1b. For the purposes of this Regulation, medical devices, ~~and~~ accessories to medical devices ***and products listed in Annex XV to which this Regulation applies pursuant to paragraph 1a*** shall hereinafter be referred to as 'devices'.

2. This Regulation shall not apply to:

(a) *in vitro* diagnostic medical devices covered by Regulation (EU) [.../...];

(b) medicinal products ***as defined in*** ~~covered by~~ Directive 2001/83/EC ~~and advanced therapy medicinal products covered by~~ ~~Regulation (EC) No 1394/2007~~. In deciding whether a product falls under Directive 2001/83/EC ~~or Regulation (EC) No 1394/2007~~ or under this Regulation, particular account shall be taken of the principal mode of action of the product.

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

(c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market ***or put into service*** ~~or used in accordance with the manufacturer's instructions~~, such blood products, plasma or cells, except for devices referred to in paragraph 4;

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

(e) transplants, tissues or cells of ~~human or~~ animal origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of ~~human or~~ animal origin, or their derivatives, which are non-viable or are rendered non-viable.

~~However, human tissues and cells that are non-viable or are rendered non-viable and that have undergone only non-substantial manipulation, in particular those listed in Annex I of Regulation (EC) No 1394/2007, and products derived from such tissues and cells, shall not be considered devices manufactured utilising tissues or cells of human origin or their derivatives~~;

(ea) transplants, tissues or cells of human origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;

(f) products, ***other than those referred to in points (c) and (e)***, that contain or consist of ***viable*** biological substances or organisms, ~~other than those referred to in points (c) and (e), that are viable~~, including living micro-organisms, bacteria, fungi or virus ***in order to achieve or support the intended purpose of the product***;

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

3. Any device which, when placed on the market or ***put into service and*** used in accordance with the manufacturer's instructions, incorporates as an integral part an *in vitro* diagnostic medical device as defined in Article 2 of Regulation (EU) [.../..] [on *in vitro* diagnostic medical devices] shall be governed by this Regulation~~, unless it is covered by Article 1(3) of that Regulation~~. The ~~relevant general safety and performance~~ requirements ~~set out in Annex I~~ of that Regulation shall apply ~~as far as the safety and performance of~~ ***to*** the *in vitro* diagnostic medical device part ~~are concerned~~.

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

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

5. Where a device is intended to administer a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, that device shall be governed by this Regulation, without prejudice to the provisions of Directive 2001/83/EC ***and 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, the product shall be governed by Directive 2001/83/EC ***or Regulation (EC) No 726/2004, as applicable***. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.

5a. Where a device, when placed on the market or put into service and used in accordance with the manufacturer's instructions, incorporates, as an integral part, tissues or cells of human origin or their derivatives covered by Directive 2004/23/EC with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation. In this case the provisions for donation, procurement and testing laid down in Directive 2004/23/EC shall apply.

However, if the action of the tissues or cells or their derivatives is principal, not ancillary to that of the device and the product is not governed by Regulation 1394/2007, the product shall be governed by Directive 2004/23/EC. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.

6. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC ~~and within the meaning of Article 3 of Directive 2006/42/EC~~.

7. This Regulation shall not affect the application of Council Directive ~~96/29/Euratom nor of Council Directive 97/43~~***2013/59***/Euratom.

8. This Regulation shall not affect national laws ~~which require~~ ***concerning the organisation, delivery or financing of health services and medical care, such as, the requirement*** that certain ***medical*** devices may only be supplied on a medical prescription***, the requirement that only certain health professionals or health care institutions may dispense or apply certain medical devices or that their application must be accompanied by specific professional counselling***.

8a. This Regulation shall be without prejudice to national laws regarding public access to official documents and regarding freedom of the press and freedom of expression in other media.

~~9. References to a Member State in this Regulation shall be understood as also including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation.~~

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

Definitions related to devices:

(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 specific medical purposes of:

- diagnosis, prevention, monitoring, 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,
- ~~control or support of conception~~,
- ~~disinfection or sterilisation of any of the above-mentioned products,~~

– ***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.

Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.

