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NOTE

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices
No. prev. doc.:	8343/1/14 REV 1 PHARM 31 SAN 156 MI 322 COMPET 202 CODEC 958
No. Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
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** - *Chapter I*

1. This document sets out Presidency proposals for texts of Chapter I of the two proposals for new regulations.

Chapter I of the Medical device proposal (Annex A)

2. The present text of Chapter I in the Proposal for a Regulation on medical devices (Annex A) is based on the text prepared by the Greek Presidency (doc. 8343/1/14 REV 1).

3. New text elements proposed in that document are set out in ***bold italics*** and corresponding deletions in ~~strikethrough~~. Additional new text elements proposed for the first time by the Italian Presidency in this document are set out in **highlighted bold underline** and corresponding deletions in highlighted bold underline strikethrough or in highlighted bold italics strikethrough depending on whether they are part of the original Commission proposal or of new elements proposed in document 8343/1/14 REV 1.

4. In order to prepare the present draft text of Chapter I of the Proposal for a Regulation on Medical devices, the Presidency also examined the following documents sent by the Secretariat, to report positions by individual Member States: DS 1861/12 PL, DS 1866/12 BE, DS 1867/12 AT, DS 1868/12 FR, DS 1870/12 NL/SE/AT, DS 1189/13 IT, DS 1256/13 UK, DS 1367/13 BE, DS 1519/13 IT, DS 1733/13 FR, DS 2046/13 DE, DS 1151/14 SE, DS 1205/14 FR, DS 1232/12 PT, DS 1002/14 DE, DS 1937/13 FR, 5073/14, 6804/14.

Chapter I of the *In vitro* diagnostic medical device proposal (Annex B)

5. The present text of Chapter I in the Proposal for a Regulation on *In vitro* diagnostic medical devices (Annex B) is based on the text prepared by the Greek Presidency (doc. 8343/1/14 REV 1).

6. New text elements proposed in that document are set out in ***bold italics*** and corresponding deletions in ~~strikethrough~~. Additional new text elements proposed for the first time by the Italian Presidency in this document are set out in **highlighted bold underline** and corresponding deletions in **~~highlighted bold underline strikethrough~~** or in ***~~highlighted bold italics strikethrough~~*** depending on whether they are part of the original Commission proposal or of new elements proposed in document 8343/1/14 REV 1.

7. In order to prepare the draft text of Chapter I of the proposed Regulation on *In vitro* diagnostic medical devices, the Presidency also examined the following documents sent by the Secretariat, to report positions by individual Member States: DS 1866/12 BE, DS 1867/12 AT, DS 1870/12 NL/SE/AT, DS 1189/13 IT, DS 1367/13 BE, DS 1519/13 IT, DS 2046/13 DE, DS 1937/13 FR, 6804/14.

Principles behind proposed changes and information concerning a forthcoming questionnaire

8. In order to prepare the present text, the Italian Presidency applied the following principles when evaluating whether a suggestion for a change to the Commission proposal should be included or not (in order of priority):
   1) suggestions that are clearly expressed and shared by several Member States;
   2) suggestions that are made by a few/single Member State (s) but which are in line with the framework.

9. In cases where there is doubt, the Italian Presidency intends to prepare a series of key questions and statements to which Member States will be invited to reply in writing (e.g. 'agree', 'disagree', 'neutral'). The answers will allow the Presidency to propose a text which should represent the views of the majority of Member States and which should become the basis for the Council Position.

10. Some of the questions that will go into the Presidency questionnaire are set out in the present document. These questions are intended for information only. The questionnaire will be a separate document in which the deadline for replies will be indicated.

11. The present draft is a possible text of Chapter I for both proposals that will be modified on the basis of the answers to the questionnaire given by delegations.

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. [1]

   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***.

[1] **DS1868 FR** replace Article 1(1) with the following: "*This Regulation establishes rules to be complied with by medical devices, and accessories to medical devices* <u>*and aesthetic devices*</u> *that are placed on the market or put into service in the Union for human use. For the purposes of this Regulation, medical devices, accessories to medical devices* <u>*and aesthetic devices*</u> *shall hereinafter be referred to as 'devices*'".

