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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 and relating to Common Specifications for "Aesthetic devices" (Section 6 of Annex I) (set out in 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 (document 17152/14) but have been modified by the incoming Latvian Presidency on some places. Changes that are either entirely new to delegations or have not yet been discussed in the Working Party are highlighted in grey regardless of which Presidency proposes them.

The texts in Annex C (except Section 6) 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 26 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 Footnotes in strikethrough are considered as outdated and will be deleted in the next document concerning the above mentioned issues unless the delegations concerned object.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 *putting* into service¹ *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 4}

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 **Pcy** the last sentence is subject to revision depending on decisions in other parts of the regulation.

⁴ **DS 1029/15 DE** Scrutiny reservation on the last sentence. **DE** alternative: replace “*applies to*” by “*lays down rules on*”.

1a.^{5 6} *This regulation shall also apply to the groups of products⁷ without an intended medical purpose that are listed in each section of 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 as from the date of entry into force of common specifications for each group of products, adopted pursuant to Article 7⁸ for each group of products that product. The common specifications for a group of products listed in each section of Annex XV shall specifically address application of Section 6 of Annex I in relation to the acceptable risks for that group of products.*⁹

*The Commission shall adopt the necessary Common Specifications per group of products listed in each section at the latest [one year after the date of application of this Regulation].*¹⁰

1b. For the purposes of this Regulation, medical devices, ~~and~~ accessories to medical devices ~~and~~ products listed in Annex XV to which this Regulation applies pursuant to paragraph 1a¹¹ shall hereinafter be referred to as ‘devices’.

2. This Regulation shall not apply to:

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

⁵ This paragraph replaces the last paragraph of Article 2(1)(a).

⁶ For suggested alternative wordings from **DE, HR** see **DS 1029/15**.

⁷ **AT** reference should be made to groups of products not to individual products.

⁸ **DE DS 1639/14** in addition suggests that Notified Bodies for the relevant conformity assessment procedures should be designated and notified in order for the Regulation to apply to the products in Annex XV. This requirement would make the application of the Regulation subject to actions of individual Member States and the **Council Legal Service** therefore has a strong reservation. **Pcy** however invites delegations to give their view on such an addition.

⁹ **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.

¹⁰ **BE, DK, IE, ES, FR, HR, IT, PT, FI** expressed that development of CS should not delay the application of the regulation. **Pcy** therefore proposes a deadline.

¹¹ **Pcy** addition aiming at making the devices in Annex XV subject to all provisions in this Regulation. Builds on interventions by **DK, ES, HR, LT, Cion**. **DE** against.

- (b) medicinal products *as defined in* covered by¹² Directive 2001/83/EC¹³ ~~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 of¹⁴ the principal mode of action of the product.
- (ba) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;**¹⁵
- (c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market¹⁶ ~~or used in accordance with the manufacturer's instructions~~, such blood products, plasma or cells, except for devices referred to in paragraph 4;
- (d) cosmetic products covered by Regulation (EC) No 1223/2009;
- (e)¹⁷ 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.

¹² ~~Reinstated words from the Cion proposal.~~

¹³ **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”.

¹⁴ ~~Reinstated words from the Cion proposal.~~

¹⁵ Following **DE** remarks.

¹⁶ **AT DS 1029** add „*or put into service*” to cover in-house blood product production and transfusion.

¹⁷ **DK DS 1008/15** has presented an alternative wording. **DE** supports **DK** wording. Alternative suggestions also from **AT, DE DS 1029/15**.

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;¹⁸

(ea)¹⁹ transplants, tissues or cells of human origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of human origin, or their derivatives, which are non-viable or are rendered non-viable and that fulfil at least one of the following conditions:

- **the cells or tissues have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved. The manipulations listed in Annex I of Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations,**
- **the cells or tissues are not intended to be used for the same essential function or functions in the recipient as in the donor.**

¹⁸ 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.

¹⁹ Wording from ~~UK DS 1005/15~~. ~~IE, IT, NL, AT, SE, Cion~~ Tentatively support UK text. ~~DE~~ against.

