonised standards, CS or other solutions applied;

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5. BENFIT-RISK ANALYSIS AND RISK MANAGEMENT

The documentation shall contain information on:

(a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and

(b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.

6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

This includes:

6.1. Information on analytical performance of the device

6.1.1. Specimen type

This Section shall describe the different specimen types that can be analysed, including their stability such as storage, where applicable specimen transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis and storage conditions such *as* duration, temperature limits and freeze/thaw cycles.

6.1.2. Analytical performance characteristics

6.1.2.1. Accuracy of measurement

(a) Trueness of measurement

This Section shall provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow an assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a certified reference material or certified reference method is available.

(b) Precision of measurement

This Section shall describe repeatability and reproducibility studies.

6.1.2.2. Analytical sensitivity

This Section shall include information about the study design and results. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.

6.1.2.3. Analytical specificity

This Section shall describe interference and cross reactivity studies performed to determine the analytical specificity in the presence of other substances/agents in the specimen.

Information shall be provided on the evaluation of potentially interfering and cross-reacting substances or agents on the assay, on the tested substance or agent type and its concentration, specimen type, analyte test concentration, and results.

Interferents and cross-reacting substances or agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

(a) substances used for patient treatment such as medicinal products;

(b) substances ingested by the patient such as alcohol, foods;

(c) substances added during specimen preparation such as preservatives, stabilisers;

(d) substances encountered in specific specimen types such as haemoglobin, lipids, bilirubin, proteins;

(e) analytes of similar structure such as precursors, metabolites or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that can mimic the test condition.

6.1.2.4. Metrological traceability of calibrator and control material values

6.1.2.5. Measuring range of the assay

This Section shall include information on the measuring range regardless of whether the measuring systems are linear or non-linear, including the limit of detection and describe information on how the range and detection limit were established.

This information shall include a description of specimen type, number of specimens, number of replicates, and specimen preparation including information on the matrix, analyte levels and how levels were established. If applicable, a description of any high dose hook effect and the data supporting the mitigation such as dilution steps shall be added.

6.1.2.6. Definition of assay cut-off

This Section shall provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, such as:

(a) the population(s) studied: demographics, selection, inclusion and exclusion criteria, number of individuals included;

(b) method or mode of characterisation of specimens; and

(c) statistical methods such as Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.

6.1.3. The analytical performance report referred to in Annex XIII.

6.2. Information on clinical performance and clinical evidence. Performance Evaluation Report

The documentation shall contain the performance evaluation report, which includes the reports on the scientific validity, the analytical and the clinical performance, as referred to in Annex XIII, together with an assessment of those reports.

The clinical performance study documents referred to in Section 2 of Part A of Annex XIII shall be included and/or fully referenced in the technical documentation.

6.3. Stability (excluding specimen stability)

This Section shall describe claimed shelf life, in use stability and shipping stability studies.

6.3.1. Claimed shelf-life

This Section shall provide information on stability testing studies to support the shelf life that is claimed for the device. Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions. The three lots do not need to be consecutive. Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claims but shall be followed up with real time stability studies.

Such detailed information shall include:

(a) the study report including the protocol, number of lots, acceptance criteria and testing intervals;

(b) where accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies shall be described;

(c) the conclusions and claimed shelf life.

6.3.2. In-use stability

This Section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device, regardless of whether real or simulated. This may include open vial stability and/or, for automated instruments, on board stability.

In the case of automated instrumentation, if calibration stability is claimed, supporting data shall be included.

Such detailed information shall include:

(a) the study report (including the protocol, acceptance criteria and testing intervals);

(b) the conclusions and claimed in-use stability.

6.3.3. Shipping stability

This Section shall provide information on shipping stability studies for one lot of devices to evaluate the tolerance of devices to the anticipated shipping conditions.

Shipping studies may be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold.

Such information shall describe:

(a) the study report (including the protocol, acceptance criteria);

(b) the method used for simulated conditions;

(c) the conclusion and recommended shipping conditions.

6.4. Software verification and validation

The documentation shall contain evidence of the validation of the software, as it is used in the finished device. Such information shall typically include the summary results of all verification, validation and testing performed in-house and applicable in an actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

6.5. Additional information required in specific cases

(a) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with regard to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

(b) In the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected.

(c) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

(d) If the device is to be connected to other equipment in order to operate as intended, a description of the resulting combination including proof that it conforms to the general safety and performance requirements set out in Annex I when connected to any such equipment having regard to the characteristics specified by the manufacturer.

ANNEX III

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 78 to 81 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

1. The post-market surveillance plan drawn up in accordance with Article 79.

   The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 78.

   (a) The post-market surveillance plan shall address the collection and utilisation of available information, in particular:

   — information concerning serious incidents, including information from PSURs, and field safety corrective actions,

   — records referring to non-serious incidents and data on any undesirable side-effects,

   — information from trend reporting,

   — relevant specialist or technical literature, databases and/or registers,

   — information, including feedbacks and complaints, provided by users, distributors and importers, and

   — publicly-available information about similar medical devices.

   (b) The post-market surveillance plan shall cover at least:

   — a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;

   — effective and appropriate methods and processes to assess the collected data;

   — suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I;

   — effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;

   — methods and protocols to manage the events subject to the trend report as provided for in Article 83, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;

   — methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;

   — reference to procedures to fulfil the manufacturers obligations laid down in Articles 78, 79 and 81;

   — systematic procedures to identify and initiate appropriate measures including corrective actions;

   — effective tools to trace and identify devices for which corrective actions might be necessary; and

   — a PMPF plan as referred to in Part B of Annex XIII, or a justification as to why a PMPF is not applicable.

2. The PSUR referred to in Article 81 and the post-market surveillance report referred to in Article 80.

ANNEX IV

EU DECLARATION OF CONFORMITY

The EU declaration of conformity shall contain the following information:

1. Name, registered trade name or registered trade mark and, if already issued, SRN referred to in Article 28 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;

2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;

3. The Basic UDI-DI as referred to in Part C of Annex VI;

4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;

5. Risk class of the device in accordance with the rules set out in Annex VIII;

6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;

7. References to any CS used and in relation to which conformity is declared;

8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;

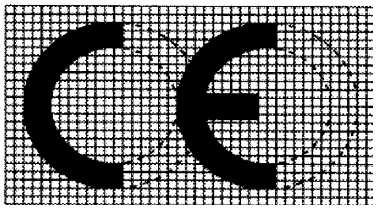
9. Where applicable, additional information;

10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

ANNEX V

CE MARKING OF CONFORMITY

1. The CE marking shall consist of the initials 'CE' taking the following form:



2. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing shall be respected.

3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

ANNEX VI

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 26(3) AND 28, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26 AND THE UDI SYSTEM

PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 26(3) AND 28

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the information referred to in Section 1 and shall ensure that the information on their devices referred to in Section 2 is complete, correct and updated by the relevant party.

1. Information relating to the economic operator

1.1. type of economic operator (manufacturer, authorised representative, or importer),

1.2. name, address and contact details of the economic operator,

1.3. where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details of that person,

1.4. name address and contact details of the person or persons responsible for regulatory compliance referred to in Article 15,

2. Information relating to the device

2.1. Basic UDI-DI,

2.2. type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,

2.3. Member State in which the device shall or has been placed on the market in the Union,

2.4. in the case of class B, class C or class D devices: Member States where the device is or is to be made available,

2.5. presence of tissues, cells, or, their derivatives, of human origin (y/n),

2.6. presence of tissues, cells or their derivatives of animal origin as referred to in Regulation (EU) No 722/2012(y/n),

2.7. presence of cells or substances of microbial origin (y/n),

2.8. risk class of the device,

2.9. where applicable, the single identification number of the performance study,

2.10. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(14), the name, address and contact details of that legal or natural person,

2.11. in the case of class C or D devices, the summary of safety and performance,

2.12. status of the device (on the market, no longer placed on the market, recalled, field safety corrective Action initiated),

2.13. indication as to whether the device is a 'new' device.

A device shall be considered to be 'new' if:

(a) there has been no such device continuously available on the Union market during the previous three years for the relevant analyte or other parameter;

(b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Union market during the previous three years.

2.14. indication as to whether the device is intended for self-testing or near-patient testing.

PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26

The manufacturer shall provide to the UDI database the UDI-DI and the following information relating to the manufacturer and the device:

1. quantity per package configuration,

2. the Basic UDI-DI as referred to in Article 24(6) and any additional UDI-DIs,

3. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),

4. if applicable, the 'unit of use' UDI-DI (where a UDI is not labelled on the device at the level of its 'unit of use', a 'unit of use' UDI-DI shall be assigned so as to associate the use of a device with a patient),

5. name and address of the manufacturer, as indicated on the label,

6. the SRN issued in accordance with Article 28(2),

7. if applicable, name and address of the authorised representative (as indicated on the label),

8. the medical device nomenclature code as provided for in Article 23,

9. risk class of the device,

10. if applicable, name or trade name,

11. if applicable, device model, reference, or catalogue number,

12. additional product description (optional),

13. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),

14. if applicable, additional trade names of the device,

15. labelled as a single use device (y/n),

16. if applicable, the maximum number of reuses,

17. device labelled sterile (y/n),

18. need for sterilisation before use (y/n),

19. URL for additional information, such as electronic instructions for use (optional),

20. if applicable, critical warnings or contra-indications,

21. status of the device (on the market, no longer placed on the market, recalled, field safety action initiated).

PART C

THE UDI SYSTEM

1. Definitions

Automatic identification and data capture ('AIDC')

AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

Unit of Use DI

The Unit of Use DI serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.

Configurable device

A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves.

Configuration

Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together as a device to achieve an intended purpose. The combination of items may be modified, adjusted or customised to meet specific needs.

UDI-DI

The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database.

Human Readable Interpretation (HRI)

HRI is a legible interpretation of the data characters encoded in the UDI carrier.

Packaging levels

Packaging levels means the various levels of device packaging that contain a fixed quantity of devices, such as a carton or case.

Production Identifier (UDI-PI)

The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production.

The different types of UDI-PI(s) include serial number, lot number, software identification and manufacturing or expiry date or both types of date.

Radio Frequency Identification ('RFID')

RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

Shipping containers

A shipping container is a container in relation to which traceability is controlled by a process specific to logistics systems.

Unique Device Identifier ('UDI')

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

The word 'Unique' does not imply serialisation of individual production units.

UDI carrier

The UDI carrier is the means of conveying the UDI by using AIDC and, if applicable, its HRI.

UDI carriers include, *inter alia*, ID/linear bar code, 2D/Matrix bar code, RFID.

2. General requirements

2.1. The affixing of the UDI is an additional requirement — it does not replace any other marking or labelling requirements laid down in Annex I to this Regulation.

2.2. The manufacturer shall assign and maintain unique UDIs for its devices.

2.3. Only the manufacturer may place the UDI on the device or its packaging.

2.4. Only coding standards provided by issuing entities designated by the Commission pursuant to Article 24(2) may be used.

3. The UDI

3.1. A UDI shall be assigned to the device itself or its packaging. Higher levels of packaging shall have their own UDI.

3.2. Shipping containers shall be exempted from the requirement in Section 3.1. By way of example, a UDI shall not be required on a logistics unit; where a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) shall not be subject to UDI requirements.