(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[2] 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] [4]

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[2] During the WP meeting on 3 May 2013 **Cion** clarified that the exception concerns only biological substances that are viable. So products that contain a non-viable biological substance may be regarded as medical devices.

[3] **UK** Change this point to read: "*products that are composed of substances or combinations of substances intended to be ingested, inhaled or administered orally, vaginally, rectally or parenterally and that are absorbed by or dispersed in the human body*." **DS 1151/14 SE** similar ideas.

[4] Document **5073/14** contains the following text for point 6.8 in Annex VII "6.*8 Rule ~~21~~ 20 "Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally ~~or~~ vaginally or parenterally and that are absorbed by or dispersed in the human body are in class III*".
ES/PL/SE/UK delete the rule as these products should be considered to be medicinal products.
AT/DE/DK/FR/PT support Cion text.
DE class III for these products is not consistent with rule 5, suggests that class IIb is applied.

BOX 1 QUESTIONNAIRE

1.1) Does your delegation believe that substances intended to be ingested, inhaled or administered orally, vaginally or rectally and that are absorbed by or dispersed in the human body should be excluded from the scope of MD Regulation **irrespective of their mode of action**?

YES	NO	Neutral	Comments / Alternative proposal

OR

1.2) Does your delegation support the Commission's proposal, which classifies devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body as Class III devices?

YES	NO	Neutral	Comments / Alternative proposal

1.3) Does your delegation believe that devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are not systemically absorbed should be classified in class IIb?

YES	NO	Neutral	Comments / Alternative proposal

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.[5]

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.[6]

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[5] **DS 1866/12 (BE)** With regard to the medical devices which incorporate as an integral part an *in vitro* diagnostic medical device it is advisable that, in order to reinforce the safety of these devices, both legislations should fully apply to the combination products which are described under Article 1 point 3 of both the Proposals for a Regulation on medical devices and for a Regulation on in vitro diagnostic medical devices.

In order also to avoid lengthy discussions on the principal intended purpose of the combination product which is either that of an in vitro diagnostic medical device or of a medical device, and taking into account that in vitro diagnostic medical devices are, in first instance medical devices, the pragmatic approach should be taken to qualify these integrally combined devices as 'medical devices'.

With regard to the applicable legislation, a modular approach would provide highest guarantee for safety and performance, where each component or part of the combination product is qualified in accordance with its intended purpose and characteristics, and accordingly subject to the relevant Regulation, including the conformity assessment. The different modules of the combination product would be subject to either the Regulation on medical devices or the Regulation on in vitro diagnostic medical devices, depending on their qualification.

[6] **DS 1367/13 BE** add "*In this case, the relevant requirements of Annex I of Directive 2001/83/EC shall apply as far as the safety, quality and usefulness of the medicinal product are concerned according to the procedure described in Annex VIII, Chapter II, point 6*"

~~***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[7] 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:

[7] **DS 1367/13 BE** suggests to replace this paragraph with: "*This Regulation shall not affect national laws which require concerning the organisation and delivery of health services and medical care, such as the requirement that certain medical devices may only be supplied on medical prescription or the requirement that only certain health professionals may dispense certain medical devices.*"

Definitions related to devices:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, ~~reagent,~~[8] material or other article, ***~~including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products,~~***[9] 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[10] ***or pathological*** process or state,
- control or support of conception,
- **cleaning,**[11] disinfection or sterilisation of any of the above-mentioned products,
- 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~~***. [12] [13]

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8 **ES** Change to: "…software, implant, reagent, *and other products for in vitro use,* material or other article, intended by the manufacturer…".

9 **DS 1867/12 AT** add "*including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products*"

10 **DS 1867/12 AT** add "*or pathological*"

11 **ES** Add: "*cleaning,* disinfection or sterilisation …".

12 **DS 1867/12 AT** add "*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*"

13 **ES** Replace this indent by

"– *providing information 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.***~~ [14]

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.