~~The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.~~

(2) 'accessory to a medical device' means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable ~~or assist~~ the 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 view of its/their intended purpose(s)***;

(3) 'custom-made device' means any device specifically made in accordance with a written prescription of ~~a doctor of medicine, of a dental practitioner or of~~ any ~~other~~ person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient.

However, mass-produced devices which need to be adapted to meet the specific requirements of ~~a doctor of medicine, a dental practitioner or~~ any ~~other~~ professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of ~~doctors of medicine, dental practitioners or~~ any ~~other~~ 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 electrical energy or any~~ ***a*** source of ~~power~~ ***energy*** other than that ~~directly~~ generated ***by the human body for that purpose or*** by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices.

~~Stand-alone software shall be considered 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 considered 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 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 an individual patient during a single procedure.

~~The single procedure may involve several uses or prolonged use on the same patient;~~

(8a) 'Falsified medical 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.

~~(9) 'single-use device for critical use' means a single-use device intended to be used for surgically invasive medical procedures;~~

(9a) '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 within a unique procedure;

(9b) '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;

(10) 'intended purpose' means the use for which the 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;

(11) '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;

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

(13) 'Unique Device Identification' ('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;

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

(14a) '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 shall not contain any cells or tissues.

(15) '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 be considered as nanomaterials.

For the purposes of the definition of nanomaterial, 'particle', 'agglomerate' and 'aggregate' are defined as follows:

- 'particle' means a minute piece of matter with defined physical boundaries;
- 'agglomerate' 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;
- 'aggregate' means a particle comprising of strongly bound or fused particles;

(15a) 'performance' means the ability of a device to achieve its intended purpose as claimed by the manufacturer;

(15b) 'safe' means the absence of unacceptable risks, when using the device according to the manufacturer's instructions for use;

(15d) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;

(15e) 'benefit-risk determination' means the integration 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 instructions of use;

Definitions related to the making available of devices:

(16) '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;

(16a) 'Compatibility' is the ability of a medical device, including software, when used together with one or more other devices in accordance with its intended purpose, to:

- *perform without losing or compromising the ability to perform as intended, and/or*
- *integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or*
- *be used together without conflict/interference or adverse reaction.*

(16b) Interoperability is the ability of two or more medical devices, including software, from the same manufacturer or from different manufacturers, to

- *exchange information and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or*
- ~~*enable the communication of one or more devices*~~ *communicate with each other, and/or*
- ~~*enable one or more devices to*~~ *work together as intended.*

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

(18) '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;

Definitions related to economic operators, users and specific processes:

(19) 'manufacturer' means the 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 his name or trademark***, regardless of whether these operations are carried out by that person himself or on his behalf by a third party***.

For the purposes of the definition of manufacturer, fully refurbishing is defined as 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 in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

(20) '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 European Union,*** to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

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

(22) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;

(23) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

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

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

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

(27) 'reprocessing' means the 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 restoration of the technical and functional safety of the used device;

Definitions related to conformity assessment:

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

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

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

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

Definitions related to clinical evaluation and clinical investigations:

(32) 'clinical evaluation' means ~~the assessment and analysis of~~ ***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 of the device when used as intended by the manufacturer;

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

(34) 'investigational device' means any device being assessed for safety and/or performance in a clinical investigation;

(35) 'clinical investigation plan' means ~~the~~ ***a*** document~~(s)~~ ***that describes*** ~~setting out~~ the rationale, objectives, design***, methodology, monitoring, statistical considerations*** and ***organisation*** ~~proposed analysis, methodology, monitoring, conduct and record-keeping~~ of ***a*** ~~the~~ clinical investigation;

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

- clinical investigation(s) of the device concerned,
- clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated,
- ~~published and/or unpublished~~ reports ***published in peer reviewed scientific literature*** on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated,
- ***generated and verified from the manufacturer's post-market surveillance system. (PMCF)***;

(37) 'sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation***, for the*** ~~and~~ management ***and for setting up the financing*** of ~~a~~ ***the*** clinical investigation;

(37a) 'subject' means an individual who participates in a clinical investigation either as recipient of an investigational device or as control;