3.3. The UDI shall contain two parts: a UDI-DI and a UDI-PI.

3.4. The UDI-DI shall be unique at each level of device packaging.

3.5. If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.

3.6. Each component that is considered to be a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.

3.7. Kits shall be assigned and bear their own UDI.

3.8. The manufacturer shall assign the UDI to a device following the relevant coding standard.

3.9. A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability. In particular, any change of one of the following UDI database data elements shall require a new UDI-DI:

(a) Name or trade name,

(b) device version or model,

(c) labelled as single use,

(d) packaged sterile,

(e) need for sterilization before use,

(f) quantity of devices provided in a package,

(g) critical warnings or contra-indications.

3.10. Manufacturers that repackage or relabel devices with their own label shall retain a record of the original device manufacturer's UDI.

4. UDI carrier

4.1. The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label and on all higher levels of device packaging. Higher levels do not include shipping containers.

4.2. In the event of there being significant space constraints on the unit of use packaging the UDI carrier may be placed on the next higher packaging level.

4.3. For single use class A and class B devices packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging but it shall appear on a higher level of packaging e.g. a carton containing several packages. However, when the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI shall be placed on the packaging.

4.4. For devices exclusively intended for retail point of sale, the UDI-PIs in AIDC shall not be required to appear on the point of sale packaging.

4.5. When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable.

4.6. If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.

4.7. If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI shall however appear on the label even if this results in there being no space for the AIDC.

4.8. The HRI format shall follow the rules of the UDI code-issuing entity.

4.9. If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities shall also be provided on the label.

4.10. Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device.

4.11. The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device.

4.12. If the UDI carrier is readily readable or scannable through the device's packaging, the placing of the UDI carrier on the packaging shall not be required.

4.13. In the case of single finished devices made up of multiple parts that must be assembled before first use, it shall be sufficient to place the UDI carrier on only one part of each device.

4.14. The UDI carrier shall be placed in a manner such that the AIDC can be accessed during normal operation or storage.

4.15. Bar code carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data.

5. General principles of the UDI database

5.1. The UDI database shall support the use of all core UDI database data elements referred to in Part B of this Annex.

5.2. Manufacturers shall be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.

5.3. Appropriate methods/procedures for validation of the data provided shall be implemented.

5.4. Manufacturers shall periodically verify the correctness of all of the data relevant to devices they have placed on the market, except for devices that are no longer available on the market.

5.5. The presence of the device UDI-DI in the UDI database shall not be assumed to mean that the device is in conformity with this Regulation.

5.6. The database shall allow for the linking of all the packaging levels of the device.

5.7. The data for new UDI-DIs shall be available at the time the device is placed on the market.

5.8. Manufacturers shall update the relevant UDI database record within 30 days of a change being made to an element, which does not require a new UDI-DI.

5.9. Internationally accepted standards for data submission and updates shall, wherever possible, be used by the UDI database.

5.10. The user interface of the UDI database shall be available in all official languages of the Union. The use of free-text fields shall, however, be minimised in order to reduce translations.

5.11. Data relating to devices that are no longer available on the market shall be retained in the UDI database.

6. Rules for specific device types

6.1. Reusable devices that are part of kits and that require cleaning, disinfection, sterilisation or refurbishing between uses

6.1.1. The UDI of such devices shall be placed on the device and shall be readable after each procedure to make the device ready for the next use;

6.1.2. The UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer.

6.2. Device software

6.2.1. UDI assignment Criteria

The UDI shall be assigned at the system level of the software. Only software which is commercially available on its own and software which constitutes a device in itself shall be subject to that requirement.

The software identification shall be considered to be the manufacturing control mechanism and shall be displayed in the UDI-PI.

6.2.2. A new UDI-DI shall be required whenever there is a modification that changes:

(a) the original performance,

(b) the safety or the intended use of the software.

(c) interpretation of data.

Such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

6.2.3. Minor software revisions shall require a new UDI-PI and not a new UDI-DI:

Minor software revisions are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency.

Minor software revisions shall be identified by a manufacturer-specific form of identification.

6.2.4. UDI placement criteria for software

(a) where the software is delivered on a physical medium, for example via *a* CD or DVD, each packaging level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging shall be identical to the UDI assigned to the system level software;

(b) the UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format such as an 'about' file, or included on the start-up screen;

(c) software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the UDI through an application programming interface (API);

(d) only the human readable portion of the UDI shall be required in electronic displays of the software. The marking of UDI using AIDC shall not be required in the electronic displays such as 'about' menu, splash screen, etc.;

(e) the human readable format of the UDI for the software shall include the application identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.

ANNEX VII

REQUIREMENTS TO BE MET BY NOTIFIED BODIES

1. ORGANISATIONAL AND GENERAL REQUIREMENTS

1.1. Legal status and organisational structure

1.1.1. Each notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect. Its legal personality and status shall be fully documented. Such documentation shall include information about ownership and the legal or natural persons exercising control over the notified body.

1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements of Section 1.2 are applicable to both the notified body and the organisation to which it belongs.

1.1.3. If a notified body wholly or partly owns legal entities established in a Member State or in a third country or is owned by another legal entity, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented. Personnel of those entities performing conformity assessment activities under this Regulation shall be subject to the applicable requirements of this Regulation.

1.1.4. The organisational structure, allocation of responsibilities, reporting lines and operation of the notified body shall be such that they ensure that there is confidence in the performance by the notified body and in the results of the conformity assessment activities it conducts.

1.1.5. The notified body shall clearly document its organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel who may have an influence upon the performance by the notified body upon the results of its conformity assessment activities.

1.1.6. The notified body shall identify the persons in top-level management that have overall authority and responsibility for each of the following:

(a) provision of adequate resources for conformity assessment activities;

(b) development of procedures and policies for the operation of the notified body;

(c) supervision of implementation of the procedures, policies and quality management systems of the notified body;

(d) supervision of the notified body's finances;

(e) activities and decisions taken by the notified body, including contractual agreements;

(f) delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities;

(g) interaction with the authority responsible for notified bodies and the obligations regarding communications with other competent authorities, the Commission and other notified bodies.

1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the device in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the device as well as of any competitors of the manufacturer. This does not preclude the notified body from carrying out conformity assessment activities for competing manufacturers.

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall document and implement a structure and procedures for safeguarding impartiality and for promoting and applying the principles of impartiality throughout its organisation, personnel and assessment activities. Such procedures shall provide for the identification, investigation and resolution of any case in which a conflict of interest may arise including involvement in consultancy services in the field of devices prior to taking up employment with the notified body. The investigation, outcome and its resolution shall be documented.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

(a) be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;

(b) be involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which they are designated, nor represent the parties engaged in those activities;

(c) engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated;

(d) offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the devices or processes under assessment; and

(e) be linked to any organisation which itself provides consultancy services as referred to in the point (d). Such restriction shall not preclude general training activities that are not client specific and that relate to regulation of devices s or to related standards.

1.2.4. Involvement in consultancy services in the field of devices prior to taking up employment with a notified body shall be fully documented at the time of employment, and potential conflicts of interests shall be monitored and resolved in accordance with this Annex. Personnel who were formerly employed by a specific client, or provided consultancy services in the field of devices to that specific client prior to taking up employment with a notified body, shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group for a period of three years.

1.2.5. The impartiality of notified bodies, of their top-level management and of the assessment personnel shall be guaranteed. The level of the remuneration of the top-level management and assessment personnel of a notified body and subcontractors involved in assessment activities shall not depend on the results of the assessments. Notified bodies shall make publicly available the declarations of interest of their top-level management.

1.2.6. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the authority responsible for notified bodies and/or the competent authority and, on the other hand, the notified body.

1.2.7. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors or of any associated body, including the activities of its owners do not affect its independence, impartiality or the objectivity of its conformity assessment activities.

1.2.8. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC in relation to fees.

1.2.9. The requirements laid down in this Section shall in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer applying for conformity assessment.

1.3. Confidentiality

1.3.1. The notified body shall have documented procedures in place ensuring that its personnel, committees, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of the conformity assessment activities, except when disclosure is required by law.

1.3.2. The personnel of a notified body shall observe professional secrecy in carrying out their tasks under this Regulation or any provision of national law giving effect to it, except in relation to the authorities responsible for notified bodies, competent authorities for devices in the Member States or the Commission. Proprietary rights shall be protected. The notified body shall have documented procedures in place in respect of the requirement of this Section.

1.4. Liability

1.4.1. The notified body shall take out appropriate liability insurance for its conformity assessment activities, unless liability is assumed by the Member State in question in accordance with national law or that Member State is directly responsible for their conformity assessment.

1.4.2. The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates.

1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities within its scope of designation and related business operations. It shall document and provide evidence of its financial capacity and its long-term economic viability, taking into account, where relevant, any specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of any relevant standardisation activities and in the activities of the notified body coordination group referred to in Article 49 of Regulation (EU) 2017/745 and that its assessment and decision-making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

1.6.2. The notified body shall take into consideration guidance and best practice documents.

2. QUALITY MANAGEMENT REQUIREMENTS

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and is capable of supporting and demonstrating the consistent fulfilment of the requirements of this Regulation.

2.2. The quality management system of the notified body shall address at least the following:

(a) management system structure and documentation, including policies and objectives for its activities;

(b) policies for assignment of activities and responsibilities to personnel;

(c) assessment and decision-making processes in accordance with the tasks, responsibilities and role of the notified body's personnel and top-level management;

(d) the planning, conduct, evaluation and, if necessary, adaptation of its conformity assessment procedures;

(e) control of documents;

(f) control of records;

(g) management reviews;

(h) internal audits;

(i) corrective and preventive actions;

(j) complaints and appeals;

(k) continuous training.

Where documents are used in various languages, the notified body shall ensure and control that they have the same content.

2.3. The top-level management of the notified body shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including subsidiaries and subcontractors involved in conformity assessment activities pursuant to this Regulation.

2.4. The notified body shall require all personnel to formally commit themselves by a signature or equivalent to comply with the procedures defined by the notified body. That commitment shall cover aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with clients. The personnel shall be required to complete written statements indicating their compliance with confidentiality, independence and impartiality principles.

3. RESOURCE REQUIREMENTS

3.1. General

3.1.1. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

In particular, notified bodies shall have the necessary personnel and possess or have access to all equipment, facilities and competence needed to perform properly the technical, scientific and administrative tasks entailed in the conformity assessment activities in relation to which they have been designated. Such requirement presupposes at all times and for each conformity assessment procedure and each type of devices in relation to which they have been designated, that the notified body has permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant devices and the corresponding technologies. Such personnel shall be in sufficient numbers to ensure that the notified body in question can perform the conformity assessment tasks, including the assessment of the medical functionality, performance evaluations and the performance and safety of devices, for which it has been designated, having regard to the requirements of this Regulation, in particular those set out in Annex I.

A notified body's cumulative competences shall be such as to enable it to assess the types of devices for which it is designated. The notified body shall have sufficient internal competence to critically evaluate assessments conducted by external expertise. Tasks which a notified body is precluded from subcontracting are set out in Section 4.1.

Personnel involved in the management of the operation of a notified body's conformity assessment activities for devices shall have appropriate knowledge to set up and operate a system for the selection of assessment and verification staff, for verification of their competence, for authorisation and allocation of their tasks, for organisation of their initial and ongoing training, and for their assignment of their duties and monitoring of those staff, in order to ensure that personnel who carry out and perform assessment and verification operations are competent to fulfil the tasks required of them.

The notified body shall identify at least one individual within its top-level management as having overall responsibility for all conformity assessment activities in relation to devices.