- (f) products that *intentionally*²⁰ contain or consist of *viable* biological substances²¹ or organisms, other than those referred to in points (c) and (e), ~~that are viable~~, including living micro-organisms, bacteria, fungi or virus;^{22 23}
- (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.~~²⁴

²⁰ “*intentionally*” is reinstated following requests from **NL, FI, Cion**.

²¹ 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.

²² **Pcy** alternative proposal:

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

²³ **DE DS 1029/15** has presented alternative wording.

²⁴ Deleted in accordance with the joint suggestion from **PT, UK (DS 1518/14)**.

3. Any device which, when placed on the market or used in accordance with the manufacturer's instructions²⁵, 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~~.^{26 27}

²⁵ **DE DS 1029/15** Replace "*used in accordance with the manufacturer's instructions*" by "*put into service*".

²⁶ **BE DS 1866/12** 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. DE DS 1029/15 against.

²⁷ **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 instructions²⁸, 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.²⁹

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.

²⁸ **DE DS 1029/15** Replace "*used in accordance with the manufacturer's instructions*" by "*put into service*".

²⁹ **BE DS 1367/13** 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/Euratom³⁰.
- 8.³¹ 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 prescription³², 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.*³³
- 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.*³⁴
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.~~³⁵

³⁰ Correction, following a suggestion in **DS 1416/14 AT**.

³¹ **BE DS 1367/13** 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.

³² Highlighted text is reinstated.

³³ Suggestion from **AT DS 1416/14**.

³⁴ **SE** suggestion during the WP meeting on 11-12 September 2014 (WD MDEV-57). **FI** support. **NL** Redundant. **DE** scrutiny reservation, concerned of the impact on confidentiality provisions.

³⁵ **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^{36, 37 38} material or other article,³⁹ **whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,**⁴⁰ 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 physiological⁴¹ **or pathological** process or state,
 - control or support of conception,⁴²
 - **cleaning,**⁴³ ~~disinfection or sterilisation of any of the above-mentioned products,~~

³⁶ Pcy proposes to reinstate “*reagent*” following requests from **ES, AT, PT, Cion. DE** against.
³⁷ ~~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...”.~~

³⁸ ~~AT DS 1029/15 add “or other product for in vitro use”.~~

³⁹ ~~AT DS 1867/12 add “including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products”~~

⁴⁰ ~~Pcy proposal based on DE DS 1029/15. ES, FR, SE, UK against. For complete DE suggestions on Article 2.1.1 see DS 1029/15, DS 1639/14.~~

⁴¹ ~~AT DS 1867/12 add “or pathological”~~

⁴² ~~DE DS 1029/15 suggests to move this indent to the next sentence.~~

⁴³ ~~ES Add: “cleaning, disinfection or sterilisation ...”.~~

- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*^{44 45}

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.

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

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~~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.~~⁴⁸

⁴⁴ **DE DS 1029/15** delete " blood and tissue donations ".

⁴⁵ **AT DS 1867/12** 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*”. **AT** support.

⁴⁶ **PL DS 1861/12** 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.*”

⁴⁷ **FR DS 1401/14** 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.*”

IE, ES, LT, NL, PL, SK, UK delete this subparagraph. **FR** suggest to change the text; **PT** support. **Pcy** suggests addressing the issue in the context of custom-made devices.

⁴⁸ 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 by its manufacturer⁴⁹ to be used together with one or several particular medical device(s) to specifically⁵⁰ enable ~~or assist~~⁵¹ 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)*⁵²;

⁴⁹ **ES** Change to read: "... an article which, whilst not being a medical device, is intended *specifically* by its manufacturer ...". **AT, PL, SE** Support.

⁵⁰ **ES** Delete: "*specifically*". **SE** Support.

⁵¹ ~~**DS 1401/14 FR** delete "*or assist*".~~

⁵² ~~**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, of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications⁵³ ⁵⁴ 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 processes⁵⁵ 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;⁵⁶

⁵³ **Pcy** proposes, based on the discussions in the WP on 9 January to delete any reference to specific groups of professionals. Alternative proposal based on Directive 2011/24/EC: “*by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued*”.

⁵⁴ **DK, PL** replace with “*other duly qualified person*”.

⁵⁵ **AT** add „*to be used in the production of custom made devices*”

⁵⁶ **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 prescriptions of a doctors of medicine, of a dental practitioners 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;”.
ES support.