(37b) 'clinical evidence' means the clinical data and clinical evaluation report pertaining to a medical device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer;

(37c) 'clinical performance' means the ability of a medical device to achieve its intended purpose as claimed by the manufacturer, including any direct or indirect medical effects on humans as well as the clinical benefit on patients resulting from the technical or functional, including diagnostic characteristics of a device, when used as intended by the manufacturer;

(37d) 'clinical benefit' means the positive impact of a device on the health of an individual, to be specified as meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis or a positive impact on patient management or public health;

(37h) 'investigator' means an individual responsible for the conduct of a clinical investigation at a clinical investigation site;

(37k) '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 case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation;

(37l) '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;

(38) '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;

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

- death,
- 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 extending the duration of hospitalisation,
  - (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
- foetal distress, foetal death or a congenital abnormality or birth defect;

(40) '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 the information supplied by the manufacturer;

Definitions related to vigilance and market surveillance:

(40a) 'Post Market Surveillance' means all activities carried out by the 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 their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

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

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

(43) '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,*** any inadequacy in the information supplied by the manufacturer and any ~~unexpected~~ undesirable side-effect;

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

- death of a patient, user or other person,
- temporary or permanent serious deterioration of the patient's, user's or other person's state of health,
- serious public health threat;

(44a) ***'serious public health threat' means any event type, which results in imminent risk of death, serious deterioration in state of health, or serious illness that may require prompt remedial action;***

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

(46) 'field safety corrective action' means corrective action taken by the 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;

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

(48) 'market surveillance' means the activities carried out and measures taken by public authorities to ***check and*** ensure that ~~products~~ ***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;

Definitions related to standards and other technical specifications:

(49) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [Ref. of future Regulation on European standardisation];

(50) 'common ~~technical~~ specifications' means a document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligations applicable to a device, process or system.

2. ~~The~~ ***Where justified in view of the similarity between a medical device placed on the market and a product without a medical purpose in respect of their characteristics and risks, the*** Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in ***Article 1(1a)*** ~~the last subparagraph of number (1) of paragraph 1~~, ***by adding new groups of products*** ~~in the light of technical progress~~, ***in order to protect the health and safety of users or other persons or other aspects of public health*** ~~and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks~~.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to adapt the definition of nanomaterial set out in number (15) of paragraph 1 in view of technical and scientific progress and taking into account definitions agreed at Union and international level.

Article 3

Regulatory status of products

1. ~~The~~ ***Without prejudice to Article 2(2) of Directive 2001/83, at a duly substantiated request of a Member State, the*** Commission ~~may~~ ***shall,*** ~~at the request of a Member State or on its own initiative~~ ***after consulting the 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 to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

1a. 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.

2. The Commission shall ensure the sharing of expertise between Member States, 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.

Chapter II

Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement

Article 4

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 which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.

3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 49.

4. Devices that are manufactured and used within ~~a single~~ health institution*s* shall be considered as being put into service. ~~The provisions regarding CE marking referred to in Article 18 and the obligations laid down in Articles 23 to 27 shall not apply to those devices, provided that manufacture and use of those devices occur under the health institution's single quality management system.~~

4a. 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, provided that the following conditions are met:

(aa) the device is not transferred to another legal entity,

(a) manufacture and use of the devices occur under appropriate quality management system, (b) the health institution establishes in its documentation that it has given due consideration as to whether 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,

(c) the health institution provides information on an annual basis on the use of such devices to their competent authority, which shall include a justification of their manufacturing, modification and use,

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

- *the name and address of the manufacturing health institution;*
- *the details necessary to identify the devices;*
- *a declaration that the devices meet the general safety and performance requirements set out in Annex I of this Regulation and, where applicable, information on which requirements are not fully met with reasoned justification,*

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

(e) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in the previous sub-subparagraph, and

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

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

These provisions do not apply to devices which are manufactured on an industrial scale.

5. The Commission ***may adopt implementing acts to ensure the uniform application of Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*** ~~shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.~~

Article 5

Distance sales

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation ~~at the latest~~ when the device is placed on the market.

2. Without prejudice to national legislation 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 Article 1(2) of Directive 98/34/EC 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.