3.1.2. The notified body shall ensure that personnel involved in conformity assessment activities maintain their qualification and expertise by implementing a system for exchange of experience and a continuous training and education programme.

3.1.3. The notified body shall clearly document the extent and limits of duties and responsibilities and the level of authorisation of to the personnel, including any subcontractors and external experts involved in conformity assessment activities and inform those personnel accordingly.

3.2. Qualification criteria in relation to personnel

3.2.1. The notified body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities, including as regards knowledge, experience and other competence required, and the required initial and ongoing training. The qualification criteria shall address the various functions within the conformity assessment process, such as auditing, product evaluation or testing, technical documentation review, decision-making, and batch release, as well as the devices, technologies and areas, such as biocompatibility, sterilisation, self and near patient-testing, companion diagnostics and performance evaluation, covered by the scope of designation.

3.2.2. The qualification criteria referred to in Section 3.2.1 shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 38(3), providing a sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined at least for the assessment of:

— biological safety,

— performance evaluation,

— devices for self and near patient testing,

— companion diagnostics,

— functional safety,

— software,

— packaging, and

— the different types of sterilisation processes.

3.2.3. The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall be employed by the notified body itself and shall not be external experts or subcontracted. They shall have proven knowledge and experience in all of the following:

— Union devices legislation and relevant guidance documents;

— the conformity assessment procedures provided for in this Regulation;

— a broad base of knowledge of device technologies and the design and manufacture of devices;

— the notified body's quality management system, related procedures and the required qualification criteria;

— training relevant to personnel involved in conformity assessment activities in relation to devices;

— adequate experience in conformity assessments under this Regulation or previously applicable law within a notified body.

3.2.4. The notified body shall have permanent availability of personnel with relevant clinical expertise and where possible such personnel shall be employed by the notified body itself. Such personnel shall be integrated throughout the notified body's assessment and decision-making process in order to:

— identify when specialist input is required for the assessment of the performance evaluation conducted by the manufacturer and identify appropriately qualified experts;

— appropriately train external clinical experts in the relevant requirements of this Regulation, CS, guidance and harmonised standards and ensure that the external clinical experts are fully aware of the context and implications of their assessment and the advice they provide;

— be able to review and scientifically challenge the clinical data contained within the performance evaluation, and any associated performance study, and appropriately guide external clinical experts in the assessment of the performance evaluation presented by the manufacturer;

— be able to scientifically evaluate and, if necessary, challenge the performance evaluation presented, and the results of the external clinical experts' assessment of the manufacturer's performance evaluation;

— be able to ascertain the comparability and consistency of the assessments of performance evaluation conducted by clinical experts;

— be able to make an assessment of the manufacturer's performance evaluation and a clinical judgement of the opinion provided by any external expert and make a recommendation to the notified body's decision maker; and

— be able to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.5. The personnel responsible for carrying out product-related reviews, (product reviewers), such as technical documentation reviews or type examination, including aspects such as performance evaluation, biological safety, sterilisation and software validation, shall have all the following proven qualifications:

— successful completion of a university or a technical college degree or an equivalent qualification in relevant studies, such as medicine, pharmacy, engineering or other relevant sciences;

— four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing, or research, of which two years shall be in the design, manufacture, testing or use of devices or technology to be assessed or related to the scientific aspects to be assessed;

— knowledge of device legislation, including the general safety and performance requirements set out in Annex I;

— appropriate knowledge and experience of relevant harmonised standards, CS and guidance documents;

— appropriate knowledge and experience of risk management and related device standards and guidance documents;

— appropriate knowledge and experience of performance evaluation;

— appropriate knowledge of the devices which they are assessing;

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those assessments;

— the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality management system (site auditors) shall have all of the following proven qualifications:

— successful completion of a university or a technical college degree or equivalent qualification in relevant studies, such as medicine, pharmacy, engineering or other relevant sciences;

— four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which two years shall be in the area of quality management;

— appropriate knowledge of devices legislation as well as related harmonised standards, CS and guidance documents;

— appropriate knowledge and experience of risk management and related device standards and guidance documents;

— appropriate knowledge of quality management systems and related l devices standards and guidance documents;

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those audits;

— training in auditing techniques enabling them to challenge quality management systems;

— the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.7. The personnel with overall responsibility for final reviews and decision-making on certification shall be employed by the notified body itself and shall not be external experts or be subcontracted. Those personnel, as a group, shall have proven knowledge and comprehensive experience of all of the following:

— devices legislation and relevant guidance documents;

— device conformity assessments relevant to this Regulation;

— the types of qualifications, experience and expertise relevant to device conformity assessment;

— a broad base of knowledge of device technologies, including sufficient experience of the conformity assessment of devices being reviewed for certification, the device industry and the design and manufacture of devices;

— the notified body's quality system, related procedures and the required qualifications for personnel involved;

— the ability to draw up records and reports demonstrating that the conformity assessment activities have been appropriately carried out.

3.3. Documentation of qualification, training and authorisation of personnel

3.3.1. The notified body shall have a procedure in place to fully document the qualification of each member of personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2. Where, in exceptional circumstances, the fulfilment of the qualification criteria set out in Section 3.2 cannot be fully demonstrated, the notified body shall justify to the authority responsible for notified bodies the authorisation of those members of personnel to carry out specific conformity assessment activities.

3.3.2. For all of its personnel referred to in Sections 3.2.3 to 3.2.7, the notified body shall establish and maintain up to date:

— a matrix detailing the authorisations and responsibilities of the personnel in respect of conformity assessment activities;

— records attesting to the required knowledge and experience for the conformity assessment activity for which they are authorised. The records shall contain a rationale for defining the scope of the responsibilities for each of the assessment personnel and records of the conformity assessment activities carried out by each of them.

3.4. Subcontractors and external experts

3.4.1. Notified bodies may, without prejudice to Section 3.2, subcontract certain clearly defined component parts of a conformity assessment activity.

The subcontracting of the auditing of quality management systems or of product-related reviews as a whole shall not be permitted, nevertheless parts of those activities may be conducted by subcontractors and external auditors and experts working on behalf of the notified body. The notified body in question shall retain full responsibility for being able to produce appropriate evidence of the competence of subcontractors and experts to fulfil their specific tasks, for making a decision based on a subcontractor's assessment and for the work conducted by subcontractors and experts on its behalf.

The following activities may not be subcontracted by notified bodies:

— review of the qualifications and monitoring of the performance of external experts;

— auditing and certification activities where the subcontracting in question is to auditing or certification organisations;

— allocation of work to external experts for specific conformity assessment activities;

— final review and decision-making functions.

3.4.2. Where a notified body subcontracts certain conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place, and shall ensure that:

— the subcontractor meets the relevant requirements of this Annex;

— subcontractors and external experts do not further subcontract work to organisations or personnel;

— the natural or legal person that applied for conformity assessment has been informed of the requirements referred to in the first and second indent.

Any subcontracting or consultation of external personnel shall be properly documented, shall not involve any intermediaries, and shall be subject to a written agreement covering, among other things, confidentiality and conflicts of interest. The notified body in question shall take full responsibility for the tasks performed by subcontractors.

3.4.3. Where subcontractors or external experts are used in the context of a conformity assessment, in particular regarding novel devices or technologies, the notified body in question shall have adequate internal competence in each product area for which it is designated that is adequate for the purpose of leading the overall conformity assessment, verifying the appropriateness and validity of expert opinions and making decisions on certification.

3.5. Monitoring of competences, training and exchange of experience

3.5.1. The notified body shall establish procedures for the initial evaluation and on-going monitoring of the competence, conformity assessment activities and performance of all internal and external personnel and subcontractors, involved in conformity assessment activities.

3.5.2. Notified bodies shall review at regular intervals, the competence of their personnel, identify training needs and draw up a training plan to maintain the required level of qualification and knowledge of individual personnel. That review shall as a minimum, verify that personnel:

— are aware of the Union and national law in force on devices, relevant harmonised standards, CS, guidance documents and the results of the coordination activities referred to in Section 1.6;

— take part in the internal exchange of experience and the continuous training and education programme referred to in Section 3.1.2.

4. PROCESS REQUIREMENTS

4.1. General

The notified body shall have in place documented processes and sufficiently detailed procedures for the conduct of each conformity assessment activity for which it is designated, comprising the individual steps from pre-application activities up to decision making and surveillance and taking into account, when necessary, the respective specificities of the devices.

The requirements laid down in Sections 4.3, 4.4, 4.7 and 4.8 shall be fulfilled as part of the internal activities of notified bodies and shall not be subcontracted.

4.2. Notified body quotations and pre-application activities

The notified body shall

(a) publish a publicly available description of the application procedure by which manufacturers can obtain certification from it. That description shall include which languages are acceptable for submission of documentation and for any related correspondence;

(b) have documented procedures relating to, and documented details about, fees charged for specific conformity assessment activities and any other financial conditions relating to notified bodies' assessment activities for devices;,

(c) have documented procedures in relation to advertising of its conformity assessment services. Those procedures shall ensure that advertising or promotional activities in no way imply or are capable of leading to an inference that their conformity assessment will offer manufacturers earlier market access or be quicker, easier or less stringent than that of other notified bodies;

(d) have documented procedures requiring the review of pre-application information including the preliminary verification that the product is covered by this Regulation and its classification prior to issuing any quotation to the manufacturer relating to a specific conformity assessment;

(e) ensure that all contracts relating to the conformity assessment activities covered by this Regulation are concluded directly between the manufacturer and the notified body and not with any other organisation.

4.3. Application review and contract

The notified body shall require a formal application signed by a manufacturer or an authorised representative containing all of the information and the manufacturer's declarations required by the relevant conformity assessment as referred to in Annexes IX to XI.

The contract between a notified body and a manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body. This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, restrict or withdraw certificates issued and the duty of the notified body to fulfil its information obligations.

The notified body shall have documented procedures to review applications, addressing:

(a) the completeness of those applications with respect to the requirements of the relevant conformity assessment procedure, as referred to in the corresponding Annex, under which approval has been sought,

(b) the verification of the qualification of products covered by those applications as devices and their respective classifications,

(c) whether the conformity assessment procedures chosen by the applicant are applicable to the device in question under this Regulation,

(d) the ability of the notified body to assess the application based on its designation, and

(e) the availability of sufficient and appropriate resources.

The outcome of each review of an application shall be documented. Refusals or withdrawals of applications shall be notified to the electronic system referred to in Article 52 and shall be accessible to other notified bodies.

4.4. Allocation of resources

The notified body shall have documented procedures to ensure that all conformity assessment activities are conducted by appropriately authorised and qualified personnel who are sufficiently experienced in the evaluation of the devices, systems and processes and related documentation that are subject to conformity assessment.

For each application, the notified body shall determine the resources needed and identify one individual responsible for ensuring that the assessment of that application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources including personnel are utilised for each of the tasks of the assessment. The allocation of tasks required to be carried out as part of the conformity assessment and any changes subsequently made to this allocation shall be documented.

4.5. Conformity assessment activities

4.5.1. General

The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.