- (4) 'active device' means any device, the operation of which depends on a source of electrical energy or any a source of power *energy*⁵⁷ other than that directly **and intentionally** generated **by the human body for that purpose** or by gravity and which acts by **changing the density of or**⁵⁸ converting this energy. Devices intended to transmit energy, substances or other elements⁵⁹ between an active device and the patient, without any significant change, shall not be considered to be active devices.^{60 61 62 63}

~~Stand alone software shall be considered an active device;~~^{64 65}

⁵⁷ PT change "power" to "energy".

⁵⁸ In order to solve the problem with electrodes not being considered active devices Pcy proposes to revert to the original Cion wording here, which was intended to solve that problem. Alternatively the wording "... acts by transmitting or converting this energy." could be used.

⁵⁹ ES Delete: "substances or other elements".

⁶⁰ Suggestion from UK DS 1295/13.

⁶¹ 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;".

⁶² ES opposed to this definition since electrodes will not be considered active devices.

⁶³ 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."

⁶⁴ ES Delete: "Stand alone software shall be considered an active device;".

⁶⁵ 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 wholly⁶⁶ absorbed, which is intended⁶⁷
- to be totally introduced into the human body or
 - to replace an epithelial surface or the surface of the eye,
- by clinical⁶⁸ intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical⁶⁹ 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 used⁷⁰ on an individual patient during a single procedure.
- ~~The single procedure may involve several uses or prolonged use on the same patient;~~⁷¹

⁶⁶ **DE DS 1029/15** delete "*or wholly*".

⁶⁷ **HU DS 1416/14** add "*by the manufacturer*"; **Pcy** it could be considered implied.

⁶⁸ **DE DS 1029/15** replace "*clinical*" by "*surgical*".

⁶⁹ **DE DS 1029/15** replace "*clinical*" by "*surgical*".

⁷⁰ **IE** suggest to add "*on a continuous basis*".

⁷¹ **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 surgically⁷² invasive medical procedures;

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⁷² **DS 1416 AT** delete “surgically” to include also devices as “cardiac catheter”.

⁷³ **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.”

⁷⁴ **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.”

⁷⁵ **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;*⁷⁶
- (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;*⁷⁷
- (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 devices⁷⁸;
- (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;

⁷⁶ This is definition (16f) from document 12538/14. No changes have been done.

⁷⁷ This is definition (16g) from document 12538/14. No changes have been done.

⁷⁸ **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;*⁷⁹

(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 unacceptable risk~~ the absence of unacceptable ~~clinical~~⁸⁰ risks, when using the device according to the manufacturer’s instructions for use;*^{81 82}

⁷⁹ 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.

⁸⁰ **ES, PT, Cion** delete “clinical”.

⁸¹ 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.

⁸² **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;*⁸³
- (15d) *‘risk’ means the combination of the probability of occurrence of harm and the severity of that harm;*⁸⁴
- (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”;*⁸⁵

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;

⁸³ This is definition (16c) from document 12538/14. No changes have been done.

⁸⁴ This is definition (16d) from document 12538/14. No changes have been done. This definition is from GHTEF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTEF definition.

⁸⁵ This is definition (16e) from document 12538/14. No changes have been done.

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

⁸⁶ **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."

⁸⁷ **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 unacceptable 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."

⁸⁸ ~~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 device⁸⁹, 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~~⁹⁰, ~~packaging and labelling of~~ a device ~~before it is placed on the market~~ or has a device designed,⁹¹ ~~or~~ manufactured or fully refurbished,⁹² and markets that device⁹³ under his ~~own~~ name or trademark^{94 95}, *regardless of whether these operations are carried out by that person himself or on his behalf by a third party.*⁹⁶

~~*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.*~~⁹⁷

⁸⁹ AT DS 1416/14 delete “other than an investigational device”. DE, PT support. PT, DE support. DE MDEV-67 add “which has not been previously placed on the market”.

⁹⁰ ES Delete: “or fully refurbishes”.

⁹¹ The highlighted text is reinstated.

⁹² ES Delete: “or fully refurbished”.

⁹³ The highlighted text is reinstated.

⁹⁴ The highlighted text is reinstated.

