Council of the European Union

Brussels, 22 December 2014
(OR. en)

16893/14

LIMITE

PHARM 101
SAN 487
MI 999
COMPET 677
CODEC 2507

Interinstitutional Files:
2012/0266 (COD)
2012/0267 (COD)

NOTE

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices
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** *- Chapters I of the two proposals*

Delegations will find attached Presidency proposals for a text of Chapter I of the proposal for a Regulation on medical devices (Annex A), a text of Annex XV of that same proposal (Annex B), texts for Annexes I, II, VII, VIII and IX regarding ingested products based on DS 1518/14 (Annex C) and a text of Chapter I of the proposal for a Regulation on *in vitro* diagnostic medical devices (Annex D).

The texts in Annexes A, B and D are based on the forthcoming consolidated text from the Italian Presidency but have been modified by the incoming Latvian Presidency on some places. Changes that are new to delegations are highlighted in grey regardless of which Presidency proposes them.

The texts in Annex C are taken together a compromise regarding ingested products and will be moved to the correct places in the proposed Regulation on Medical devices provided they find sufficient support in the Working Party.

This document is intended as a basis for the discussions in the Working Party on 9 January. Footnotes in strikethrough are considered as outdated and will be deleted in the next document concerning the above mentioned issues unless the delegations concerned object.

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

Chapter I

Scope and definitions

Article 1

Scope

1. This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with~~ ~~by medical devices and accessories to medical devices that are placed~~ ***concerning the placing on the market, making available*** on the market or put***ting*** into service[1] ***of medical devices and accessories to medical devices for human use*** in the Union ~~for human use~~.[2] ***This regulation also ~~establishes rules to be complied with by sponsors who take the responsibility for~~ applies to clinical investigations ~~and investigational~~ on medical devices conducted in the Union.***[3]

---

[1] **DE** "*putting into service*" should be better defined (see DS 1639/14), **CZ** support; ~~**Cion** defends keeping "*putting into service*"~~

[2] ~~**DK, DE, EL** support the Cion proposal; **ES, FR, PT** add "*making available*"; **SE,UK** proposed a compromise text circulated during the WP meeting on 11-12 September 2014 (WD MDEV-57)~~

[3] **DS 1868/12 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*'".

1a.[4] ***This regulation shall apply also to the products listed in Annex XV, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose, following the adoption of relevant common specifications pursuant to Article 7 for that***[5] ***product.***[6]

1b. 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~~[7] Directive 2001/83/EC[8] ~~and advanced therapy medicinal products covered by Regulation (EC) No 1394/2007~~. In deciding whether a product falls under Directive 2001/83/EC ~~or Regulation (EC) No 1394/2007~~ or under this Regulation, particular account shall be taken of[9] the principal mode of action of the product.

(ba) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;[10]

(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;

---

4 This paragraph replaces the last paragraph of Article 2(1)(a).

5 **AT** reference should be made to groups of products not to individual products.

6 **DS 1403/14 DK** the products listed in Annex XV should not be part of the definition of a medical device and it should be stipulated in Article 1 paragraph 1 if these products fall under the scope of the Regulation on medical devices. **DE, PL, SE** also oppose including aesthetic products into the scope of this regulation.

7 ~~Reinstated words from the Cion proposal.~~

8 **DE, IE, EL, NL, AT** support the wording "*covered by*". **Pcy** "*as defined in*" is a more appropriate legal drafting in point (b) since some medicinal products are excluded from Directive 2001/83, by virtue of Art. 3 thereof (e.g. magistral formula, prepared in pharmacies), but that does not mean that they become "medical devices".

9 ~~Reinstated words from the Cion proposal~~.

10 Following **DE** remarks.

(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 ***any of the manipulations*** ~~those~~ listed in Annex I of Regulation (EC) No 1394/2007, ~~and products derived from such tissues and cells,~~ shall not be ***covered by this Regulation*** ~~considered devices manufactured utilising tissues or cells of human origin or their derivatives~~;[11]

(f) products that ***intentionally***[12] contain or consist of ***viable*** biological substances[13] or organisms***,*** other than those referred to in points (c) and (e)***,*** ~~that are viable~~, 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.***~~ [14] [15] [16]

---

[11] Several Delegations (**DK, DE, ES, FR, NL, AT**) consider unclear the second subparagraph of Article 1(2)(e); during the Working Party meeting on 11-12 September 2014 **Cion** proposed an alternative text included in the **Pcy** proposal. New text seems to be clearer than the previous one. WP 11.11.2014: **BE, IE, FR, NL, AT, SE, UK** not satisfied with the second subparagraph of Article 1(2)(e). **DS 1406/14 UK** delete the entire subparagraph.

[12] "*intentionally*" is reinstated following requests from **NL**, **FI**, **Cion**.

[13] 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.

[14] ~~**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.~~

[15] ~~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.~~

~~**DK, DE, FR, AT, PT** support Cion text.~~

~~**DE** class III for these products is not consistent with rule 5, suggests that class IIb is applied.~~

[16] Deleted in accordance with the **UK+PT** joint proposal (**DS 1518/14**)

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~~ ***to*** the *in vitro* diagnostic medical device part ~~are concerned~~.[17] [18]

---

[17] **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 pieces of legislation 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.

IE, ES, AT support.

[18] **BE** suggestion circulated during the WP meeting on 11-12 September 2014 (WD MDEV-57)

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.[19]

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.