The notified body shall have expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI and in particular the following requirements:

— to appropriately plan the conduct of each individual project,

— to ensure that the composition of the assessment teams is such that there is sufficient experience in relation to the technology concerned, and that there is continuous objectivity and independence, and to provide for rotation of the members of the assessment team at appropriate intervals,

— to specify the rationale for fixing time limits for completion of conformity assessment activities,

— to assess the manufacturer's technical documentation and the solutions adopted to meet the requirements laid down in Annex I,

— to review the manufacturer's procedures and documentation relating to performance evaluation,

— to address the interface between the manufacturer's risk management process and its appraisal and analysis of the performance evaluation and to evaluate their relevance for the demonstration of conformity with the relevant requirements in Annex I,

— to carry out the 'specific procedures' referred to in Section 5 of Annex IX,

— in the case of class B or C devices, to assess the technical documentation of devices selected on a representative basis,

— to plan and periodically carry out appropriate surveillance audits and assessments, to carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits,

— relating to the sampling of devices verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,

— to evaluate and verify a manufacturer's compliance with relevant Annexes.

The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.

4.5.2. Quality management system auditing

(a) As part of the assessment of the quality management system a, a notified body shall prior to an audit and in accordance with its documented procedures:

— assess the documentation submitted in accordance with the relevant conformity assessment Annex, and draw up an audit programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of a manufacturer's quality management system and to determine whether it meets the requirements of this Regulation,

— identify links between and allocation of responsibilities among, the various manufacturing sites, and identify relevant suppliers and/or subcontractors of the manufacturer, and consider the need to specifically audit any of those suppliers or subcontractors or both,

— clearly define, for each audit identified in the audit programme, the objectives, criteria and scope of the audit, and draw up an audit plan that adequately addresses and takes account of the specific requirements for the devices, technologies and processes involved,

— draw up and keep up to date, for class B and class C devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate,

— select and assign appropriately qualified and authorised personnel for conducting the individual audits. The respective roles, responsibilities and authorities of the team members shall be clearly defined and documented.

(b) Based on the audit programme it has drawn up, the notified body shall, in accordance with its documented procedures:

— audit the manufacturer's quality management system in order to verify that the quality management system ensures that the devices covered conform to the relevant provisions of this Regulation which apply to devices at every stage, from design through final quality control to ongoing surveillance, and shall determine whether the requirements of this Regulation are met,

— based on relevant technical documentation, and in order to determine whether the manufacturer meets the requirements referred to in the relevant conformity assessment Annex, review and audit the manufacturer's processes and subsystems,– in particular for:

— design and development,

— production and process controls,

— product documentation,

— purchasing controls including verification of purchased devices,

— corrective and preventive actions including for post-market surveillance, and

— PMPF,

— and review and audit requirements and provisions adopted by the manufacturer, including those in relation to fulfilling the general safety and performance requirements set out in Annex I,

— the documentation shall be sampled in such as a manner as to reflect the risks associated with the intended use of the device, the complexity of the manufacturing technologies, the range and classes of devices produced and any available post-market surveillance information,

— if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers,

— conduct assessments of the technical documentation based on its sampling plan and taking account of Section 4.5.4. for performance evaluation,

— the notified body shall ensure that audit findings are appropriately and consistently classified in accordance with the requirements of this Regulation and with relevant standards, or with best practice documents developed or adopted by the MDCG.

4.5.3. Product verification

Assessment of the technical documentation

For assessment of the technical documentation conducted in accordance with Chapter II of Annex IX, notified bodies shall have sufficient expertise, facilities and documented procedures for:

— the allocation of appropriately qualified and authorised personnel for the examination of individual aspects, such as use of the device, biocompatibility, performance evaluation, risk management and sterilisation, and

— the assessment of conformity of the design with this Regulation, and taking account of Sections 4.5.4. and 4.5.5. This assessment shall include the examination of the implementation by manufacturers of incoming, in-process and final checks and the results thereof. If further tests or other evidence is required for the assessment of conformity with the requirements of this Regulation, the notified body in question shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Type-examinations

The notified body shall have documented procedures, sufficient expertise and facilities for the type-examination of devices in accordance with Annex X including the capacity to:

— examine and assess the technical documentation, taking account of Sections 4.5.4. and 4.5.5, and verify that the type has been manufactured in conformity with that documentation;

— establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility;

— document its rationale for the selection of those parameters;

— carry out the appropriate examinations and tests in order to verify that the solutions adopted by the manufacturer meet the general safety and performance requirements set out in Annex I. Such examinations and tests shall include all tests necessary to verify that the manufacturer has in fact applied the relevant standards it has opted to use;

— agree with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body;

— assume full responsibility for test results. Test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

Verification by examination and testing of every product batch

The notified body shall:

(a) have documented procedures, sufficient expertise and facilities for the verification by examination and testing of every product batch in accordance with Annexes IX and XI;

(b) establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility in order to:

— verify, for class C devices, the conformity of the device with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to those devices,

— confirm, for class B devices, the conformity with the technical documentation referred to in Annexes II and III and with the requirements of this Regulation which apply to those devices,

(c) document its rationale for the selection of the parameters referred to in point (b);

(d) have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of this Regulation by examining and testing every product batch as specified in Section 5 of Annex XI;

(e) have documented procedures providing for the reaching of an agreement with the applicant concerning when and where necessary tests that are not to be carried out by the notified body itself are to be performed;

(f) assume full responsibility for test results in accordance with documented procedures; test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

4.5.4. Performance evaluation assessment

The assessment by notified bodies of procedures and documentation shall address the results of literature searches and all validation, verification and testing performed and conclusions drawn, and shall typically include considering the use of alternative materials and substances and take account of the packaging, stability including shelf life of the finished device. Where no new testing has been undertaken by a manufacturer or where there have been deviations from procedures, the notified body in question shall critically examine the justification presented by the manufacturer.

The notified body shall have documented procedures in place relating to the assessment of a manufacturer's procedures and documentation relating to performance evaluation both for initial conformity assessment and on an ongoing basis. The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address:

(a) the planning, conduct, assessment, reporting and updating of the performance evaluation as referred to in Annex XIII,

(b) post-market surveillance and post-market performance follow up,

(c) the interface with the risk management process,

(d) the appraisal and analysis of the available data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I,

(e) the conclusions drawn with regard to the clinical evidence and drawing up of the performance evaluation report.

The procedures referred to in the second paragraph shall take into consideration available CS, guidance and best practice documents.

The notified body's assessment of performance evaluations as referred to in Annex XIII shall cover:

— the intended use specified by the manufacturer and claims for the device defined by it,

— the planning of the performance evaluation,

— the methodology for the literature search,

— relevant documentation from the literature search,

— the performance studies,

— post-market surveillance and post-market performance follow up,

— validity of equivalence claimed in relation to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices,

— the performance evaluation report,

— justifications in relation to non-performance of performance studies or PMPF.

In relation to data from performance studies included within the performance evaluation, the notified body in question shall ensure that the conclusions drawn by the manufacturer are valid in the light of the approved performance study plan.

The notified body shall ensure that the performance evaluation adequately addresses the relevant safety and performance requirements provided for in Annex I, that it is appropriately aligned with the risk management requirements and that it is conducted in accordance with Annex XIII and that it is appropriately reflected in the information provided relating to the device.

4.5.5. Specific Procedures

The notified body shall have documented procedures, sufficient expertise and facilities for the procedures referred to in Section 5 of Annex IX, for which they are designated.

In the case of companion diagnostics, the notified body shall have documented procedures in place that aim to fulfil the requirements of this Regulation in relation to consultation of the EMA or a medicinal products competent authority during its assessment of such types of device.

4.6. Reporting

The notified body shall:

— ensure that all steps of the conformity assessment are documented so that the conclusions of the assessment are clear and demonstrate compliance with the requirements of this Regulation and can represent objective evidence of such compliance to persons that are not themselves involved in the assessment, for example personnel in designating authorities,

— ensure that records that are sufficient to provide a discernible audit trail are available for quality management system audits,

— clearly document the conclusions of its assessment of performance evaluation in a performance evaluation assessment report,

— for each specific project, provide a detailed report which shall be based on a standard format containing a minimum set of elements determined by the MDCG.

The report of the notified body shall:

— clearly document the outcome of its assessment and draw clear conclusions from the verification of the manufacturer's conformity with the requirements of this Regulation,

— make a recommendation for a final review and for a final decision to be taken by the notified body; this recommendation shall be signed off by the member of personnel responsible in the notified body,

— be provided to the manufacturer in question.

4.7. Final review

The notified body shall prior to making a final decision:

— ensure that the personnel assigned for the final review and decision making on specific projects are appropriately authorised and are different from the personnel who have conducted the assessments,

— verify that the report or reports and supporting documentation needed for decision making, including concerning resolution of non-conformities noted during assessment, are complete and sufficient with respect to the scope of the application, and

— verify whether there are any unresolved non-conformities preventing issuance of a certificate.

4.8. Decisions and certifications

The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, restriction and withdrawal of certificates. Those procedures shall include the notification requirements laid down in Chapter V of this Regulation. The procedures shall allow the notified body in question to:

— decide, based on the assessment documentation and additional information available whether the requirements of this Regulation are fulfilled,

— decide, based on the results of its assessment of the performance evaluation and risk management whether the post-market surveillance plan, including the PMPF plan, is adequate,

— decide on specific milestones for further review by the notified body of the up to date performance evaluation,

— decide whether specific conditions or provisions need to be defined for the certification,

— decide, based on the novelty, risk classification, performance evaluation and conclusions from the risk analysis of the device, on a period of certification not exceeding five years,

— clearly document decision making and approval steps including approval by signature of the members of personnel responsible,

— clearly document responsibilities and mechanisms for communication of decisions, in particular, where the final signatory of a certificate differs from the decision maker or decision makers or does not fulfil the requirements laid down in Section 3.2.7.,

— issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII for a period of validity not exceeding five years and shall indicate whether there are specific conditions or limitations associated with the certification,

— issue a certificate or certificates for the applicant alone and shall not issue certificates covering multiple entities,

— ensure that the manufacturer is notified of the outcome of the assessment and the resultant decision and that they are entered into the electronic system referred to in Article 52.

4.9. Changes and modifications

The notified body shall have documented procedures and contractual arrangements with manufacturers in place relating to the manufacturers' information obligations and the assessment of changes to:

— the approved quality management system or systems or to the product-range covered,

— the approved design of a device,

— the approved type of a device,

— any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.5.

The procedures and contractual arrangements referred to in the first paragraph shall include measures for checking the significance of the changes referred to in the first paragraph.

In accordance with its documented procedures, the notified body in question shall:

— ensure that manufacturers submit for prior approval plans for changes as referred to in the first paragraph and relevant information relating to such changes,

— assess the changes proposed and verify whether, after these changes, the quality management system, or the design of a device or type of a device, still meets the requirements of this Regulation,

— notify the manufacturer of its decision and provide a report or, as applicable, a supplementary report, which shall contain the justified conclusions of its assessment.

4.10. Surveillance activities and post-certification monitoring

The notified body shall have documented procedures:

— defining how and when surveillance activities of manufacturers are to be conducted. Those procedures shall include arrangements for unannounced on-site audits of manufacturers and, where applicable, subcontractors and suppliers carrying out product tests and the monitoring of compliance with any conditions binding manufacturers and associated with certification decisions, such as updates to clinical data at defined intervals,

— for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. Such information shall be taken into account in the planning and conduct of surveillance activities,

— to review vigilance data to which they have access under to Article 87 in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.