⁹⁵ ES Delete: “or trademark”.

⁹⁶ 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.

⁹⁷ 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 already⁹⁸ 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;⁹⁹
100

- (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**¹⁰¹, 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;

⁹⁸ ES Replace the introductory part of this sentence with: "*It will also be considered manufacturer whoever fully refurbishes* a device already ...".

⁹⁹ NL, UK, Cion reinstate Cion proposal.

¹⁰⁰ The highlighted text is reinstated.

¹⁰¹ DS 1189/13 IT add “*located outside the European Union*”;

- (24) ‘health institution’ means an organisation whose **primary**¹⁰² purpose is the care or treatment of patients or the promotion of public health¹⁰³;
- (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;

¹⁰² **HU** Delete “*primary*”. **NL, Cion** reinstate "*primary*". **UK** suggests to include also research; **IE, NL** support;

¹⁰³ **ES** Delete: "*or the promotion of public health*".

~~(28a)~~¹⁰⁴ *'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;*^{105 106}

(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;

¹⁰⁴ DS 1937/13 FR add definition of "state of the art".

¹⁰⁵ 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.'*"

¹⁰⁶ BE, DK, DE, ES, LT, PL, SE, UK, Cion delete this definition.

Definitions related to clinical evaluation and clinical investigations¹⁰⁷:

(32) ‘clinical evaluation’ means the assessment and analysis¹⁰⁸ 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;¹⁰⁹

(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;¹¹⁰

¹⁰⁷ 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.

¹⁰⁸ **DS 1002/14 DE** replace “*the assessment and the analysis*” with “*a systematic and planned process to continuously generate, collect and analyse*”

¹⁰⁹ **DK, PL** reinstate Cion proposal.

¹¹⁰ **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***¹¹¹ 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***¹¹²;
- (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;
- 113
- (37a) ***‘subject’ means an individual who participates in a clinical investigation either as recipient of an investigational product or as control;***¹¹⁴
- (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;***¹¹⁵

¹¹¹ **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.

¹¹² ~~This text, introduced in document 12538/14 has been moved.~~

¹¹³ This definition as here reworded closely follows that that in Regulation (EU) No 536/2014 on clinical trials.

¹¹⁴ Definition from **DS 1002/14 DE**.

¹¹⁵ Definition from GHTEF/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;~~*^{116 117}
- (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;~~*^{118 119}
- (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);~~*¹²⁰
- (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;~~*¹²¹

¹¹⁶ Definition from GHTF/SC/N4:2012.

¹¹⁷ **IE** delete this definition.

¹¹⁸ Definition from **DS 1002/14 DE**.

¹¹⁹ Definition deleted following a suggestion from **UK**.

¹²⁰ Definition deleted following a suggestion from **UK**.

¹²¹ 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**¹²² 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;^{123 124}*
- (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;^{125 126}*
127
- (37j) *‘coordinating investigator’ is an investigator who is appointed by the sponsor to coordinate work in a multicentre clinical investigation;^{128 129 130}*

¹²² ES, NL, Cion against “*identical*”; PT suggests to consider similar technical characteristics and the same biological and clinical characteristics, following MEDDEV.

¹²³ 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;*".

¹²⁴ Original definition in 12538/14 from **DS 1002/14 DE**.

¹²⁵ 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;*".

¹²⁶ Original definition in 12538/14 from **DS 1002/14 DE**.

¹²⁷ NL, UK delete this definition.

¹²⁸ There is no corresponding definition in Regulation (EU) No 536/2014 (on clinical trials).

¹²⁹ Definition from **DS 1002/14 DE**

¹³⁰ NL, UK delete this definition.

- (37k) *'informed consent' means ~~a statement by which~~ a subject's free and voluntarily ~~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;*^{131 132 133}
- (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;*¹³⁴
- (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;

¹³¹ Original definition from **DS 1002/14 DE**.

¹³² 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;*"

¹³³ NL delete this definition.

¹³⁴ 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 available¹³⁵ or put into service for the purpose of identifying any need to immediately apply any necessary ~~corrections~~, corrective or preventive actions.¹³⁶

(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;

¹³⁵ DK, PL add “made available”.