---

[19] **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*"

7. This Regulation shall not affect the application of Council Directive ~~96/29/Euratom nor of Council Directive 97/43~~***2013/59***/Euratom[20].

8.[21] This Regulation shall not affect national ~~laws which require~~ ***legislation with requirements concerning the organisation, delivery or financing of health services and medical care, such as,*** ~~that~~ ***~~inter alia,~~ the requirement that ~~only certain health professionals or health care institutions may dispense or apply~~*** certain ***medical*** devices may only be supplied on a medical prescription[22]***, the requirement that only certain health professionals or health care institutions may dispense or apply certain medical devices or that their application must be accompanied by specific professional counselling***.[23]

8a. This Regulation shall be without prejudice to national laws regarding public access to official documents and regarding freedom of the press and freedom of expression in other media.[24]

~~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.~~ [25]

---

[20] Correction~~, following a suggestion in **DS 1416/14 AT**~~.

[21] **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.*" **FR, AT** support.

[22] Highlighted text is reinstated.

[23] Suggestion from **DS 1416/14 AT**.

[24] **SE** suggestion during the WP meeting on 11-12 September 2014 (WD MDEV-57). **FI** support. **NL** Redundant.

[25] **Pcy** proposal based on oral advice from the Council Legal Service in the Working Party.

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[26],[27] material or other article,[28] 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[29] ***or pathological*** process or state,
- control or support of conception,
- ~~***cleaning,***~~[30] ~~disinfection or sterilisation of any of the above-mentioned products,~~
- ***providing information by means of in vitro examination of specimens derived from the human body, including blood and tissue donations,***[31]

---

[26] **Pcy** proposes to reinstate "*reagent*" following requests from **ES, AT, PT Cion**.

[27] **ES** Change to: "…software, implant, reagent, *and other products for in vitro use,* material or other article, intended by the manufacturer…". **AT, PT** support; **BE** opposed: "the addition of "*other products for in vitro use*" would enlarge the scope of the Medical Device Regulation. As an example, as there is no exclusion of products for general laboratory use, instruments or apparatus used in the analysis of biopsies may be brought into the scope of a medical device. Examples may include instruments intended to be used for paraffin processing of tissue, microtomes, automatic staining instruments, microscopes…".

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

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

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

[31] **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*".

ES suggests to instead add

"– *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.

[32]

Products specifically intended for the cleaning, disinfection or sterilisation of medical devices shall be considered medical devices.

~~***Equipment intended to be used by health professionals and specifically designed to prepare a medical device for the care of the patients, with the exception of those used in a pharmacy to prepare a medicinal product, shall be considered medical devices.***~~[33]

[34]

~~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.~~[35]

---

[32] **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.*"

[33] **DS 1401/14 FR** add "*Equipment intended to be used by health professionals and specifically designed to prepare a medical device or a therapeutic product for the care of the patients, with the exception of those used in a pharmacy to prepare a medicinal product, shall be considered medical devices.*"

[34] **IE, ES, LT, NL, PL, SK, UK** delete this subparagraph. **FR** suggest to change the text; **PT** support.

[35] Deletion following the addition of the new paragraph 1a in Article 1. Against deletion: **ES, FR**.

(2) 'accessory to a medical device' means an article which, whilst not being a medical device, is intended[36] by its manufacturer[37] to be used together with one or several particular medical device(s) to specifically[38] [39] enable ~~or assist~~[40] the device(s) to be used in accordance with its/their intended purpose(s) ***or to specifically assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)***[41];

---

[36] ~~Following the meeting on 11-12 September, **Pcy** has deleted the word "*specifically*", which was added in document 12538/14.~~

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

[38] ~~Following the meeting on 11-12 September, **Pcy** proposes to reinstate the word "*specifically*" from the Cion proposal, which was deleted in document 12538/14~~.

[39] **ES** Delete: "*specifically*".

[40] **DS 1401/14 FR** delete "*or assist*".

[41] **DS 1401/14 FR** add "*or to specifically assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)*".

(3) 'custom-made device' means any device specifically made in accordance with a written prescription of a ~~***medical***~~ doctor of medicine[42], of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications[43] 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;[44]

---

42 **Pcy** proposes to reinstate the term "*doctor of medicine*" throughout this regulation since it is the term used in Directive 2005/36/EC on the recognition of professional qualifications.

43 **DK, PL** replace with "*other duly qualified person*"

44 **DS 1205/14 FR** replace the second paragraph 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~~ ***a*** source of ~~power~~ ***energy***[45] other than that directly generated ***by the human body or*** by gravity and which acts by ~~changing the density of or~~ converting this energy. Devices intended to transmit energy, substances or other elements[46] between an active device and the patient, without any significant change, shall not be considered to be active devices.[47] [48] [49] [50]

~~Stand alone software shall be considered an active device;~~[51] [52]

---

45 **PT** change "*power*" to "*energy*".

46 **ES** Delete: "*substances or other elements*".

47 **DS 1295/13 UK** suggestion.

48 **DE, PL** suggest to revert to 90/385/EEC directive text:
"*'active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;*".

49 **ES** opposed to this definition since electrodes will not be considered active devices.

50 **ES** suggests the following definition "*'active device' means any device, the operation of which depends on any source of energy other than that directly generated by the human body or by gravity and which acts by transmitting 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.*".

51 **ES** Delete: "*Stand alone software shall be considered an active device;*".