The notified body in question shall, upon receipt of information about vigilance cases from a manufacturer or competent authorities, decide on which of the following options to apply:

— not to take action on the basis that the vigilance case is clearly not related to the certification granted,

— observe the manufacturer's and competent authorities' activities and the results of the manufacturer's investigation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken,

— perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced audits and product testing, where it is likely that the certification granted is at risk,

— increase the frequency of surveillance audits,

— review specific products or processes on the occasion of the next audit of the manufacturer, or

— take any other relevant measure.

In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to:

— conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in Section 4.5.,

— ensure that it adequately assesses the manufacturer's documentation on, and application of, the provisions on vigilance, the post-market surveillance and PMPF,

— sample and test devices and technical documentation, during audits, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved quality management system,

— ensure that the manufacturer complies with the documentation and information obligations laid down in the relevant Annexes and that its procedures take into account best practices in the implementation of quality management systems,

— ensure that the manufacturer does not use quality management system or device approvals in a misleading manner,

— gather sufficient information to determine if the quality management system continues to comply with the requirements of this Regulation,

— ask the manufacturer, if non-conformities are detected, for corrections, corrective actions, and where applicable preventive actions, and

— where necessary, impose specific restrictions on the relevant certificate, or suspend or withdraw it.

The notified body shall, if listed as part of the conditions for certification:

— conduct an in-depth review of the performance evaluation as most recently updated by the manufacturer based on the manufacturer's post-market surveillance, on its PMPF and on clinical literature relevant to the condition being treated with the device or on clinical literature relevant to similar devices,

— clearly document the outcome of the in-depth review and address any specific concerns to the manufacturer or impose any specific conditions on it,

— ensure that the performance evaluation as most recently updated is appropriately reflected in the instructions for use and, where applicable, the summary of safety and performance.

4.11. Re-certification

The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates shall occur at least every five years.

The notified body shall have documented procedures relating to renewals of EU technical documentation assessment certificates and EU type-examination certificates and those procedures shall require the manufacturer in question to submit a summary of changes and scientific findings for the device, including:

(a) all changes to the originally approved device, including changes not yet notified,

(b) experience gained from post-market surveillance,

(c) experience from risk-management,

(d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,

(e) experience from reviews of the performance evaluation, including the results of any performance studies and PMPF,

(f) changes to the requirements, to components of the device or to the scientific or regulatory environment,

(g) changes to applied or new harmonised standards, CS or equivalent documents, and

(h) changes in medical, scientific and technical knowledge, such as:

— new treatments,

— changes in test methods,

— new scientific findings on materials and components, including findings on their biocompatibility,

— experience from studies on comparable devices,

— data from registers and registries,

— experience from performance studies with comparable devices.

The notified body shall have documented procedures to assess the information referred to in the second paragraph and shall pay particular attention to clinical data from post-market surveillance and PMPF activities undertaken since the previous certification or re-certification, including appropriate updates to manufacturers' performance evaluation reports.

For the decision on the re-certification, the notified body in question shall use the same methods and principles as for the initial certification decision. If necessary, separate forms shall be established for re-certification taking into account the steps to be taken for certification, such as application and application review.

ANNEX VIII

CLASSIFICATION RULES

1. IMPLEMENTING RULES

1.1. Application of the classification rules shall be governed by the intended purpose of the devices.

1.2. If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.

1.3. Accessories for an *in vitro* diagnostic medical device shall be classified in their own right separately from the device with which they are used.

1.4. Software, which drives a device or influences the use of a device, shall fall within the same class as the device.

If the software is independent of any other device, it shall be classified in its own right.

1.5. Calibrators intended to be used with a device shall be classified in the same class as the device.

1.6. Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.

1.7. The manufacturer shall take into consideration all classification and implementation rules in order to establish the proper classification for the device.

1.8. Where a manufacturer states multiple intended purposes for a device, and as a result the device falls into more than one class, it shall be classified in the higher class.

1.9. If several classification rules apply to the same device, the rule resulting in the higher classification shall apply.

1.10. Each of the classification rules shall apply to first line assays, confirmatory assays and supplemental assays.

2. CLASSIFICATION RULES

2.1. Rule 1

Devices intended to be used for the following purposes are classified as class D:

— detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration;

— detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation;

— determining the infectious load of a life-threatening disease where monitoring is critical in the process of patient management.

2.2. Rule 2

Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as class C, except when intended to determine any of the following markers:

— ABO system [A (ABO1), B (ABO2), AB (ABO3)];

— Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)];

— Kell system [Kel1 (K)];

— Kidd system [JK1 (Jka), JK2 (Jkb)];

— Duffy system [FY1 (Fya), FY2 (Fyb)];

in which case they are classified as class D.

2.3. Rule 3

Devices are classified as class C if they are intended:

(a) for detecting the presence of, or exposure to, a sexually transmitted agent;

(b) for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;

(c) for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested, or to the individual's offspring;

(d) for pre-natal screening of women in order to determine their immune status towards transmissible agents;

(e) for determining infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

(f) to be used as companion diagnostics;

(g) to be used for disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

(h) to be used in screening, diagnosis, or staging of cancer;

(i) for human genetic testing;

(j) for monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

(k) for management of patients suffering from a life-threatening disease or condition;

(l) for screening for congenital disorders in the embryo or foetus;

(m) for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.

2.4. Rule 4

(a) Devices intended for self-testing are classified as class C, except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, *erythrocytes*, *leucocytes* and bacteria in urine, which are classified as class B.

(b) Devices intended for near-patient testing are classified in their own right.

2.5. Rule 5

The following devices are classified as class A:

(a) products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures relating to a specific examination;

(b) instruments intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures;

(c) specimen receptacles.

2.6. Rule 6

Devices not covered by the above-mentioned classification rules are classified as class B.

2.7. Rule 7

Devices which are controls without a quantitative or qualitative assigned value are classified as class B.

ANNEX IX

CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

CHAPTER I

QUALITY MANAGEMENT SYSTEM

1. The manufacturer shall establish, document and implement a quality management system, as described in Article 10(8), and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2, and shall be subject to audit as laid down in Sections 2.3 and 2.4 and to surveillance as specified in Section 3.

2. Quality management system assessment

2.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

— the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative the name of the authorised representative and the address of the authorised representative's registered place of business,

— all relevant information on the device or group of devices covered by the quality management system,

— a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,

— a draft of an EU declaration of conformity in accordance with Article 17 and Annex IV for the device model covered by the conformity assessment procedure,

— the documentation on the manufacturer's quality management system,

— a documented description of the procedures in place to fulfil the obligations arising from by the quality management system and required under this Regulation and of the undertaking by the manufacturer in question to apply those procedures,

— a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,

— the documentation on the manufacturer's post-market surveillance system, and, where applicable, on the PMPF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87,

— a description of the procedures in place to keep up to date the post-market surveillance system and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87, as well as the undertaking by the manufacturer to apply those procedures,

— documentation on the performance evaluation plan, and

— a description of the procedures in place to keep up to date the performance evaluation plan, taking into account the state of the art.

2.2. Implementation of the quality management system shall ensure compliance with this Regulation. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) the manufacturer's quality objectives;

(b) the organisation of the business and in particular:

— the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority,

— the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform,

— where the design, manufacture, and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,

— where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate;

(c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover:

— the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of, and compliance with, conformity assessment procedures,

— identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS into account and, where opted for, harmonised standards,

— risk management as referred to in Section 3 of Annex I,

— the performance evaluation, pursuant to Article 56 and Annex XIII, including PMPF,

— solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,

— solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I,

— the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture, and

— management of design or quality management system changes;

(d) the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation, and the relevant documents, and

(e) the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annexes II and III.

2.3. Audit

The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 2.2. Where the manufacturer uses a harmonised standard or CS related to a quality management system, the notified body shall assess conformity with those standards or CS. The notified body shall assume that a quality management system which satisfies the relevant harmonised standards or CS conforms to the requirements covered by those standards or CS, unless it duly substantiate not doing so.

The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned in accordance with Sections 4.3. to 4.5. of Annex VII. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.

Moreover, in the case of class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation for devices selected on a representative basis in accordance with provisions in Sections 4.4 to 4.8. In choosing representative samples the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 99 and in particular, the novelty of the technology, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken.

If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of tits decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.

2.4. The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether, after those changes, the quality management system still meets the requirements referred to in Section 2.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.

3. Surveillance assessment applicable to class C and class D devices

3.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality management system.

3.2. The manufacturer shall give authorisation to the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular:

— the documentation on its quality management system,

— the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMPF plan, for a representative sample of devices, and of the provisions on vigilance set out in Articles 82 to 87,

— the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 4 of Annex I,

— the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

3.3. Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

3.4. The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, the site of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 3.3 or be performed in addition to that surveillance assessment. The notified body shall establish a plan for such unannounced on-site audits but shall not disclose it to the manufacturer.

Within the context of such unannounced on-site audits, the notified body shall test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation. Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, sampling referred to in the second paragraph, notified bodies shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation. Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer in question with an on-site audit report which shall include, if applicable, the result of the sample test.

3.5. In the case of class C devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 of for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3.

3.6. Notified bodies shall ensure that the composition of the assessment team is such that there is sufficient experience with the evaluation of the devices, systems and processes concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall neither lead nor attend audits for more than three consecutive years in respect of the same manufacturer.

3.7. If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

CHAPTER II

ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4. Assessment of the technical documentation of class B, C and D devices and batch verification applicable to class D devices

4.1. In addition to the obligation laid down in Section 2, the manufacturer of devices shall lodge with the notified body an application for the assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in Section 2.

4.2. The application shall describe the design, manufacture and performance of the device in question. It shall include the technical documentation as referred to in Annexes II and III.

In the case of devices for self-testing or near-patient testing, the application shall also include the aspects referred to in point (b) of Section 5.1.

4.3. The notified body shall examine the application by using staff, employed by it, with proven knowledge and experience in the evaluation of the technology, and the devices concerned and the evaluation of clinical evidence. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

4.4. The notified body shall review the clinical evidence presented by the manufacturer in the performance evaluation report and the related performance evaluation that was conducted. The notified body shall use employed device reviewers with sufficient clinical expertise and including external clinical experts with direct and current experience relating to the clinical application of the device in question for the purposes of that review.

4.5. The notified body shall, in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity.

4.6. The notified body shall verify that the clinical evidence and the performance evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. That verification shall include consideration of the adequacy of the benefit-risk determination, the risk management, the instructions for use, the user training and the manufacturer's post-market surveillance plan, and include a review of the need for, and the adequacy of, the PMPF plan proposed, where applicable.

4.7. Based on its assessment of the clinical evidence, the notified body shall consider the performance evaluation and the benefit-risk determination, and whether specific milestones need to be defined to allow the notified body to review updates to the clinical evidence that result from post-market surveillance and PMPF data.

4.8. The notified body shall clearly document the outcome of its assessment in the performance evaluation assessment report.

4.9. Before issuing an EU technical documentation assessment certificate, the notified body shall request an EU reference laboratory, where designated in accordance with Article 100, to verify the performance claimed by the manufacturer and the compliance of the device with the CS, where available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The verification shall include laboratory tests by the EU reference laboratory as referred to in Article 48(5).

In addition, the notified body shall, in the cases referred to in Article 48(6) of this Regulation, consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 in accordance with the procedure laid down in Article 48(6) of this Regulation on the performance evaluation report of the manufacturer.

The EU reference laboratory shall provide a scientific opinion within 60 days.