¹³⁶ 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**¹³⁷ 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,¹³⁸
- serious public health threat;

139

(44a) ‘serious public health threat’ means any event type, which results in imminent risk of death, serious ~~injury~~ deterioration in state of health¹⁴⁰, or serious illness that may requires prompt remedial action;^{141 142 143}

¹³⁷ The highlighted text is reinstated.

¹³⁸ 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.

¹³⁹ UK Add "- foetal distress, foetal death or a congenital abnormality or birth defect;".

SE support.

¹⁴⁰ The highlighted text is reinstated.

¹⁴¹ 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.”

¹⁴² Definition from GHTEF/SC/N4/2012 Edition 2.

¹⁴³ 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 situation¹⁴⁴ ~~including product design modifications as well as modifications concerning the production process or technique~~¹⁴⁵;
- (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**¹⁴⁶ 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;

147

¹⁴⁴ **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*”.

¹⁴⁵ **DK, UK, PL** opposed to addition. Prefer Cion text.

¹⁴⁶ **DS 6804/14 DE** add “*check and to ensure that ~~products~~ devices*”

¹⁴⁷ **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,***¹⁴⁸ 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.

¹⁴⁸ Text added following a suggestion from UK. In MDEV-54 it was pointed out that this power touches on the scope of the Regulation, making the list in Annex XV, in principle, an open list.

Article 3

Regulatory status of products¹⁴⁹

1. ~~The~~ *Without prejudice to Article 2(2) of Directive 2001/83¹⁵⁰, at a duly substantiated request of a Member State¹⁵¹, the Commission may shall¹⁵², at the request of a Member State or on its own initiative and following consultation with after consulting the MDCG and interested parties¹⁵³*, 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.*

¹⁴⁹ **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;"~~

¹⁵⁰ Pcy proposal in response to issue raised by BE and DK.

¹⁵¹ DE not agree on the wording "at a duly substantiated request"; AT support

¹⁵² FR Replace: "may" with "shall". UK Against. DE, AT add a deadline for acting.

¹⁵³ 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),~~¹⁵⁴ 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.
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¹⁵⁴ **DK, ES, SE, Cion** delete “*through MDCG referred to in Article 80(d)*”.

ANNEX XV^{155 156}

**LIST OF PRODUCTS¹⁵⁷ COVERED BY THE LAST SUBPARAGRAPH
 SUBPARAGRAPH OF THE DEFINITION OF 'MEDICAL DEVICE'
 REFERRED TO IN NUMBER (1) OF ARTICLE 12(1a)¹⁵⁸**

1. Contact lenses *or equivalent articles* ~~Articles~~¹⁵⁹ *intended to be introduced into or onto*¹⁶⁰ *the eye with no corrective*¹⁶¹ *function*;¹⁶²
2. Implants *intended to be totally introduced into the human body through surgically invasive means* for modification *of the anatomy* or fixation of body parts¹⁶³ *excluding piercings*;¹⁶⁴

¹⁵⁵ This annex is based on a suggestion from **UK** following the discussions in the WP on 16 September.

¹⁵⁶ Changes compared to the text in document 12772/14 are highlighted.

¹⁵⁷ **ES** considers the defined product groups as too broad.

¹⁵⁸ 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.

¹⁵⁹ **Pcy** proposal in response to **Cion** that found "Articles" too broad and suggested to limit to "contact lenses".

¹⁶⁰ **AT DS 1029/15** add "or onto". **Cion** support.

¹⁶¹ **Cion** replace "corrective" with "medical".

¹⁶² **DE DS 1029/15** replace this entry with "Contact lenses with no corrective optical function". **DK, ES, NL** support.

¹⁶³ **DK** delete "fixation of body parts". Paragraph 2 should be better defined, piercings and tattoos should be excluded. **COM** supports.

¹⁶⁴ **DE DS 1029/15** replace this entry with "Products intended to be totally or partially introduced into the human body through surgically invasive means for the purposes of modifying the physical appearance of human beings with the exception of tattooing products and piercings.". **NL** support.