52 **LV Pcy** proposes to delete: "*Stand alone software shall be considered an active device;*" and to address this issue in Annex VII, Chapter II, Section 3, which **IT Pcy** proposed to change as follows:
"*Software ~~Stand alone software~~, which has a medical purpose and drives a device or influences the use of a device, falls automatically in the same class as the device.*
If ~~stand alone~~ the software is independent of any other device, it is classified in its own right."

The **IT Pcy** proposal is based on a **DE** suggestion. This would require a new definition:
"*'Stand-alone software' means a software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.*"

IT Pcy alternative text
"*Software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If the software is independent of any other device , it is classified in its own right.*". **FR, SE, UK, Cion** are noted to support this text.

(5) 'implantable device' means any device, including those that are partially or wholly absorbed, which is intended[53]

– 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[54] on an individual patient during a single procedure.
~~The single procedure may involve several uses or prolonged use on the same patient;~~[55]

[53] **DS 1416/14 HU** add "*by the manufacturer*"; **Pcy** it could be considered implied.
[54] **IE** suggest to add "*on a continuous basis*".
[55] **CZ, DE, LT, PT** delete "*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~~[56] invasive medical procedures;

[57]

[58] [59]

[56] **DS 1416 AT** delete "*surgically*" to include also devices as "*cardiac catheter*".

[57] ~~**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.*~~"

[58] **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."

[59] **BE, DK, DE, LT, HU, AT, PT** consider the definition of a falsified medical device unnecessary since there are no related provisions; **CZ, HR** support the inclusion of the definition.

(9a) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose within a unique procedure;[60]

(9b) 'system' means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose;[61]

(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[62];

(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;

---

60 This is definition (16f) from document 12538/14. No changes have been done.
61 This is definition (16g) from document 12538/14. No changes have been done.
62 **ES** replace the end of the definition by: "… or on the *sales* packaging;". **PT** support.

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

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

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

– 'particle' means a minute piece of matter with defined physical boundaries;
– 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
– 'aggregate' means a particle comprising of strongly bound or fused particles;

(15a) 'performance' means ~~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~~ the ability of a medical device to achieve its intended purpose as claimed by the manufacturer;[63]

(15b) '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~~ the absence of unacceptable ~~clinical~~[64] ***risks, when using the device according to the manufacturer's instructions for use;***[65] [66]

---

[63] This definition replaces definition (16a) in document 12538/14. As now proposed, the definition is taken from GHTF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTF definition.

[64] **ES, PT, Cion** delete "*clinical*".

[65] This definition replaces definition (16b) in document 12538/14. As now proposed, the definition is taken from GHTF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTF definition.

[66] **DK**, **PL** object to inclusion of the proposed definition.

(15c) '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;[67]

(15d) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;[68]

(15e) '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";[69]

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;

---

[67] This is definition (16c) from document 12538/14. No changes have been done.

[68] This is definition (16d) from document 12538/14. No changes have been done. This definition is from GHTF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTF definition.

[69] This is definition (16e) from document 12538/14. No changes have been done.

70 71 72

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

---

70 **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."

71 **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."

72 ~~Definitions (16a) - (16g) in document 12538/14 have been replaced by definitions (9a), (9b) and (15a) - (15e).~~

(18) 'putting into service' means the stage at which a device, other than an investigational device[73], 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 ~~***with responsibility for the design,***~~ ~~who~~ manufactures ***or fully refurbishes***[74] ~~***, packaging and labelling of***~~ a device ~~***before it is placed on the market***~~ or has a device designed,[75] ~~***or***~~ manufactured or fully refurbished,[76] and markets that device[77] under his ~~***own***~~ name or trademark[78] [79]***, regardless of whether these operations are carried out by that person himself or on his behalf by a third party***.[80]

~~***The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.***~~[81]

---

73 **DS 1416/14 AT** delete "*other than an investigational device*". **PT** support.

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

75 The highlighted text is reinstated.

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

77 The highlighted text is reinstated.

78 The highlighted text is reinstated.

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

80 **DS 1189/13 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 manufacturers can produce medical devices or alternatively can have their medical devices produced by a third party on their behalf.

81 **DE** replace with the 93/42/EEC definition. **DK** support (**DS 1403/14**).

For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already[82] 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;[83] [84]

(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***[85]***,*** 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;

---

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

[83] **NL, UK, Cion** reinstate Cion proposal.

[84] The highlighted text is reinstated.

[85] **DS 1189/13 IT** add "*located outside the European Union*";

(24) 'health institution' means an organisation whose primary[86] purpose is the care or treatment of patients or the promotion of public health[87];

(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;

[86] **HU** Delete "*primary*". **NL, Cion** reinstate "*primary*". **UK** suggests to include also research; **IE, NL** support;

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

~~*(28a)*~~[88] ~~*'state of the art' means the highest level of knowledge and development achieved at a particular time. It is established using accessible and usable data such as standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases;*~~[89] [90]

(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;

---

[88] **DS 1937/13 FR** add definition of "*state of the art*".

[89] **DK, DE, AT** do not agree with the definition proposed in document 12538/14.
DS 1439/14 BE "'*state of the art' 'the level of knowledge and development achieved in a technique or method. It is established using accessible and usable data such as standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases*.".

[90] **BE, DK, DE, ES, LT, PL, SE, UK**, **Cion** delete this definition.