BOX 2 QUESTIONNAIRE

1) Does your delegation believe that agents for transport, nutrition and storage of organs, tissues and cells intended for transplantation should be considered medical devices, **regardless of principal mode of action of the product**?

YES	NO	Neutral	Comments / Alternative proposal

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[14] **DS 1861/12 PL** add "*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.*"

(2) 'accessory to a medical device' means an article which, **whilst not being a medical device,**[15] ~~whilst not being a medical device,~~ is intended **specifically** by its manufacturer[16] to be used together with one or several particular medical device(s) to ~~**specifically**~~[17] 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;[18]

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15 **Pcy** proposes to reinstate the **Cion** text.

16 **ES** Change to read: "… an article which, whilst not being a medical device, is intended *specifically* by its manufacturer …".

17 **ES** Delete: "*specifically*".

18 **DS 1205/14 FR** replace with "However, ~~mass-produced devices which need to be adapted~~ **"standard processed devices" manufactured on the bases of the anatomical characteristics of each patient** 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~~ **shall not be considered to be custom-made devices;**
However devices which need to be adapted to meet the specific anatomical characteristics of the patient in accordance with a ~~the~~ written prescription~~s~~ of a doctor~~s~~ of medicine, of a dental practitioner~~s~~ or of any other ~~authorised~~ person authorised by national law by virtue of this person's professional qualifications which are manufactured by means of standard process without specific design characteristics 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[19] 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;[20]

(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;

[19] **ES** Delete: "*substances or other elements*".
[20] **ES** Delete: "*Stand alone software shall be considered an active device;*".

(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.*~~ [21]

[21] **DS 1868/12 FR** add:
"*“Aesthetic devices” means: Any instrument, apparatus, appliance, implant, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings to provide a desired change in visual appearance, without therapeutic or reconstructive purpose, by its total introduction into the human body, by placing it in contact with the surface of the eye or by inducing cell or tissue modifications, 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.*
Tattoos and body piercing are not considered as aesthetic devices."

(9b) **'Falsified medical device' means any device with a false presentation:**

- **of its identity, including its packaging and labelling, its name, its design and manufacturing characteristics and, if appropriate, its components or its expiry date**
- **of its origin, referring to its manufacturer, its country of manufacture or its country of origin and, if appropriate, of that of its various components, or**
- **of its history, incorporating its CE marking certificates and documents relating to CE marking procedures, its technical documentation, its traceability, or to authorisations issued by non-EU countries.**

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights; [22]

(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[23];

(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;

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[22] **DS 1733/13 (FR), DS1205/14 FR** add the following definition:
"*'Falsified medical device' means any device with a false presentation:*
of its identity, including its packaging and labelling, its name, its design and manufacturing characteristics and, if appropriate, its components or its expiry date
of its origin, referring to its manufacturer, its country of manufacture or its country of origin and, if appropriate, of that of its various components
or of its history, incorporating its CE marking certificates and documents relating to CE marking procedures, its technical documentation, its traceability, or to authorisations issued by non-EU countries.
This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights."

[23] **ES** replace the end of the definition by: "… or on the *sales* packaging;".

(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;

[24] [25]

(16a) ‘performance’ means any technical characteristics, any effects and any benefit of the device when used for the intended purpose and in accordance with the instructions of use;

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[24] **DS 1367/13 BE** add the following definitions:

"*(16a) ‘performance’ means any technical characteristics, any effects and any benefit of the device when used for the intended purpose and in accordance with the instructions of use.*

(16b) ‘safety’ means the avoidance of risk (or harm) caused by the device or associated with its use.

(16c) ‘benefit’ means the device’s positive impact on health based on clinical data; referred to as clinical efficacy when based on clinical investigations and as clinical effectiveness when based on clinical experience after placing on the market. Benefit can also mean a positive impact on patient management or public health, for example for diagnostics.

(16d) ‘risk’ (or harm) means the device’s negative impact on the overall health based on clinical investigations, other clinical data and vigilance reports. For diagnostics, the risk from false-positive or false-negative results should also be considered.