The scientific opinion of the EU reference laboratory and, where applicable, the views of the experts consulted, pursuant to the procedure laid down in Article 48(6), and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall, when making its decision, give due consideration to the views expressed in the scientific opinion of the EU reference laboratory, and, where applicable, to the views expressed by the experts consulted pursuant to Article 48(6). The notified body shall not deliver the certificate if the scientific opinion of the EU reference laboratory is unfavourable.

4.10. The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a performance evaluation assessment report. If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the technical documentation assessment, the conditions of the certificate's validity, the data needed for identification of the approved device, and, where appropriate, a description of the intended purpose of the device.

4.11. Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

Where the changes could affect compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU technical documentation assessment certificate, the notified body shall consult the EU reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CS or with other solutions chosen by the manufacturer, to ensure a level of safety and performance that is at least equivalent, is maintained.

The EU reference laboratory shall provide a scientific opinion within 60 days.

4.12. To verify conformity of manufactured class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body, without delay, the relevant reports on those tests. Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the notified body or the manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests. The EU reference laboratory shall inform the notified body about its findings.

4.13. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed timeframe, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

5. Assessment of the technical documentation of specific types of devices

5.1. Assessment of the technical documentation of class B, C and D devices for self-testing and near-patient testing

(a) The manufacturer of class B, C and D devices for self-testing and near-patient testing shall lodge with the notified body an application for the assessment of the technical documentation.

(b) The application shall enable the design of the device characteristics and performance(s) to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed. It shall include:

(i) test reports, including results of studies carried out with intended users;

(ii) where practicable, an example of the device; if required, the device shall be returned on completion of the technical documentation assessment;

(iii) data showing the suitability of the device in view of its intended purpose for self-testing or near patient-testing;

(iv) the information to be provided with the device on its label and its instructions for use.

The notified body may require the application to be completed by carrying out further tests or by providing further proof to allow assessment of conformity with the requirements of this Regulation.

(c) The notified body shall verify the compliance of the device with the relevant requirements set out in Annex I of this Regulation.

(d) The notified body shall assess the application, by using staff, employed by it, with proven knowledge and experience regarding the technology concerned and the intended purpose of the device and provide the manufacturer with a technical documentation assessment report.

(e) If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the assessment, the conditions of its validity, the data needed for the identification of the approved devices and, where appropriate, a description of the intended purpose of the device.

(f) Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes, it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

5.2. Assessment of the technical documentation of companion diagnostics

(a) The manufacturer of a companion diagnostic shall lodge with the notified body an application for the assessment of the technical documentation. The notified body shall assess that application in accordance with the procedure laid down in Sections 4.1 to 4.8 of this Annex.

(b) The application shall enable the characteristics and performance of the device to be understood, and shall enable conformity with the design-related requirements of this Regulation to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned.

(c) The notified body shall, before issuing an EU technical documentation assessment certificate for the companion diagnostic and on the basis of the draft summary of safety and performance and the draft instructions for use, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as 'the medicinal products authority consulted' depending on which has been consulted under this point, regarding the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex to Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]), the notified body shall seek the opinion of the EMA. If the medicinal product concerned is already authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products authority, or the EMA, that is responsible for the authorisation.

(d) The medicinal products authority consulted shall provide its opinion, within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days on justified grounds. The opinion and any possible update shall be included in the documentation of the notified body concerning the device.

(e) The notified body shall give due consideration to the scientific opinion referred to in point (d) when making its decision. The notified body shall convey its final decision to the medicinal products authority consulted. The EU technical documentation assessment certificate shall be delivered in accordance with point (e) of Section 5.1.

([1]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

(f) Before changes affecting the performance and/or the intended use and/or the suitability of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes and seek the opinion of the medicinal products authority consulted. The medicinal products authority consulted shall give its opinion within 30 days of receipt of the all the necessary documentation regarding the changes. A supplement to the EU technical documentation assessment certificate shall be issued in accordance with point (f) of Section 5.1.

CHAPTER III

ADMINISTRATIVE PROVISIONS

6. The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, it's authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in the fifth indent of Section 2.1. and, in particular, the data and records arising from the procedures referred to in point (c) of the second paragraph of Section 2.2.,

— information on the changes referred to in Section 2.4.,

— the documentation referred to in Sections 4.2. and point (b) of Section 5.1., and

— the decisions and reports from the notified body as referred to in this Annex.

7. Each Member State shall require that the documentation referred to in Section 6 is kept at the disposal of competent authorities for the period indicated in that Section in case a manufacturer, or its authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of that period.

ANNEX X

CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions of this Regulation.

2. Application

The manufacturer shall lodge an application for assessment with a notified body. The application shall include:

— the name of the manufacturer and the address of its registered place of business and, if the application is lodged by the authorised representative, the name of the authorised representative and the address of its registered place of business,

— the technical documentation referred to in Annexes II and III. The applicant shall make a representative sample of the device production envisaged ('type') available to the notified body. The notified body may request other samples as necessary,

— in the case of devices for self-testing or near-patient testing, test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in relation to its intended purpose for self-testing or near patient-testing,

— where practicable, an example of the device. If required, the device shall be returned on completion of the technical documentation assessment;

— data showing the suitability of the device in relation to its intended purpose for self-testing or near-patient testing,

— the information to be provided with the device on its label and its instructions for use, and

— a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that was refused by another notified body or was withdrawn by the manufacturer or its authorised representative before that other notified body made its final assessment.

3. Assessment

The notified body shall:

(a) examine the application, by using staff with proven knowledge and experience in the evaluation of the technology, and the devices concerned and the evaluation of clinical evidence. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests;

(b) examine and assess the technical documentation for conformity with the requirements of this Regulation that are applicable to the device and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable standards referred to in Article 8 or with applicable CS, and record items not designed on the basis of the relevant standards referred to in Article 8 or of the relevant CS;

(c) review the clinical evidence presented by the manufacturer in the performance evaluation report in accordance with Section 1.3.2 of Annex XIII. The notified body shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the clinical application of the device in question for the purposes of that review;

(d) in circumstances in which the clinical evidence is partly or totally based on data from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity;

(e) clearly document the outcome of its assessment in the performance evaluation assessment report referred to in Section 4.8 of Annex IX;

(f) carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements laid down in this Regulation in the event that the standards referred to in Article 8 or the CS have not been applied. Where the device has to be connected to another device or devices in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device or devices having the characteristics specified by the manufacturer;

(g) carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, in the event that the manufacturer has chosen to apply the relevant harmonised standards, those standards have actually been applied;

(h) agree with the applicant on the place where the necessary assessments and tests are to be carried out;

(i) draw up an EU type-examination report on the results of the assessments and tests carried out under points (a) to (g);

(j) in the case of class D devices, request the EU reference laboratory, where designated in accordance with Article 100, to verify the performance claimed by the manufacturer and the compliance of the device with the CS, where available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The verification shall include laboratory tests by the EU reference laboratory in accordance with Article 48(5).

In addition, the notified body shall, in the cases referred to in Article 48(6) of this Regulation, consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 following the procedure laid down in Article 48(6) of this Regulation on the performance evaluation report of the manufacturer.

The EU reference laboratory shall provide a scientific opinion within 60 days.

The scientific opinion of the EU reference laboratory and, where the procedure laid down in Article 48(6) is applicable, the views of the experts consulted, and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the EU reference laboratory, and, where applicable, to the views expressed by the experts consulted in accordance with Article 48(6), when making its decision. The notified body shall not deliver the certificate if the scientific opinion of the EU reference laboratory is unfavourable;

(k) for companion diagnostics, seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMA (either of which to be hereinafter referred to as 'the medicinal products authority consulted' depending on which has been consulted under this point) on the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. If the medicinal product concerned is already authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products competent authority, or the EMA, that is responsible for the authorisation. The medicinal products authority consulted shall deliver its opinion within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days on justified grounds. The opinion of the medicinal products authority consulted and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion expressed by the medicinal products authority consulted when making its decision. It shall convey its final decision to the medicinal products authority consulted; and

(l) draw up an EU type-examination report on the results of the assessments and tests carried out, and scientific opinions provided under, points (a) to (k), including a performance evaluation assessment report for class C or class D devices or covered by the third indent of Section 2.

4. Certificate

If the type conforms to this Regulation, the notified body shall issue an EU type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the type examination assessment, the conditions of certificate's validity and the data needed for identification of the type approved. The certificate shall be drawn up in accordance with Annex XII. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.

5. Changes to the type

5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type or of its intended purpose and conditions of use.

5.2. Changes to the approved device including limitations of its intended purpose and conditions of use shall require further approval from the notified body which issued the EU type-examination certificate where such changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the EU type-examination certificate.

5.3. Changes to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, shall necessitate a new application for a conformity assessment.

5.4. Where the changes could affect the performance claimed by the manufacturer or compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU type-examination certificate, the notified body shall consult the EU reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.

The EU reference laboratory shall provide a scientific opinion within 60 days.

5.5. Where the changes affect the performance or the intended use of a companion diagnostic approved through the EU type-examination certificate or its suitability in relation to a medicinal product, the notified body shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA. The medicinal products authority consulted shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.

6. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the documentation referred to in the second indent of Section 2,

— information on the changes referred to in Section 5,

— copies of EU type-examination certificates, scientific opinions and reports and their additions/supplements.

Section 7 of Annex IX shall apply.

ANNEX XI

CONFORMITY ASSESSMENT BASED ON PRODUCTION QUALITY ASSURANCE

1. The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented, shall carry out final verification, as specified in Section 3, and shall be subject to the surveillance referred to in Section 4.

2. When the manufacturer fulfils the obligations laid down in Section 1, it shall draw up and keep an EU declaration of conformity in accordance with Article 17 and Annex IV for the device covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer shall be deemed to ensure, and to declare, that the device concerned meets the requirements of this Regulation which apply to the device, and in the case of class C and class D devices that undergo a type examination, conforms to the type described in the EU type-examination certificate.

3. Quality management system

3.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body.

The application shall include:

— all elements listed in Section 2.1 of Annex IX,

— the technical documentation referred to in Annexes II and III for the types approved,

— a copy of the EU type-examination certificates referred to in Section 4 of Annex X; if the EU type-examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application.

3.2. Implementation of the quality management system shall be such as to ensure that there is compliance with the type described in the EU type-examination certificate and with the provisions of this Regulation which apply to the devices at each stage. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

That documentation shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 2.2. of Annex IX.

3.3. The first and second paragraphs of Section 2.3 of Annex IX shall apply.

If the quality management system is such that it ensures that the devices conform to the type described in the EU type-examination certificate and conform to the relevant provisions of this Regulation, the notified body shall issue an EU production quality assurance certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. That decision shall contain the conclusions of the notified body's audit and a reasoned assessment.

3.4. Section 2.4 of Annex IX shall apply.

4. Surveillance

Section 3.1, the first, second and fourth indents of Section 3.2, Sections 3.3, 3.4, 3.6 and 3.7 of Annex IX shall apply.

5. Verification of manufactured class D devices

5.1. In the case of class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body without delay the relevant reports on

those tests. Furthermore, the manufacturer shall make samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the notified body or the manufacturer, shall send samples of the manufactured devices or batches of devices to an EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate laboratory tests. The EU reference laboratory shall inform the notified body about its findings.

5.2. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed timeframe, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

6. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in the fifth indent of Section 2.1 of Annex IX,

— the documentation referred to in the eighth indent of Section 2.1 of Annex IX, including the EU type-examination certificate referred to in Annex X,

— information on the changes referred to in Section 2.4 of Annex IX, and

— the decisions and reports from the notified body as referred to in Sections 2.3., 3.3. and 3.4. of Annex IX.