Definitions related to clinical evaluation and clinical investigations[91]:

(32) 'clinical evaluation' means the assessment and analysis[92] 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;[93]

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

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

(35) 'clinical investigation plan' means ~~the~~ ***a*** document~~(s)~~ ***that describes*** ~~setting out~~ the ~~rationale,~~ objectives, design***, methodology, statistical considerations*** and ***organisation*** ~~proposed analysis, methodology, monitoring, conduct and record keeping~~ of ***a*** ~~the~~ clinical investigation;[94]

---

91 In response to requests by several delegations and Cion during the WP held on 11-12 September 2014, **Pcy** here has, where appropriate, harmonized the definitions with those included in Regulation (EU) No 536/2014 on clinical trials and document GHTF/SC/N4:2012.

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

93 ~~**DK, PL** reinstate Cion proposal.~~

94 ~~**FR** suggests to align with the definition of "*protocol*" in Regulation (EU) No 536/2014. That definition reads:~~
~~" *'Protocol' means a document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial. The term 'protocol' encompasses successive versions of the protocol and protocol modifications;*"~~

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

– clinical investigation(s) of the device concerned,

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

– ~~published and/or unpublished~~ reports ***published in peer reviewed scientific literature***[95] 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***~~[96];

(37) 'sponsor' means an individual, ~~***legal or physical person,***~~ company, institution or organisation ~~***who***~~ which takes responsibility for ***the*** ~~***setting up of financing***~~, initiation***, for the*** ~~and~~ management ***and for setting up the financing*** of ~~a~~ ***the*** clinical investigation; [97]

(***37a) 'subject' means an individual who participates in a clinical investigation either as recipient of an investigational product or as control;***[98]

(37b) 'clinical evidence' means the clinical data and clinical evaluation report pertaining to a medical device ~~***of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer;***~~[99]

---

[95] **DS 1002/14 DE** replace "*published and/or unpublished*" with "*published in peer reviewed scientific literature*"; **DK** do not limit to peer-reviewed scientific literature.

[96] ~~This text, introduced in document 12538/14 has been moved.~~

[97] This definition as here reworded closely follows that that in Regulation (EU) No 536/2014 on clinical trials.

[98] Definition from **DS 1002/14 DE**.

[99] Definition from GHTF/SC/N4:2012.

(37c) 'clinical performance' means the ability of a medical device to achieve its intended purpose as claimed by the manufacturer ~~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;~~[100] [101]

~~(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;~~[102] [103]

~~(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);~~ [104]

~~(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;~~[105]

---

100 Definition from GHTF/SC/N4:2012.
101 **IE** delete this definition.
102 Definition from **DS 1002/14 DE**.
103 Definition deleted following a suggestion from **UK**.
104 Definition deleted following a suggestion from **UK**.
105 Definition deleted following a suggestion from **UK**.

(37g) 'equivalence' means the ability of two or more devices, with the same intended purpose, to have similar ~~identical~~[106] technical characteristics~~,~~ and the same biological and clinical characteristics, when used as intended by their respective manufacturers, to such an extent that there would not be a clinically significant difference in the safety and performance of the devices;

(37h) 'investigator' means an individual responsible for the conduct of a ~~to perform critical clinical investigation related procedures or to make important~~ clinical investigation ~~related decisions~~ at a clinical investigation site;[107] [108]

(37i) 'principal investigator' means an investigator who is the responsible leader of a ~~leads an investigation~~ team of investigators at ~~an~~ a clinical investigation site;[109] [110] [111]

(37j) 'coordinating investigator' is an investigator who is appointed by the sponsor to coordinate work in a multicentre clinical investigation;[112] [113] [114]

---

[106] **ES, NL, Cion** against "*identical*"; **PT** suggests to consider similar technical characteristics and the same biological and clinical characteristics, following MEDDEV.

[107] 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;*".

[108] Original definition in 12538/14 from **DS 1002/14 DE**.

[109] 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;*".

[110] Original definition in 12538/14 from **DS 1002/14 DE**.

[111] **NL, UK** delete this definition.

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

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

[114] **NL, UK** delete this definition.

(37k) 'informed consent' means ~~a statement by which~~ a subject's free and voluntar~~il~~y ~~confirms~~ expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation; [115] [116] [117]

(37l) 'Ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations; [118]

(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;

---

[115] Original definition from **DS 1002/14 DE**.

[116] 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;*".

[117] NL delete this definition.

[118] Definition from Regulation (EU) No 536/2014 (on clinical trials).

(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, made available[119] or put into service for the purpose of identifying any need to immediately apply any necessary ~~corrections,~~ corrective or preventive actions.[120]

(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;

---

[119] **DK, PL** add "*made available*".

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

(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[121] 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,[122]

– serious public health threat;

[123]

(44a) 'serious public health threat' means any event type, which results in imminent risk of death, serious ~~injury~~ deterioration in state of health[124], or serious illness that may requires~~ prompt remedial action;[125] [126] [127]

---

[121] The highlighted text is reinstated.

[122] **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,".
SE support.

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

[124] The highlighted text is reinstated.

[125] **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.*"

[126] Definition from GHTF/SC/N4/2012 Edition 2.

[127] **PT** add the second paragraph of the definition of ***'serious public health threat'*** given in MEDDEV 2.12-1, rev. 8.

(45) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation[128] ~~***including product design modifications as well as modifications concerning the production process or technique***~~[129];

(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***[130] 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;

[131]

---

[128] **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*".