(16e) ‘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.

(16f) ‘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.

(16g) ‘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."

[25] **DS 1519/13 IT** add the following definitions:

"*(16a) ‘benefit’ means the positive effect on health, evaluated upon valid scientific clinical evidence, obtained using a medical device for the intended purpose and in accordance with the instructions of use*

(16b) ‘safety’ means reasonable assurance, evaluated upon valid scientific clinical evidence, that a medical device, when used for the intended purpose and in accordance with the instructions of use, provides positive effect on health outweighed the probable risks and is freedom from inacceptable risk. Safety also means avoidance of risk caused by a medical device or its use in users or other subjects

(16c) ‘risk’ means the combination of the probability of occurrence of harm and severity of that harm

(16d) ‘benefit-risk determination’ means the integration of all assessments of benefit and risk of possible relevance for the use of the medical device for the intended purpose, when used in accordance with the instructions of use."

(16b) **'safety' means reasonable assurance, evaluated upon valid scientific clinical evidence, that a medical device, when used for the intended purpose and in accordance with the instructions of use, provides positive effect on health outweighed the probable risks and is freedom from inacceptable risk;**

(16c) **'benefit' means the positive effect on health, evaluated upon valid scientific clinical evidence, obtained using a medical device for the intended purpose and in accordance with the instructions of use;**

(16d) **'risk' means the combination of the probability of occurrence of harm and severity of that harm;**

(16e) **'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the medical device for the intended purpose, when used in accordance with the instructions of use";**

(16f) **'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;**

(16g) **'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;**

(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**~~[26] a device or has a device designed~~**,**~~ **or** manufactured ~~**or fully refurbished**~~[27], and markets that device under his name or trademark[28]**, regardless of whether these operations are carried out by that person himself or on his behalf by a third party**.[29]

~~**For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of**~~ **Any person who fully refurbishes** a device already[30] placed on the market or put into service, or ~~**the making of**~~ **makes** 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**, shall be considered a manufacturer**;

(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**[31]**,** 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;

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26 **ES** Delete: "*or fully refurbishes*".

27 **ES** Delete: "*or fully refurbished*".

28 **ES** Delete: "*or trademark*".

29 **DS1189/13 IT** add "*regardless of whether these operations are carried out by that person himself or on his behalf by a third party*". This sentence would clarify that a manufacturer can produce medical devices or in alternative can make their medical devices be produced by a third party on his behalf.

30 **ES** Replace the introductory part of this sentence with: "*It will also be considered manufacturer whoever fully refurbishes* a device already …".

31 **DS 1189/13 IT** add "*located outside the European Union*";

(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[32];

(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;

(28a) ‘state of the art’ means all accessible and usable knowledge in order to design and manufacture a device according to security and performance requirements, without having to prove any inventive activity. It could be established using standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases;[33]

(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;

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[32] **ES** Delete: "*or the promotion of public health*".

[33] **DS 1937/13 FR** add definition of “*state of the art*”.

(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 **a systematic and planned process to continuously generate, collect and analyse** ~~**the assessment and analysis**~~[34] 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;

[34] **DS 1002/14 DE** replace "*the assessment and the analysis*" with "*a systematic and planned process to continuously generate, collect and analyse*"

(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 **published in peer reviewed scientific literature**[35];

(37) 'sponsor' means an individual, ***legal or physical person,*** company, institution or organisation wh***o*** ~~ich~~ takes responsibility for **the setting up of financing**, 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; [35']

(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; [35']

(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; [35']

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[35] **DS 1002/14 DE** replace "*published and/or unpublished*" with "*published in peer reviewed scientific literature*"

[35'] Definition from **DS 1002/14 DE**

(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; [35']

(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;

(37h) 'Investigator' means an individual responsible to perform critical clinical-investigation-related procedures or to make important clinical investigation-related decisions; [36] [37]

(37i) 'principal investigator' means an investigator who leads an investigation team at an investigation site; [38] [39]