Section 7 of Annex IX shall apply.

ANNEX XII

CERTIFICATES ISSUED BY A NOTIFIED BODY

CHAPTER I

GENERAL REQUIREMENTS

1. Certificates shall be drawn up in one of the official languages of the Union.

2. Each certificate shall refer to only one conformity assessment procedure.

3. Certificates shall only be issued to one manufacturer. The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system referred to in Article 27.

4. The scope of the certificates shall unambiguously describe the device or devices covered:

   (a) EU technical documentation assessment certificates and EU type-examination certificates shall include a clear identification, including the name, model and type, of the device or devices, the intended purpose as indicated by the manufacturer in the instructions for use and in relation to which the device has been assessed in the conformity assessment procedure, risk classification and the Basic UDI-DI as referred to in Article 24(6).

   (b) EU quality management system certificates and EU production quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification and the intended purpose.

5. The notified body shall be able to demonstrate on request, which (individual) devices are covered by the certificate. The notified body shall set up a system that enables the determination of the devices, including their classification, covered by the certificate.

6. Certificates shall contain, if applicable, a note that, for the placing on the market of the device or devices it covers, another certificate issued in accordance with this Regulation is required.

7. EU quality management system certificates and EU production quality assurance certificates for class A sterile devices shall include a statement that the audit by the notified body was limited to the aspects of manufacture concerned with securing and maintaining sterile conditions.

8. Where a certificate is supplemented, modified or re-issued, the new certificate shall contain a reference to the preceding certificate and its date of issue with identification of the changes.

CHAPTER II

MINIMUM CONTENT OF THE CERTIFICATES

1. name, address and identification number of the notified body;

2. name and address of the manufacturer and, if applicable, of the authorised representative;

3. unique number identifying the certificate;

4. if already issued, the SRN of the manufacturer referred to in Article 28(2);

5. date of issue;

6. date of expiry;

7. data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of this Annex;

8. if applicable, reference to any previous certificate as specified in Section 8 of Chapter I;

9. reference to this Regulation and the relevant Annex in accordance with which the conformity assessment has been carried out;

10. examinations and tests performed, e.g. reference to relevant CS, harmonised standards, test reports and audit report(s);

11. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered;

12. if applicable, information about the surveillance by the notified body;

13. conclusions of the notified body's conformity assessment with regard to the relevant Annex;

14. conditions for or limitations to the validity of the certificate;

15. legally binding signature of the notified body in accordance with the applicable national law.

ANNEX XIII

PERFORMANCE EVALUATION, PERFORMANCE STUDIES AND POST-MARKET PERFORMANCE FOLLOW-UP

PART A

PERFORMANCE EVALUATION AND PERFORMANCE STUDIES

1. PERFORMANCE EVALUATION

Performance evaluation of a device is a continuous process by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose as stated by the manufacturer. To plan, continuously conduct and document a performance evaluation, the manufacturer shall establish and update a performance evaluation plan. The performance evaluation plan shall specify the characteristics and the performance of the device and the process and criteria applied to generate the necessary clinical evidence.

The performance evaluation shall be thorough and objective, considering both favourable and unfavourable data.

Its depth and extent shall be proportionate and appropriate to the characteristics of the device including the risks, risk class, performance and its intended purpose.

1.1. Performance evaluation plan

As a general rule, the performance evaluation plan shall include at least:

— a specification of the intended purpose of the device;

— a specification of the characteristics of the device as described in Section 9 of Chapter II of Annex I and in point (c) of Section 20.4.1. of Chapter III of Annex I;

— a specification of the analyte or marker to be determined by the device;

— a specification of the intended use of the device;

— identification of certified reference materials or reference measurement procedures to allow for metrological traceability;

— a clear identification of specified target patient groups with clear indications, limitations and contra-indications;

— an identification of the general safety and performance requirements as laid down in Sections 1 to 9 of Annex I that require support from relevant scientific validity and analytical and clinical performance data;

— a specification of methods, including the appropriate statistical tools, used for the examination of the analytical and clinical performance of the device and of the limitations of the device and information provided by it;

— a description of the state of the art, including an identification of existing relevant standards, CS, guidance or best practices documents;

— an indication and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the intended purpose or purposes and for the analytical and clinical performance of the device;

— for software qualified as a device, an identification and specification of reference databases and other sources of data used as the basis for its decision making;

— an outline of the different development phases including the sequence and means of determination of the scientific validity, the analytical and clinical performance, including an indication of milestones and a description of potential acceptance criteria;

— the PMPF planning as referred to in Part B of this Annex.

Where any of the above mentioned elements are not deemed appropriate in the Performance Evaluation Plan due to the specific device characteristics a justification shall be provided in the plan.

1.2. Demonstration of the scientific validity and the analytical and clinical performance:

As a general methodological principle the manufacturer shall:

— identify through a systematic scientific literature review the available data relevant to the device and its intended purpose and identify any remaining unaddressed issues or gaps in the data;

— appraise all relevant data by evaluating their suitability for establishing the safety and performance of the device;

— generate any new or additional data necessary to address outstanding issues.

1.2.1. Demonstration of the scientific validity

The manufacturer shall demonstrate the scientific validity based on one or a combination of the following sources:

— relevant information on the scientific validity of devices measuring the same analyte or marker;

— scientific (peer-reviewed) literature;

— consensus expert opinions/positions from relevant professional associations;

— results from proof of concept studies;

— results from clinical performance studies.

The scientific validity of the analyte or marker shall be demonstrated and documented in the scientific validity report.

1.2.2. Demonstration of the analytical performance

The manufacturer shall demonstrate the analytical performance of the device in relation to all the parameters described in point (a) of Section 9.1 of Annex I, unless any omission can be justified as not applicable.

As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.

For novel markers or other markers without available certified reference materials or reference measurement procedures, it may not be possible to demonstrate trueness. If there are no comparative methods, different approaches may be used if demonstrated to be appropriate, such as comparison to some other well-documented methods or the composite reference standard. In the absence of such approaches, a clinical performance study comparing performance of the novel device to the current clinical standard practice is required.

Analytical performance shall be demonstrated and documented in the analytical performance report.

1.2.3. Demonstration of the clinical performance

The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in point (b) of Section 9.1. of Annex I, unless any omission can be justified as not applicable.

Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:

— clinical performance studies;

— scientific peer-reviewed literature;

— published experience gained by routine diagnostic testing.

Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.

Clinical performance shall be demonstrated and documented in the clinical performance report.

1.3. Clinical evidence and performance evaluation report

1.3.1. The manufacturer shall assess all relevant scientific validity, analytical and clinical performance data to verify the conformity of its device with the general safety and performance requirements as referred to in Annex I. The amount and quality of that data shall allow the manufacturer to make a qualified assessment whether the device will achieve the intended clinical benefit or benefits and safety, when used as intended by the manufacturer. The data and conclusions drawn from this assessment shall constitute the clinical evidence for the device. The clinical evidence shall scientifically demonstrate that the intended clinical benefit or benefits and safety will be achieved according to the state of the art in medicine.

1.3.2. Performance evaluation report

The clinical evidence shall be documented in a performance evaluation report. This report shall include the scientific validity report, the analytical performance report, the clinical performance report and an assessment of those reports allowing demonstration of the clinical evidence.

The performance evaluation report shall in particular include:

— the justification for the approach taken to gather the clinical evidence;

— the literature search methodology and the literature search protocol and literature search report of a literature review;

— the technology on which the device is based, the intended purpose of the device and any claims made about the device's performance or safety;

— the nature and extent of the scientific validity and the analytical and clinical performance data that has been evaluated;

— the clinical evidence as the acceptable performances against the state of the art in medicine;

— any new conclusions derived from PMPF reports in accordance with Part B of this Annex.

1.3.3. The clinical evidence and its assessment in the performance evaluation report shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's PMPF plan in accordance with Part B of this Annex, as part of the performance evaluation and the post-market surveillance system referred to in Article 10(9). The performance evaluation report shall be part of the technical documentation. Both favourable and unfavourable data considered in the performance evaluation shall be included in the technical documentation.

2. CLINICAL PERFORMANCE STUDIES

2.1. Purpose of clinical performance studies

The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine

diagnostic testing. This information is used to demonstrate compliance with the relevant general safety and performance requirements with respect to clinical performance. When clinical performance studies are conducted, the data obtained shall be used in the performance evaluation process and be part of the clinical evidence for the device.

2.2. Ethical considerations for clinical performance studies

Each step in the clinical performance study, from the initial consideration of the need for and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles.

2.3. Methods for clinical performance studies

2.3.1. Clinical performance study design type

Clinical performance studies shall be designed in such a way as to maximize the relevance of the data while minimising potential bias.

2.3.2. Clinical performance study plan

Clinical performance studies shall be performed on the basis of a clinical performance study plan (CPSP).

The CPSP shall define the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study. It shall contain in particular the following information:

(a) the single identification number of the clinical performance study, as referred to in Article 66(1);

(b) identification of the sponsor, including the name, address of the registered place of business and contact details of the sponsor and, if applicable, the name, address of the registered place of business and contact details of its contact person or legal representative pursuant to Article 58(4) established in the Union;

(c) information on the investigator or investigators, namely principal, coordinating or other investigator; qualifications; contact details, and investigation site or sites, such as number, qualification, contact details and, in the case of devices for self-testing, the location and number of lay persons involved;

(d) the starting date and scheduled duration for the clinical performance study;

(e) identification and description of the device, its intended purpose, the analyte or analytes or marker or markers, the metrological traceability, and the manufacturer;

(f) information about the type of specimens under investigation;

(g) overall synopsis of the clinical performance study, its design type, such as observational, interventional, together with the objectives and hypotheses of the study, reference to the current state of the art in diagnosis and/or medicine;

(h) a description of the expected risks and benefits of the device and of the clinical performance study in the context of the state of the art in clinical practice, and with the exception of studies using left-over samples, the medical procedures involved and patient management;

(i) the instructions for use of the device or test protocol, the necessary training and experience of the user, the appropriate calibration procedures and means of control, the indication of any other devices, medical devices, medicinal product or other articles to be included or excluded and the specifications on any comparator or comparative method used as reference;

(j) description of and justification for the design of the clinical performance study, its scientific robustness and validity, including the statistical design, and details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors;

(k) the analytical performance in accordance with point (a) of Section 9.1 of Chapter I of Annex I with justification for any omission;

(l) parameters of clinical performance in accordance with point (b) of Section 9.1 of Annex I to be determined, with justification for any omission; and with the exception of studies using left-over samples the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions;

(m) information on the performance study population: specifications of the subjects, selection criteria, size of performance study population, representativity of target population and, if applicable, information on vulnerable subjects involved, such as children, pregnant women, immuno-compromised or elderly subjects;

(n) information on use of data out of left over specimens banks, genetic or tissue banks, patient or disease registries etc. with description of reliability and representativity and statistical analysis approach; assurance of relevant method for determining the true clinical status of patient specimens;

(o) monitoring plan;

(p) data management;

(q) decision algorithms;

(r) policy regarding any amendments, including those in accordance with Article 71, to or deviations from the CPSP, with a clear prohibition of use of waivers from the CPSP;

(s) accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical performance study and the return of unused, expired or malfunctioning devices;

(t) statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical performance studies as well as with the applicable regulatory requirements;

(u) description of the informed consent process, including a copy of the patient information sheet and consent forms;

(v) procedures for safety recording and reporting, including definitions of recordable and reportable events, and procedures and timelines for reporting;

(w) criteria and procedures for suspension or early termination of the clinical performance study;

(x) criteria and procedures for follow up of subjects following completion of a performance study, procedures for follow up of subjects in the case of suspension or early termination, procedures for follow up of subjects who have withdrawn their consent and procedures for subjects lost to follow up;

(y) procedures for communication of test results outside the study, including communication of test results to the performance study subjects;

(z) policy as regards the establishment of the clinical performance study report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 2.2;

(aa) list of the technical and functional features of the device indicating those that are covered by the performance study;

(ab) bibliography.