[129] **DK, UK, PL** opposed to addition. Prefer Cion text.

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

[131] **DS 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*".
Pcy 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 activities. 7 Member States believe that the definition should include also responsibilities and tasks of manufacturers and other economic operators.

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 ***Article 1(1a)*** ~~the last subparagraph of number (1) of paragraph 1~~, in the light of technical progress***, in order to protect the health and safety of patients, users or other persons or other aspects of public health,***[132] 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.

[132] Text added following a suggestion from **UK**.

Article 3

Regulatory status of products[133]

1. ~~The~~ ***Without prejudice to Article 2(2) of Directive 2001/83***[134]***, at a duly substantiated request of a Member State***[135]***, the*** Commission ~~may~~ ***shall***[136], ~~at the request of a Member State or on its own initiative~~ ***and following consultation with*** ***after consulting the MDCG and interested parties***[137], by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

1a. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1.

---

133 **~~DS 1189/13 IT~~** ~~replace paragraphs 1 and 2 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;*"~~

134 **Pcy** proposal in response to issue raised by **BE** and **DK**.

135 **DE** not agree on the wording "at a duly substantiated request"; AT support

136 **FR** Replace: "*may*" with "*shall*". **UK** Against. **DE, AT** add a deadline for acting.

137 **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),***[138] 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.

_____

[138] **DK, ES, SE, Cion** delete "*through MDCG referred to in Article 80(d)*".

ANNEX XV[139] [140]

LIST OF PRODUCTS ~~COVERED BY THE LAST~~ *~~SUBPARAGRPAH~~* *~~SUBPARAGRAPH~~* ~~OF THE DEFINITION OF 'MEDICAL DEVICE'~~ REFERRED TO IN ~~NUMBER (1) OF~~ ARTICLE *1* ~~2~~(1*a*)[141]

1. ~~Contact lenses~~ ***Articles intended to be introduced into the eye with no corrective function***;
2. Implants ***intended to be totally introduced into the human body through surgically invasive means*** for modification ***of the anatomy*** or fixation of body parts;
3. ***Substances, combinations of substances, or articles intended to be used for facial*** ~~Facial~~ or other dermal or mucous membrane ~~fillers~~ ***filling by subcutaneous or intradermal injection***;
4. Equipment ***intended to be used to reduce, remove or destroy adipose tissue, such as equipment*** for liposuction***, lipolysis or lipoplasty***;

~~5. Invasive laser equipment intended to be used on the human body;~~

6. ***High intensity electromagnetic radiation (infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense*** ~~Intense~~ pulsed light equipment ***for skin resurfacing, tattoo or hair removal;***

6a. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain;

---

[139] This annex is based on a suggestion from **UK** following the discussions in the WP on 16 September.

[140] Changes compared to the text in document 12772/14 are highlighted.

[141] The title of this annex is adapted following the introduction of the new paragraph 1a in Article 1 and the removal of aesthetic devices from the definition of medical device.

~~*7. Tooth whitening or bleaching products with a concentration of hydrogen peroxide higher than 6%*~~. [142]

---

[142] **DS 1189/13 IT** add to the Annex XV list tooth whiteners with a concentration of hydrogen peroxide higher than 6%.
"We have some concerns in relation to products with concentrations of hydrogen peroxide higher than 6%, that are still placed on the market with CE marking and EC Conformity Certificates issued by NBs.

Based on the Italian database we have a lot of products ranging from 6 to 50% of hydrogen peroxide marketed in Italy, manufactured by several European manufacturers and CE marked by different European NBs (list available).

Although we agree that some of them do not have a medical purpose, our concern is that if they cannot be marketed as medical devices, they could enter the market as free sale products unless a general ban is foreseen. As free sale products, they would elude the vigilance system. The fact that these products are not cosmetics nor medical devices does not exempt us from safeguarding the health of European citizens.

In order to try to solve this problem we propose to include them in the Annex XV list since other products not provided with a medical purpose (aesthetic implants) have already been included in the recently released MD regulation at Article 2 "Definitions" 1:
"The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose."

Furthermore, in order to limit their use, and taking into consideration that some of them are invasive, a restrictive use by dentists and other healthcare providers should be considered in the provision.

This kind of restricted use could be foreseen also for those products provided with a cosmetic purpose beside a medical purpose which could be qualified as medical devices."

ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS[143]

7. Chemical, physical and biological properties

7.1. The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I 'General Requirements'. Particular attention shall be paid to:

(a) …

(b) the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the device ***and, where relevant, absorption, distribution, metabolism and excretion***[144];

(c) …

9. Devices incorporating a substance considered to be a medicinal product and devices *that are* composed of substances or combination*s* of substances ~~intended to be ingested, inhaled or administered rectally or vaginally~~ *that are absorbed by or locally dispersed in the human body*

9.1. In the case of devices referred to in the first subparagraph of Article 1(4), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as laid down in the applicable conformity assessment procedure in this Regulation.

---

143 The text in Annex C is taken from DS 1518/14 containing suggestions elaborated by **PT** and **UK**. Changes compared to the **Cion** proposal are highlighted in grey. "Intermediate changes" that were indicated as deleted in DS 1518/14 are not included here.

144 The terminology relating to '*dynamic and kinetic activities*' suggested by **PT** has been amended here; UK experts are of the view that what is meant by '*dynamic*' is unclear and that the proposed wording here is clearer.

