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from:	General Secretariat
to:	Working Party on Pharmaceuticals and Medical Devices
No. Cion prop.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312
Subject:	Proposal for a Regulation of the European Parliament and of the Council on Medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices – *Presidency proposal for Chapters I*

Delegations will find in the Annexes Presidency draft texts for Chapter I of the proposal on medical devices and for Chapter I of the proposal on *in vitro* medical devices, submitted for their agreement.

Annex A contains Chapter I of the medical devices proposal and Annex B Chapter I of the *in vitro* diagnostic medical devices proposal.

Text Conventions:

New text, added to the Commission proposal is indicated in ***bold italics***.

Deletions of text in the Commission proposal are indicated with ~~strikethrough~~.

In this revised text, Article 3 is added. Apart from that the text is identical to that of 8343/14.

ANNEX A

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

(Text with EEA relevance)

Chapter I

Scope and definitions

Article 1

Scope

1. This Regulation establishes rules to be complied with ~~by medical devices and accessories to medical devices that are placed~~ ***when making available*** on the market or put***ting*** into service in the Union ***medical devices and accessories to medical devices*** for human use.
   For the purposes of this Regulation, medical devices and accessories to medical devices 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 ***as defined in*** ~~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 ***shall be taken into account in particular***.
   (c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market ~~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 ***which function as an accessory to the medical device***, shall not be considered devices manufactured utilising tissues or cells of human origin or their derivatives ***and this Regulation shall therefore apply***;

(f) products that ***intentionally*** contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable ***when introduced into the human body***, including living micro-organisms, bacteria, fungi or virus;

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

(h) products intended to be ingested, inhaled or administered orally, vaginally or rectally which shall fall under Directive 2001/83/EC.

3. Any device which, when placed on the market or 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 the *in vitro* diagnostic medical device part are concerned.

4. Where a device, when placed on the market or 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.

For the purposes of this paragraph, it shall be considered that a device incorporates a medicinal substance as an integral part, if the device and the substance are physically or chemically combined at the time of use.

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.

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/Euratom.

8. This Regulation shall not affect national laws which require that ***inter alia*** certain devices may only be supplied on a medical prescription.

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, ***including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products,*** 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,

– ***provision of information concerning a physiological or pathological process or state, a congenital abnormality, the predisposition to a medical condition or a disease, or to determine the safety and compatibility with potential recipients, to predict treatment response or reactions or to define or monitor therapeutic measures by means of in vitro examination of specimens derived from the human body, including 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.

Agents for transport, nutrition and storage of organs, tissues and cells intended for transplantation shall be considered medical devices, regardless of principal mode of action of the product.

The implantable or other invasive products***, or products for delivering significant amounts and/or intensities of energy onto or into the human body***, 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);

(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 ***medical*** 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 ***medical*** 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 source of power other than that directly generated 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;

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

(9a) ‘device for aesthetic purposes’ means any instrument, apparatus, appliance, software, implant, material, substance or other article, intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of modifying physical appearance, without a therapeutic or reconstructive purpose, by means of implantation in the human body, by adhering to the surface of the eye, or by inducing a reaction in tissues or cells on the external or other parts of the human body. Tattooing and piercing products shall not be considered devices for aesthetic purposes.

(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;

(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;

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;

(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.

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 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 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 document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of 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 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;

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

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

(37b) 'clinical evidence' means clinical data 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 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, inter alia through the use of diagnostic devices for screening.

(37e) 'efficacy' means the ability of a medical device to achieve the intended clinical benefit(s) to patients, in the intended target group(s), when the device is used as intended by the manufacturer, under ideal circumstances (as in a pre-market clinical investigation).

(37f) 'effectiveness' means the ability of a medical device to achieve the intended clinical benefit(s) to patients, in the intended target group(s), when the device is used as intended by the manufacturer, under normal circumstances of health care practices.

(37g) 'equivalence' means the ability of two or more devices to have similar technical, biological and clinical characteristics, when used as intended by their respective manufacturers, to such an extent that there would be not a clinically significant difference in the safety and performance of the devices.

(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 and 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 or put into service for the purpose of identifying any need to immediately apply any necessary corrections, 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,*** 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 which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action;

(45) ‘corrective action’ means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation ***including product design modifications as well as modifications concerning the production process or technique***;

(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;

(48a) ‘vigilance’ means activities carried out by public authorities to systematically collect information on risks of devices available on the EU market, to assess this information and the underlying risks and measures taken to ensure that devices do not endanger health, safety or any other aspect of public health.

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 […/…];

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

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in the last subparagraph of number (1) of paragraph 1, in the light of technical progress 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 Commission may, at the request of a Member State or on its own initiative, 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).

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.

ANNEX B

2012/0267 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on *in vitro* diagnostic medical devices

(Text with EEA relevance)

Chapter I

Scope and definitions

Article 1

Scope

1. This Regulation establishes rules to be complied with ~~by *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices that are placed~~ ***when making available*** on the market or put***ting*** into service in the Union ***in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices*** for human use.