3. **Substances, combinations of substances, or articles intended to be used for facial** ~~Facial~~ or other dermal or mucous membrane fillers **filling by subcutaneous** ¹⁶⁵ ~~or~~ **intra**dermal **injection or other introduction**; ^{166 167 168 169}
4. Equipment **intended to be used to reduce, remove or destroy adipose tissue**¹⁷⁰, such as **equipment** for liposuction, **lipolysis or lipoplasty**; ^{171 172}
5. Invasive laser equipment intended to be used on the human body;
6. **High intensity electromagnetic radiation (infra-red, visible light and**¹⁷³ **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**¹⁷⁴ **skin resurfacing, tattoo**¹⁷⁵ **or hair removal**; ¹⁷⁶
- 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**; ¹⁷⁷

¹⁶⁵ AT DS 1029/15 add "*submucous*".

¹⁶⁶ DE DS 1029/15 this entry is redundant. Products covered in entry 2.

¹⁶⁷ ES, Cion there are fillers which are not injected. ES therefore replace "*injection*" by "*introduction*".

¹⁶⁸ AT DS 1029/15 add "*or other introduction*".

¹⁶⁹ DK prefers original Cion proposal

¹⁷⁰ HR delete examples from paragraphs 4 and 6.

¹⁷¹ DE DS 1029/15 replace this entry with "*Equipment for not medically indicated liposuction, lipolysis and lipoplasty*". NL supports.

¹⁷² DK replace paragraph 4 with "*Equipment for liposuction, lipolysis or lipoplasty*".

¹⁷³ AT DS 1029/15 replace "*and*" by "*and/or*".

¹⁷⁴ DE DS 1029/15 add "*not medically indicated*".

¹⁷⁵ AT DS 1029/15 products for tattooing and piercing must be explicitly excluded. ES, NL same request.

¹⁷⁶ DK replace paragraph 6 with: "*invasive laser equipment intended to be used on the human body for skin resurfacing or tattoo removal and intense pulsed light equipment for hair removal*".

¹⁷⁷ DK, DE, ES, NL, Cion against or reserves on including these products. They raise lots of issues e.g. ethical.

7. ~~*Tooth whitening or bleaching products with a concentration of hydrogen peroxide higher than 6%.*~~¹⁷⁸

¹⁷⁸ **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 REQUIREMENTS¹⁷⁹

I. General requirements

...

- 6.¹⁸⁰ For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, the general requirements set out in Sections 1 and 5¹⁸¹ shall be understood that the device, when used under the conditions and for the purposes intended, shall not present any risk or only ~~the a minimal, minimum~~ acceptable risks¹⁸² related to the product's use which is consistent with a high level of protection for the safety and health of persons^{183 184}.

II. Requirements regarding design and construction

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) ...

¹⁷⁹ 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.

¹⁸⁰ The footnotes in Section 6 are taken from document DS 1536/14.

¹⁸¹ **AT** add reference to Section 2b.

¹⁸² The aim of this piece of legislation is risk minimization. The standard concept for addressing such issues is "*maximum acceptable risk*", **Pcy** consequently proposes not to use "*minimum acceptable risk*" which is not used elsewhere in this piece of legislation.

¹⁸³ It was not decided which safety requirement should apply to such products.

¹⁸⁴ **DK, DE, SE** against including aesthetic devices into the scope of the Regulation; **BE, ES, AT** in favour of including aesthetic devices into the scope of the regulation; **AT, DE** suggest to provide for specific requirements; **NL, UK** support for specific requirements; **AT, UK** ask for a transitional period for the implementation of the regulation for aesthetic devices.

- (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*¹⁸⁵;
- (c) ...

9. Devices incorporating a substance considered to be a medicinal product and devices *that are composed of substances or combinations of substances intended to be ingested, inhaled or administered rectally or vaginally that are absorbed by or locally dispersed*¹⁸⁶ 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.

¹⁸⁵ 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.

¹⁸⁶ **DE DS 1029/15** "*locally dispersed*" should be defined in Article 2.

9.2. Devices that are composed of substances or combinations 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 body¹⁸⁷ shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC¹⁸⁸ *including*¹⁸⁹ *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*¹⁹⁰.

...

19.2. Information on the label

The label shall bear the following particulars:

(a) ...

...

¹⁸⁷ 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.~~

¹⁸⁸ **DE DS 1029/15** prefer to lay down requirements in Annex I to this regulation instead of referring to Directive 2001/83/EC.