9.2. Devices that are composed of substances or combination***s*** of substances ***that are*** intended to be ~~ingested, inhaled or administered rectally or vaginally~~ ***introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane*** and that are absorbed by or ***locally*** dispersed in the human body[145] shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC ***including consideration of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as laid down in the applicable conformity assessment procedure in this Regulation***.

…

19.2. Information on the label

The label shall bear the following particulars:

(a) …

…

(q) If the device is intended for clinical investigation only, an indication of that fact.

(r) In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent(s) responsible for achieving the principal intended action.

---

145 Most experts were concerned that the routes of administration proposed by the Commission's proposal were incomplete. There are three possible options to address this: (i) extend the list to cover substance devices introduced into the body via all administration routes (this could read *'devices that are composed of substances or combination of substances that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane and that are absorbed by or* ***locally*** *dispersed in the human body'*); (ii) remove any reference to mode of administration (to read *'devices that are composed of substances or combination of substances that are absorbed by or dispersed in the human body'*) or (iii) include reference to the pharmaceutical dosage forms of the European Pharmacopoeia~~, as seemed to be the preferred option of experts at the meeting and thus has been proposed in the text~~.

19.3. Information in the instructions for use

The instructions for use shall contain the following particulars:

(a) The particulars referred to in points 19.2. a), c), e), f), k), l)***,*** ~~and~~ n) ***and r)***.

…

(o) Information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information should cover, where appropriate:

- warnings, precautions and/or measures to be taken in the event of malfunction …

…

- precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user.
- ***in the case of devices that are composed of substances or combination of substances that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side effects and risks relating to overdose.***

(p) Warnings or precautions to be taken in order to facilitate the safe disposal of …

ANNEX II

TECHNICAL DOCUMENTATION

1.1. Device description and specification

…

(i) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its functionality ***and, where relevant, its qualitative and quantitative composition***. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

…

6.2. Additional information in specific cases

…

(b) Where a device is manufactured utilising …

(ba) in the case of devices that are composed of substances or combination of substances that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane and that are absorbed by or locally dispersed in the human body, detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions, or otherwise justification for the absence of such studies, regarding:

- ***absorption, distribution, metabolism and excretion*;**
- ***possible interactions, or of their products of metabolism, with other devices, medicinal products or other substances, considering the target population, and their associated medical conditions;***
- ***local tolerance;***
- ***toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable according to total exposure to the device.***

(c) In the case of devices …

ANNEX VII

CLASSIFICATION CRITERIA

6.9 Rule 21

Devices that are composed of substances or combination***s*** of substances ***that are*** intended to be ~~ingested, inhaled or administered rectally or vaginally~~ ***introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane*** and that are absorbed by or ***locally*** dispersed in the human body are***:*** ~~:~~

- in class III ***if they, or their products of metabolism, are systemically absorbed by the human body,***
- ***in class IIb if they, or their products of metabolism, are locally dispersed but not absorbed by the human body*** ~~.~~***, except if they are administered on skin or mucous membrane via a body orifice, in which case they are in class IIa.***

ANNEX VIII

CONFORMITY ASSESSMENT BASED ON FULL QUALITY ASSURANCE AND DESIGN EXAMINATION

…

6. Specific procedures

…

6.3. Procedure in the case of devices that are composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body

(a) For devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane and that are absorbed by or locally dispersed in the human body, the quality and safety of the device shall be verified by analogy with the relevant requirements laid down in Annex I to Directive 2001/83/EC. This shall include consideration of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions.

(b) For devices in class IIb, the notified body shall assess the clinical evaluation report for every device covered by the EU design-examination certificate before issuing a certificate.

(c) In addition, for devices, or their products of metabolism, that are absorbed by the human body in order to achieve their intended effect, the notified body shall seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA'), acting particularly through its Committee on Human Medicinal Products in accordance with Regulation (EC) No 726/2004, on the compliance of the device with the relevant requirements laid down in Annex I to Directive 2001/83/EC.

(d) The opinion of the medicinal products competent authority or the EMA shall be drawn up within 150 days.

(e) The scientific opinion of the medicinal products competent authority or the EMA, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.

ANNEX IX

CONFORMITY ASSESSMENT BASED ON TYPE EXAMINATION

…

6. Specific procedures

The provisions regarding the specific procedures in the case of devices incorporating a medicinal substance, or devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable***, or devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane and that are absorbed by or locally dispersed in the human body*** set out in Annex VIII, Section 6, apply with the proviso that any reference to an EU design-examination certificate shall be understood as reference to an EU type-examination certificate.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on *in vitro* diagnostic medical devices

Chapter I

Scope and definitions[146]

Article 1

Scope

1.[147] This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with by *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices that are placed~~ ***when concerning the placing on the market, making available*** on the market or put***ting*** into service of **in vitro** ***diagnostic medical devices and accessories to*** **in vitro** ***diagnostic medical devices for human use*** [148] in the Union ~~***in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices*** for human use~~. ***This regulation also*** ~~***establishes rules to be complied with by sponsors who take the responsibility for***~~ ***applies to clinical performance studies on*** **in vitro** ***diagnostic medical devices conducted in the Union.***

1a.[149] 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'.