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[36] The corresponding definition in Regulation (EU) No 536/2014 (on clinical trials) reads: "*'Investigator' means an individual responsible for the conduct of a clinical trial at a clinical trial site*;"

[37] Definition from **DS 1002/14 DE**

[38] The corresponding definition in Regulation (EU) No 536/2014 (on clinical trials) reads: "'Principal investigator' means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site;"

[39] Definition from **DS 1002/14 DE**

(37l) **'coordinating investigator' is an investigator who is appointed by the sponsor to coordinate work in a multicentre clinical investigation;** [40] [41]

(37m) **'Informed consent' means a statement by which a subject voluntarily confirms his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the investigation that are relevant to the subject's decision to participate;** [42] [43]

(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;

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[40] There is no corresponding definition in Regulation (EU) No 536/2014 (on clinical trials).

[41] Definition from **DS 1002/14 DE**

[42] Definition from **DS 1002/14 DE**

[43] The corresponding definition in Regulation (EU) No 536/2014 (on clinical trials) reads: "'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial 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 trial;"

(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. [44]

(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] **DS 1870/12 NL, AT, SE** add "*post market surveillance*" definition.

(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,[45]

– serious public health threat;

[46]

(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;[47]

(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***[48];

(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;

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45 **UK** Add "… person's state of health, *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,".

46 **UK** Add "- *foetal distress, foetal death or a congenital abnormality or birth defect;*".

47 **DS 2046/13 DE** add "*'serious public health treat' means any event which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action.*"

48 **DS 2046/13 DE** add "*reduce or prevent the recurrence of safety related risk; this includes product design modifications as well as modifications concerning the production process or technique*"

(48) 'market surveillance' means the activities carried out and measures taken by public authorities to ***check and*** ensure that ~~products~~ ***devices***[49] 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.***~~[50]

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.

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[49] **Doc 6804/14 DE** add "*check and to ensure that ~~products~~ devices*"

[50] **Doc 6804/14 DE** add "*'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*".
Presidency comment: Following the results of questionnaire (DS 1350/14) the Presidency proposes to delete the definition of "vigilance". 24/28 Member States replied to the questionnaire. The majority of Member States (14/28) does not agree with the proposed definition of "vigilance", only 4 Member States support the proposed definition and 2 Member States are neutral. Among the 12 Member States that do not agree with the definition, six (EE, IE, ES, FR, PT, UK) do not consider necessary to define vigilance's activities. 7 Member States believe that the definition should include also responsibilities and tasks of manufacturers and other economic operators.

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. [51]~~The~~ **Without prejudice to Article 2(2) of Directive 2001/83, the**[52] Commission ~~may~~ **shall**[53], at the request of a Member State ~~or on its own initiative~~ **and following consultation with the MDCG and interested parties**[54], 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).

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[51] **DS 1189/13 IT** replace with:

"*1. The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, representing the opinion of Member States, 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 through MDCG , referred to in Article 80(d) 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."

Furthermore add **to article 80d**:

"*(d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical investigations, vigilance, and market surveillance, and borderline and classifications;*"

[52] Presidency proposal in response to issue raised by BE and DK.

[53] **FR** Replace: "*may*" with "*shall*". **UK** Against.

[54] **UK** Replace: "*on its own initiative*" with "*and following consultation with the MDCG and interested parties*".

2. The Commission shall ensure the sharing of expertise between Member States**, through MDCG, referred to in Article 80(d),** 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

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. [55] [56]

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.