   For the purposes of this Regulation, *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'.

2. This Regulation shall not apply to:
   (a) products for general laboratory use, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;
   (b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;
   (c) ~~higher metrological order~~ ***internationally certified*** reference materials.
   (d) materials used for external quality assessment schemes
   (e) research-use only products

3. Any device which, when placed on the market or used in accordance with the manufacturer's instructions, incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices without being an *in vitro* diagnostic medical device, shall be governed by this Regulation, provided that the principal intended purpose of the combination is that of an *in vitro* diagnostic medical device referred to in Article 2(2) of this Regulation. The relevant general safety and performance requirements set out in Annex I to Regulation (EU) [Ref. of future Regulation on medical devices] shall apply as far as the safety and performance of the medical device part that is not an *in vitro* diagnostic medical device are concerned.

4. 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.

5. This Regulation shall not affect the application of Council Directive 96/29/Euratom, nor of Council Directive 97/43/Euratom.

6. This Regulation shall not affect national laws which require that ***inter alia*** certain devices may only be supplied on a medical prescription.

7. 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

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, ***including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products*** 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 concerning a physiological or pathological process or state, a congenital abnormality, the predisposition to a medical condition or a disease, or to determine the safety and compatibility with potential recipients, to predict treatment response or reactions or to define or monitor therapeutic measures by means of in vitro examination of specimens derived from the human body, including 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 intended function by such means.

(2) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

– concerning a physiological or pathological ***process or*** state;
– concerning a congenital abnormality;
– concerning the predisposition to a medical condition or a disease;
– to determine the safety and compatibility with potential recipients;
– to predict treatment response or reactions;
– to define or monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. For the purposes of this Regulation, 'specimen receptacle' means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

(3) 'accessory to an *in vitro* diagnostic medical device' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable or assist the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s);

(3a) '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;

(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons;

(5) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient;

(6) 'companion diagnostic' means a device specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy;

(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) 'kit' means a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof

(9) '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;

(10) '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;

(11) '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;

(12) '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;

Definitions related to the making available of devices:

(13) 'making available on the market' means any supply of a device, other than a device for performance evaluation, 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;

(14) 'placing on the market' means the first making available of a device, other than a device for performance evaluation, on the Union market;

(15) 'putting into service' means the stage at which a device, other than a device for performance evaluation, 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:

(16) '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.
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;

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

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

(19) '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;

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

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

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

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

Definitions related to conformity assessment:

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

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

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

(27) '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 evidence:

(28) 'clinical evidence' means the information that supports the scientific validity and performance for the use of a device as intended by the manufacturer;

(29) 'scientific validity of an analyse' means the association of an analyse to a clinical condition or a physiological state;

(30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting the intended purpose of the device;

(31) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyse;

(32) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user;

(33) 'clinical performance study' means a study undertaken to establish or confirm the clinical performance of a device;

(34) 'clinical performance study protocol' means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study;

(35) 'performance evaluation' means the assessment and analysis of data to establish or verify the analytical and, where applicable, the clinical performance of a device;

(36) 'device for performance evaluation' means a device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside the manufacturer's own premises. Devices intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation;

(37) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;

(38) 'diagnostic specificity' means the ability of a device to recognize the absence of a target marker associated with a particular disease or condition;

(39) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;

(40) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;

(41) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;

(42) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;

(43) 'likelihood ratio' means the likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state;

(44) 'calibrators and control materials' means any substance, material or article intended by the manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended purpose of that device;

(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical performance study;

(45a) equivalence means the ability of two or more devices to have similar clinical and analytical characteristics when used as intended by their respective manufacturer, to such an extent that there would be not a clinically significant difference in the performance of the devices.

(46) '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 performance study, whether or not related to the device for performance evaluation;

(47) '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.

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

Definitions related to vigilance and market surveillance:

(48a) 'Post Market Surveillance' means all activities carried out by the manufacturers and 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 or put into service for the purpose of identifying any need to immediately apply any necessary corrections, corrective or preventive actions.

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

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

(51) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market ***including use-error,*** , any inadequacy in the information supplied by the manufacturer and any ~~unexpected~~ undesirable effect;

(52) '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;

(52a) 'serious public health threat' means any event which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action;

(53) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation ***including product design modifications as well as modifications concerning the production process or technique***;

(54) '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;

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

(56) '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;

(56a) 'vigilance' means activities carried out by public authorities to systematically collect information on risks of devices available on the EU market, to assess this information and the underlying risks and measures taken to ensure that devices do not endanger health, safety or any other aspect of public health.

Definitions related to standards and other technical specifications:

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

(58) '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.

Article 3

Regulatory status of products

1. The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an in vitro diagnostic medical devices or of an accessory to an in vitro diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

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