---

146 This chapter is taken from the consolidated text under preparation by the IT Presidency.

147 This paragraph is aligned to the wording of the proposed Regulation on Medical Devices.

148 **AT** add "*and performance evaluation devices*" . **IE** support

149 As part of the alignment with the MD proposal a separate number is given to this paragraph.

2. This Regulation shall not apply to:

(a) products for general laboratory use, unless such products, in view of their characteristics, are specifically [150] 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.[151]

[150] **NL** replace "*specifically*" with "*exclusively*"

[151] **UK** delete e), **AT** support e), **IE** insert definition of "*research use only*".

3.[152] 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~~ ***that*** 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~~ of ***this*** Regulation ~~(EU) [Ref. of future Regulation on medical devices]~~ shall apply ~~as far as the safety and performance of~~ ***to*** the ~~medical device~~ part that is ~~not~~ an *in vitro* diagnostic medical device ~~are concerned~~.[153] [154]

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.

---

[152] Following MD Proposal - **BE** suggestion circulated during the WP meeting on 11-12 September 2014 (WD MDEV-57)

[153] **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.*" **AT** support

[154] **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. **IE, ES, AT** support

5. This Regulation shall not affect the application of Council Directive ~~96/29/Euratom, nor of Council Directive 97/43~~ ***2013/59/***Euratom.[155]

6. This Regulation shall not affect national ~~laws which require~~ ***legislation with requirements concerning the organisation, delivery or financing of health services and medical care, such as*** ~~that~~ ***inter alia, the requirement that only certain health professionals or health care institutions may dispense or apply*** certain devices [156] ***may only be supplied on a medical prescription or that their application must be accompanied by specific professional counselling***.[157]

6a. This Regulation shall be without prejudice to national laws regarding public access to official documents and regarding freedom of the press and freedom of expression in other media.[158]

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~~ [159]

---

155 Correction, following a suggestion in **DS 1416/14 AT**

156 **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.*" **FR, AT** support.

157 Suggestion from **DS 1416/14 AT**.

158 **SE** suggestion during the WP meeting on 11-12 September 2014 (WD MDEV-57).

159 **Pcy** proposal based on oral advice from the Council Legal Service in the Working Party.

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[160],[161] material or other article, [162] 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***[163] process or state,
- control or support of conception,
- ~~***cleaning,***~~[164] ~~disinfection or sterilisation of any of the above-mentioned products,~~
- ***providing information by means of in vitro examination of specimens derived from the human body, including blood and tissue donations,***[165]

---

[160] **Pcy** proposes to reinstate "*reagent*" following requests from **ES, AT, PT Cion**.

[161] **ES** Change to: "…software, implant, reagent, *and other products for in vitro use,* material or other article, intended by the manufacturer…". **AT, PT** support; **BE** opposed: "the addition of "*other products for in vitro use*" would enlarge the scope of the Medical Device Regulation. As an example, as there is no exclusion of products for general laboratory use, instruments or apparatus used in the analysis of biopsies may be brought into the scope of a medical device. Examples may include instruments intended to be used for paraffin processing of tissue, microtomes, automatic staining instruments, microscopes…".

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

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

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

[165] Alignment with the definition in the MD Regulation.

– ~~*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;*~~[166] [167] [168]

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.

Products specifically intended for the cleaning, disinfection or sterilisation of medical devices shall be considered medical devices.

[169]

---

166 Following MD proposal

167 **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*"

168 **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;*". **AT** support

169 **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.*"

~~***Equipment intended to be used by health professionals and specifically designed to prepare a medical device for the care of the patients, with the exception of those used in a pharmacy to prepare a medicinal product, shall be considered medical devices.***~~[170] [171]

~~***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.***~~[172]

(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[173] 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.

---

[170] **DS 1401/14 FR** add "*Equipment intended to be used by health professionals and specifically designed to prepare a medical device or a therapeutic product for the care of the patients, with the exception of those used in a pharmacy to prepare a medicinal product, shall be considered medical devices.*"

[171] **IE, ES**, **LT**, **NL**, **PL**, **SK**, **UK**, **Cion** delete this subparagraph; **FR** suggests to change the text; **PT** support.

[172] Deletion following the addition of the new paragraph 1a in Article 1 of the MD Regulation.

[173] **BE** delete "*define or*".

(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~~ [174] [175] by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically [176] [177] enable ~~or assist~~ [178]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;~~[179]

(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; [180]

(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;

---

174 Following the meeting on 11-12 September, **Pcy** proposes to delete the word "*specifically*", which was added in document 12538/14.

175 **ES** add "*specifically*".

176 Following the meeting on 11-12 September, **Pcy** proposes to reinstate the word "*specifically*" from the Cion proposal, which was deleted in document 12538/14.

177 **ES** delete "*specifically*".

178 **FR** delete "*assist*" in order to avoid inclusion of laboratory generic use devices. **AT, SE, BE** support.

179 **BE, FR, NL, AT, UK** delete (3a).

180 **FR, AT, Cion** adopt FDA definition **UK** adopt Parliament amendment.

(8)[181] '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.~~ [182]

(8a) 'kit' means a set of components that are packaged [183]***together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof***

(8b) '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;[184]

(8c) '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;[185]

(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[186];

(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;

---

181 **NL** delete (8).

182 **CZ, DE, LT, PT** delete "*The single procedure may involve several uses or prolonged use on the same patient*".