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[55] **UK** Add "*Where the conformity assessment of any part of such a combination product would require the involvement of a notified body, that notified body shall be competent to assess both the part that is an in vitro diagnostic medical device and the part that is a medical device that is not an in vitro diagnostic medical device.*"

[56] **DS 1866/12 BE** With regard to the medical devices which incorporate as an integral part an in vitro diagnostic medical device it is advisable that, in order to reinforce the safety of these devices, both legislations should fully apply to the combination products which are described under Article 1 point 3 of both the Proposals for a Regulation on medical devices and for a Regulation on in vitro diagnostic medical devices.
In order also to avoid lengthy discussions on the principal intended purpose of the combination product which is either that of an in vitro diagnostic medical device or of a medical device, and taking into account that in vitro diagnostic medical devices are, in first instance medical devices, the pragmatic approach should be taken to qualify these integrally combined devices as 'medical devices'.
With regard to the applicable legislation, a modular approach would provide highest guarantee for safety and performance, where each component or part of the combination product is qualified in accordance with its intended purpose and characteristics, and accordingly subject to the relevant Regulation, including the conformity assessment. The different modules of the combination product would be subject to either the Regulation on medical devices or the Regulation on in vitro diagnostic medical devices, depending on their qualification.

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,~~[57] material or other article, ***~~including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products~~***[58] 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***[59] process or state,

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[57] **ES** Change to: "…software, implant, reagent, *and other products for in vitro use,* material or other article, intended by the manufacturer…".

[58] **DS 1867/12 AT** add "*including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products*".

[59] **DS 1867/12 AT** add "*or pathological*"

– control or support of conception,

– **cleaning,** [60]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;~~***[61] [62] [63]

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.

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[60] **ES** Add: "*cleaning,* disinfection or sterilisation …".

[61] Following MD proposal

[62] **DS 1867/12 AT** add "*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*"

[63] **ES** Replace this indent by

"– *providing information by means of in vitro examination of specimens derived from the human body, including blood and tissue donations;*".

(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[64] 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 **specifically**[65] by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to ~~**specifically**~~[66] 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;

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64 **BE** delete "*define or*".
65 **ES** add "*specifically*".
66 **ES** delete "*specifically*".

(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[67];

(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;

[67] **ES** replace the end of the definition by: "… or on the *sales* packaging;".

(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;

[68]

(13a) 'performance' means any technical characteristics, any effects and any benefits of the device when used for the intended purpose and in accordance with the instructions of use;

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[68] **DS 1367/13 BE** add the following definitions:
"*(13a) 'performance' means any technical characteristics, any effects and any benefit of the device when used for the intended purpose and in accordance with the instructions of use.*
(13b) 'safety' means the avoidance of risk (or harm) caused by the device or associated with its use.
(13c) 'benefit' means the device's positive impact on health based on clinical data; referred to as clinical efficacy when based on clinical investigations and as clinical effectiveness when based on clinical experience after placing on the market. Benefit can also mean a positive impact on patient management or public health, for example for diagnostics.
(13d) 'risk' (or harm) means the device's negative impact on the overall health based on clinical investigations, other clinical data and vigilance reports. For diagnostics, the risk from false-positive or false-negative results should also be considered.
(13e) '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.
(13f) '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.
(13g) '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.".

[69]

(13b) ‘safety’ means reasonable assurance, evaluated upon valid scientific clinical evidence, that a medical device, when used for the intended purpose and in accordance with the instructions of use, provides positive effect on health outweighed the probable risks and is freedom from inacceptable risk;

(13c) ‘benefit’ means the positive effect on health, evaluated upon valid scientific clinical evidence, obtained using an in vitro diagnostic medical device for the intended purpose and in accordance with the instructions of use;

(13d) ‘risk’ means the combination of the probability of occurrence of harm and severity of that harm;

(13e) ‘benefit-risk determination’ means the integration of all assessments of benefit and risk of possible relevance for the use of the in vitro diagnostic device for the intended purpose, when used in accordance with the instructions of use;

(13f) ‘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;

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[69] **DS 1519/13 IT** add the following definitions:
"*(13a) ‘benefit’ means the positive effect on health, evaluated upon valid scientific clinical evidence, obtained using a medical device for the intended purpose and in accordance with the instructions of use*
(13b) ‘safety’ means reasonable assurance, evaluated upon valid scientific clinical evidence, that a medical device, when used for the intended purpose and in accordance with the instructions of use, provides positive effect on health outweighed the probable risks and is freedom from inacceptable risk. Safety also means avoidance of risk caused by a medical device or its use in users or other subjects
(12c) ‘risk’ means the combination of the probability of occurrence of harm and severity of that harm
(13d) ‘benefit-risk determination’ means the integration of all assessments of benefit and risk of possible relevance for the use of the medical device for the intended purpose, when used in accordance with the instructions of use.".