If part of the information referred to in the second paragraph is submitted in a separate document, it shall be referenced in the CPSP. For studies using left-over samples, points (u), (x), (y) and (z) shall not apply.

Where any of the elements referred to in the second paragraph are not deemed appropriate for inclusion in the CPSP due to the specific study design chosen, such as use of left-over samples versus interventional clinical performance studies, a justification shall be provided.

2.3.3. Clinical performance study report

A clinical performance study report, signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol plan, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.

3. OTHER PERFORMANCE STUDIES

By analogy, the performance study plan referred to in Section 2.3.2, and the performance study report, referred to in Section 2.3.3, shall be documented for other performance studies than clinical performance studies.

PART B

POST-MARKET PERFORMANCE FOLLOW-UP

4. PMPF shall be understood to be a continuous process that updates the performance evaluation referred to in Article 56 and Part A of this Annex and shall be specifically addressed in the manufacturer's post-market surveillance plan. When conducting PMPF, the manufacturer shall proactively collect and evaluate performance and relevant scientific data from the use of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety, performance and scientific validity throughout the expected lifetime of the device, of ensuring the continued acceptability of the benefit-risk ratio and of detecting emerging risks on the basis of factual evidence.

5. PMPF shall be performed pursuant to a documented method laid down in a PMPF plan.

5.1. The PMPF plan shall specify the methods and procedures for proactively collecting and evaluating safety, performance and scientific data with the aim of:

(a) confirming the safety and performance of the device throughout its expected lifetime,

(b) identifying previously unknown risks or limits to performance and contra-indications,

(c) identifying and analysing emergent risks on the basis of factual evidence,

(d) ensuring the continued acceptability of the clinical evidence and of the benefit-risk ratio referred to in Sections 1 and 8 of Chapter I of Annex I, and

(e) identifying possible systematic misuse.

5.2. The PMPF plan shall include at least:

(a) the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of performance or scientific data;

(b) the specific methods and procedures of PMPF to be applied, such as ring trials and other quality assurance activities, epidemiological studies, evaluation of suitable patient or disease registers, genetic databanks or post-market clinical performance studies;

(c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);

(d) a reference to the relevant parts of the performance evaluation report referred to in Section 1.3 of this Annex and to the risk management referred to in Section 3 of Annex I;

(e) the specific objectives to be addressed by the PMPF;

(f) an evaluation of the performance data relating to equivalent or similar devices, and the current state of the art;

(g) reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMPF, and;

(h) a detailed and adequately justified time schedule for PMPF activities, such as analysis of PMPF data and reporting, to be undertaken by the manufacturer.

6. The manufacturer shall analyse the findings of the PMPF and document the results in a PMPF evaluation report that shall update the performance evaluation report and be part of the technical documentation.

7. The conclusions of the PMPF evaluation report shall be taken into account for the performance evaluation referred to in Article 56 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMPF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

8. If PMPF is not deemed appropriate for a specific device then a justification shall be provided and documented within the performance evaluation report.

ANNEX XIV

INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND CERTAIN OTHER PERFORMANCE STUDIES

CHAPTER I

DOCUMENTATION REGARDING THE APPLICATION FOR INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND OTHER PERFORMANCE STUDIES INVOLVING RISKS FOR THE SUBJECTS OF THE STUDIES

For devices intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects of the studies, the sponsor shall draw up and submit the application in accordance with Article 58 accompanied by the following documents:

1. Application form

The application form shall be duly filled in, containing the following information:

1.1. name, address and contact details of the sponsor and, if applicable, name, address and contact details of its contact person or legal representative in accordance with Article 58(4) established in the Union;

1.2. if different from those in Section 1.1, name, address and contact details of the manufacturer of the device intended for performance evaluation and, if applicable, of its authorised representative;

1.3. title of the performance study;

1.4. single identification number in accordance with Article 66(1);

1.5. status of the performance study, such as. the first submission, resubmission, significant amendment;

1.6. details and/ or reference to the performance study plan, such as including details of the design phase of the performance study;

1.7. if the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or in the case of significant amendment, reference to the original application. The sponsor shall identify all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews;

1.8. if the application is submitted in parallel with an application for a clinical trial in accordance with Regulation (EU) No 536/2014, reference to the official registration number of the clinical trial;

1.9. identification of the Member States and third countries in which the clinical performance study is to be conducted as part of a multicentre or multinational study at the time of application;

1.10. brief description of the device for performance study, its classification and other information necessary for the identification of the device and device type;

1.11. summary of the performance study plan;

1.12. if applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device;

1.13. evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical performance study in accordance with the performance study plan;

1.14. details of the anticipated start date and duration of the performance study;

1.15. details to identify the notified body, if already involved at the stage of application for the performance study;

1.16. confirmation that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application;

1.17. the statement referred to in Section 4.1.

2. Investigator's brochure

The investigator's brochure (IB) shall contain the information on the device for performance study that is relevant for the study and available at the time of application. Any updates to the IB or other relevant information that is newly available shall be brought to the attention of the investigators in a timely manner. The IB shall be clearly identified and contain in particular the following information:

2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule pursuant to Annex VIII, design and manufacturing of the device and reference to previous and similar generations of the device.

2.2. Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements, as well as, to the extent that such information is available, information to be placed the label, and instructions for use to be provided with the device when placed on the market. In addition, information relating to any relevant training required.

2.3. Analytical performance.

2.4. Existing clinical data, in particular:

— from relevant peer-reviewed scientific literature and available consensus expert opinions or positions from relevant professional associations relating to the safety, performance, clinical benefits to patients, design characteristics, scientific validity, clinical performance and intended purpose of the device and/or of equivalent or similar devices;

— other relevant clinical data available relating to the safety, scientific validity, clinical performance, clinical benefits to patients, design characteristics and intended purpose of similar devices, including details of their similarities and differences with the device in question.

2.5. Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks and warnings.

2.6. In the case of devices that include tissues, cells and substances of human, animal or microbial origins detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to those tissues, cells and substances.

2.7. A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and CS applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking.

2.8. A detailed description of the clinical procedures and diagnostic tests used in the course of the performance study and in particular information on any deviation from normal clinical practice.

3. Performance study plan as referred to in Sections 2 and 3 of Annex XIII.

4. Other information

4.1. A signed statement by the natural or legal person responsible for the manufacture of the device for performance study that the device in question conforms to the general safety and performance requirements laid down in Annex I apart from the aspects covered by the clinical performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

4.2. Where applicable according to national law, a copy of the opinion or opinions of the ethics committee or committees concerned. Where under national law the opinion or opinions of the ethics committee or committees is not required at the time of the submission of the application, a copy of the opinion or opinions shall be submitted as soon as available.

4.3. Proof of insurance cover or indemnification of subjects in case of injury, pursuant to Article 65 and the corresponding national law.

4.4. Documents to be used to obtain informed consent, including the patient information sheet and the informed consent document.

4.5 Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:

— organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;

— a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects;

— a description of measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects.

4.6. Full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports shall be submitted to the competent authority reviewing an application upon request.

CHAPTER II

OTHER OBLIGATIONS OF THE SPONSOR

1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter I of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the device intended for performance study, that obligation may be fulfilled by that person on behalf of the sponsor.

2. The sponsor shall have an agreement in place to ensure that any serious adverse events or any other event as referred to in Article 76(2) are reported by the investigator or investigators to the sponsor in a timely manner.

3. The documentation mentioned in this Annex shall be kept for a period of time of at least 10 years after the clinical performance study with the device in question has ended, or, in the event that the device is subsequently placed on the market, for at least 10 years after the last device has been placed on the market.

Each Member State shall require that the documentation referred to in this Annex is kept at the disposal of the competent authorities for the period indicated in the first subparagraph in case the sponsor, or his contact person, established within its territory, goes bankrupt or ceases its activity prior to the end of this period.

4. The sponsor shall appoint a monitor that is independent of the investigation site to ensure that the clinical performance study is conducted in accordance with the Clinical Performance Study Plan, the principles of good clinical practice and this Regulation.

5. The sponsor shall complete the follow-up of investigation subjects.

ANNEX XV

CORRELATION TABLE

Directive 98/79/EC	This Regulation
Article 1(1)	Article 1(1)
Article 1(2)	Article 2
Article 1(3)	points (54) and (55) of Article 2
Article 1(4)	—
Article 1(5)	Article 5(4) and (5)
Article 1(6)	Article 1(9)
Article 1(7)	Article 1(5)
Article 2	Article 5(1)
Article 3	Article 5(2)
Article 4(1)	Article 21
Article 4(2)	Article 19(1) and (2)
Article 4(3)	Article 19(3)
Article 4(4)	Article 10(10)
Article 4(5)	Article 18(6)
Article 5(1)	Article 8(1)
Article 5(2)	—
Article 5(3)	Article 9
Article 6	—
Article 7	Article 107
Article 8	Articles 89 and 92
Article 9(1) first subparagraph	Article 48(10) first subparagraph
Article 9(1) second subparagraph	Article 48(3) second subparagraph, Article 48(7) second subparagraph and Article 48(9) second subparagraph
Article 9(2)	Article 48(3) to (6)
Article 9(3)	Article 48(3) to (9)
Article 9(4)	Article 5(6)
Article 9(5)	—
Article 9(6)	Article 11(3) and (4)
Article 9(7)	Article 10(7)
Article 9(8)	Article 49(1)
Article 9(9)	Article 49(4)

Directive 98/79/EC	This Regulation
Article 9(10)	Article 51(2)
Article 9(11)	Article 48(12)
Article 9(12)	Article 54(1)
Article 9(13)	Article 48(2)
Article 10(1) and (2), second sentence of Article 10(3) and Article 10(4)	Articles 26(3), 27 and 28
Article 10(3), first sentence	Article 11(1)
Article 11(1)	Articles 82(1) and 84(2)
Article 11(2)	Article 82(10) and Article 82(11) first subparagraph
Article 11(3)	Article 84(7)
Article 11(4)	—
Article 11(5)	Article 86
Article 12	Article 30
Article 13	Article 93
Article 14(1)(a)	—
Article 14(1)(b)	Article 47(3) and (6)
Article 14(2)	—
Article 14(3)	—
Article 15(1)	Article 38 and Article 39
Article 15(2)	Article 32
Article 15(3)	Article 40(2) and (4)
Article 15(4)	—
Article 15(5)	Article 51(5)
Article 15(6)	Article 51(4)
Article 15(7)	Article 34(2) and Article 40(2)
Article 16	Article 18
Article 17	Articles 89 to 92
Article 18	Article 94
Article 19	Article 102
Article 20	Article 97
Article 21	—
Article 22	—
Article 23	—
Article 24	—

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