183 **NL** replace "packaged" with "intended to be used"

184 This is definition (13f) from document 12538/14. No changes have been done.

185 This is definition (13g) from document 12538/14. No changes have been done.

186 **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;

(12a) '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~~ the ability of a medical device to achieve its intended purpose as claimed by the manufacturer;[187]

(12b) '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~~ the absence of unacceptable ~~clinical~~[188] ***risks, when using the device according to the manufacturer's instructions for use;***[189]

(12c) '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;[190]

(12d) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;[191]

---

[187] This definition replaces definition (13a) in document 12538/14. Changes to that definition are indicated. As now proposed, the definition is taken from GHTF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTF definition.

[188] **ES, PT, Cion** delete "*clinical*".

[189] This definition replaces definition (13b) in document 12538/14. Changes to that definition are indicated. As now proposed, the definition is taken from GHTF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTF definition.

[190] This is definition (13c) from document 12538/14. No changes have been done.

[191] This is definition (13d) from document 12538/14. No changes have been done. This definition is from GHTF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTF definition.

(12e) '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";[192] [193] [194]

---

[192] This is definition (13e) from document 12538/14. No changes have been done.

[193] **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.".

[194] **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

(13c) '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.".

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;

(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;

(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;

(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)[195] 'manufacturer' means the natural or legal person who manufactures or fully refurbishes[196] a device or has a device designed, manufactured or fully refurbished[197], and markets that device under his name or trademark[198]***, regardless of whether these operations are carried out by that person himself or on his behalf by a third party***.[199]

~~***The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.***~~[200]

For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already[201] placed on the market or put into service, or the

---

195 **Pcy** replace with the 98/79/EC definition.

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

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

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

199 **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.

200 Following MD proposal.

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

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;[202]

[202] Cion proposal reinstated following interventions by **NL, UK** and **Cion**.

(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***[203]**,** 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***[204] purpose is the care or treatment of patients or the promotion of public health[205];

(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;

---

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

[204] Following MD proposal **- HU** Delete "*primary*". **NL, Cion** reinstate primary. **UK** suggests to include also research; **IE, NL** support;

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

~~*(24a)*~~[206] ~~*"state of the art" means the highest level of all accessible and usable knowledge and development achieved at a particular time. in order to design and manufacture a device according to security and performance requirements, without having to prove any inventive activity. It is could be established using accessible and usable data such as standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases;*~~ [207] [208] [209]

(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[210] 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;

---

206 Following MD Proposal

207 **DS 1937/13 FR** add definition of "*state of the art*".

208 **DK, DE, AT** do not agree with the definition proposed in document 12538/14.
DS 1439/14 BE "*'state of the art' 'the level of knowledge and development achieved in a technique or method. It is established using accessible and usable data such as standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases*.".

209 **BE, DK, DE, ES, LT, SE, UK, Cion** delete this definition

210 **BE** Replace "*that supports*" with "*supported by*".

(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[211], 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;

(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;

---

[211] **BE** Delete "*, where applicable,*".

(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, with the same intended purpose, to have ~~similar~~ ~~identical~~ similar[212] technical characteristics, and the same clinical and analytical characteristics when used as intended by their respective manufacturer, to such an extent that there would not be a clinical significant difference in the performance of the devices. **[213]**

(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;

---

212 **ES, NL Cion** object to "*identical*"; **PT** suggests to consider similar technical characteristics and the same biological and clinical characteristics, following MEDDEV.

213 **BE** delete (45a).

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, made available[214] or put into service for the purpose of identifying any need to immediately apply any necessary ~~corrections~~, corrective or preventive actions.[215]

(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;

---

[214] Following MD proposal **- DK** add "*made available*".

[215] **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,[216]

– serious public health threat;
[217]

(52a)[218] ***'serious public health threat' means any event type which results in imminent risk of death, serious ~~injury~~ deterioration in state of health, or serious illness that may requires prompt remedial action;***[219] [220]

(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~~***[221];

---

[216] **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,".
SE support

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

[218] Definition from GHTF/SC/N4/2012 Edition 2

[219] **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.*"

[220] **PT** add the second paragraph of the definition of *'serious public health threat'* given in MEDDEV 2.12-1, rev. 8.

[221] **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*"

(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***[222] 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;***~~[223]

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];

---

[222] **6804/14 DE** add "*check and to* ensure that ~~*products*~~ *devices*".

[223] **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) 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 (IE, EE, 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.

(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[224]

1. ***~~The~~ Without prejudice to Article 2(2) of Directive 2001/83***[225]***, at a duly substantiated request of a Member State,***[226] ***the*** Commission ***~~may~~ shall***[227], ~~at the request of a Member State or on its own initiative and following consultation~~ ***with the MDCG ~~and interested parties~~,***[228] 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).

1a. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1.

2. The Commission shall ensure the sharing of expertise between Member States***, through MDCG,***[229] ***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.

---

[224] Following MD Proposal Definition from GHTF/SC/N4/2012 Edition 2.
[225] Following MD Proposal - **Pcy** proposal in response to issue raised by **BE** and **DK**.
[226] **DE** not agree on the wording "at a duly substantiated request"; **AT** support
[227] **FR** Replace: "*may*" with "*shall*". **UK** Against. **DE, AT** add a deadline for acting.
[228] **UK** Replace: "*on its own initiative*" by "*and following consultation with the MDCG and interested parties*".
[229] **DK, ES**, **SE**, **Cion** delete "*through MDCG referred to in Article 80(d)*".