(13g) '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;

(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~~[70] a device or has a device designed~~,~~ **or** manufactured ~~or fully refurbished~~[71], and markets that device under his name or trademark[72]**, regardless of whether these operations are carried out by that person himself or on his behalf by a third party**[73].

~~For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of~~ **Any person who fully refurbishes** a device already[74] placed on the market or put into service, or ~~the making of~~ **makes** 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**, shall be considered a manufacturer**;

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70 **ES** Delete: "*or fully refurbishes*".

71 **ES** Delete: "*or fully refurbished*".

72 **ES** Delete: "*or trademark*".

73 **DS1189/13 IT** add "r*egardless of whether these operations are carried out by that person himself or on his behalf by a third party*". This sentence would clarify that a manufacturer can produce medical devices or in alternative can make their medical devices be produced by a third party on his behalf.

74 **ES** Replace the introductory part of this sentence with: "*It will also be considered manufacturer whoever fully refurbishes* a device already …".

(17) '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**[75] **,** 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[76];

(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;

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[75] **DS 1189/13 IT** add "*located outside the European Union*".

[76] **ES** Delete: "*or the promotion of public health*".

(24a) "state of the art" means all accessible and usable knowledge in order to design and manufacture a device according to security and performance requirements, without having to prove any inventive activity. It could be established using standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases;[77]

(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[78] the scientific validity and performance for the use of a device as intended by the manufacturer;

(29) 'scientific validity of an analyte' means the association of an analyte 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[79], 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 analyte;

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77 **DS 1937/13 FR** add definition of "*state of the art*".
78 **BE** Replace "*that supports*" with "*supported by*".
79 **BE** Delete "*, where applicable,*".

(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. [80]

(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;

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[80] **DS 1870/12 SE, AT, NL** add definition of "*post market surveillance*".

(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,[81]

– serious public health threat;

[82]

(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;[83]

(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***[84];

(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;

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[81] **UK** Add "… person's state of health, *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,".

[82] **UK** Add "- *foetal distress, foetal death or a congenital abnormality or birth defect;*".

[83] **DS 2046/13 DE** add "*'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.*"

[84] **DS 2046/13 DE** add "*reduce or prevent the recurrence of safety related risk; this includes product design modifications as well as modifications concerning the production process or technique*"

(56) 'market surveillance' means the activities carried out and measures taken by public authorities to ***check and*** ensure that ~~products~~ ***devices***[85] 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;***~~[86]

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.

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[85] **6804/14 DE** add "<u>*check and to*</u> ensure that ~~*products*~~ <u>*devices*</u>".

[86] **6804/14 DE** add "*'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*"
<u>Presidency comment:</u> Following the results of questionnaire (DS 1350/14) Presidency proposes to delete the definition of "vigilance". 24/28 Member States replied to the questionnaire. The majority of Member States (14/28) does not agree with the proposed definition of "vigilance", only 4 Member States support the proposed definition and 2 Member States are neutral. Among the 12 Member States that do not agree with the definition, six (EE, IE, ES, FR, PT, UK) do not consider necessary to define vigilance's activities. 7 Member States believe that the definition should include also responsibilities and tasks of manufacturers and other economic operators.

Article 3

Regulatory status of products[87]

1. ~~The~~ **Without prejudice to Article 2(2) of Directive 2001/83, the**[88] Commission ~~may~~ **shall**, at the request of a Member State ~~or on its own initiative~~ **and following consultation with the MDCG and interested parties**, 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**, through MDCG, referred to in Article 77(d),** 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.

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[87] This article might need to be aligned to changes the corresponding article of the Medical Device Regulation. Compare footnotes by **FR**, **IT** and **UK**.

[88] Presidency proposal in response to issue raised by **BE** and **DK**.