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)

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.

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.

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[(2)] 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.

(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 inter-connected 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[(3)] 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;

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[(4)] 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.

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[(5)], 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..

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[(6)]..

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

The President

A. TAJANI

For the Council

The President

I. BORG

(**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).

(**2**) 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).

(**3**) 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).

(**4**) 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).

(**5**) 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).'.

(**6**) 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).'.

Status:
Point in time view as at 05/04/2017.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council.