¹⁸⁹ **DE DS 1029/15** add "*... including the relevant scientific guidelines specifying these requirements published by the EMA and consideration ...*".

¹⁹⁰ **DE DS 1029/15** delete "*, as laid down in the applicable conformity assessment procedure in this Regulation.*". **DK** questions the meaning of the same part of the sentence.

- (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.*

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 metabolism¹⁹¹ 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 ...

¹⁹¹ DE DS 1029/15 delete " and its products of metabolism " .

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.*

192

(c) In the case of devices ...

¹⁹² CZ DS 1029/15 add new indent:

"- *sensitisation, irritation, implantation and heamocompatibility*".

ANNEX VII
CLASSIFICATION CRITERIA

6.9 Rule 21

Devices that are composed of substances or combinations 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 applied administered on skin or mucous membrane* and that are absorbed by or *locally* dispersed in the human body are:-

- in class III¹⁹³ *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 administered¹⁹⁴ on skin or mucous membrane via a body orifice, in which case they are in class IIa.*^{195 196}

¹⁹³ **DE DS 1029/15** replace "III" by "IIb" and delete ", or their products of metabolism,".

¹⁹⁴ **FR DS 1007/15** replace "administered" with "deposited".

¹⁹⁵ **DE DS 1029/15** replace this indent with "In class IIa in all other cases".

¹⁹⁶ **Cion** rules on what falls into Class IIa are not sufficiently clear.

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 safety¹⁹⁷ of the device shall be verified by analogy with the relevant requirements¹⁹⁸ laid down in Annex I to Directive 2001/83/EC¹⁹⁹. 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 certificate²⁰⁰ before issuing a certificate.²⁰¹*

¹⁹⁷ CZ DS 1029/15 replace "quality and safety" with "quality, safety and efficacy".

¹⁹⁸ DK finds "the relevant requirements" and "include consideration" too unclear.

¹⁹⁹ DE DS 1029/15 add "as well as relevant scientific guidelines published by the EMA and specifying these requirements".

²⁰⁰ Cion questions if this is the correct procedure.

²⁰¹ DE DS 1029/15 delete this indent.

- (c) *In addition, for devices, or their products of metabolism, that are²⁰² absorbed by the human body in order to achieve their intended effect²⁰³, the notified body shall seek²⁰⁴ 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.²⁰⁵*
- (d) *The opinion of the medicinal products competent authority or the EMA shall be drawn up within 150 days.²⁰⁶*
- (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.²⁰⁷*

²⁰² CZ DS 1029/15 add "*dispersed or*".

²⁰³ CZ DS 1029/15 delete "*in order to achieve their intended effect*".

²⁰⁴ FR DS 1007/15 replace the first part of the sentence with "*In addition, for devices in class IIb and III, the notified body shall seek...* ".

²⁰⁵ DE DS 1029/15 delete this indent.

²⁰⁶ DE DS 1029/15 delete this indent.

²⁰⁷ DE DS 1029/15 delete this indent.

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 definitions²⁰⁸

Article 1

Scope

- 1.²⁰⁹ 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 putting into service of *in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices for human use*~~²¹⁰ 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***²¹¹.

- 1a.***²¹² 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'.

²⁰⁸ This chapter is taken from the consolidated text under preparation by the IT Presidency.

²⁰⁹ This paragraph is aligned to the wording of the proposed Regulation on Medical Devices.

²¹⁰ **AT** add “*and performance evaluation devices*” . **IE** support

²¹¹ **Pcy** last sentence is subject to revision depending on decisions in other parts of the regulation.
DS 1029 DE Scrutiny reservation on the last sentence. **DE** alternative: replace “*applies to*” by “*lays down rules on*”

²¹² 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 ²¹³ 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.***²¹⁴

²¹³ NL replace “*specifically*” with “*exclusively*”

²¹⁴ UK delete e), AT support e), IE insert definition of “*research use only*”.

- 3.²¹⁵ Any device which, when placed on the market or used in accordance with the manufacturer's instructions²¹⁶, 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~~.^{217 218}
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.

²¹⁵ Following MD Proposal - **BE** suggestion circulated during the WP meeting on 11-12 September 2014 (WD MDEV-57)

²¹⁶ DE: Replace „used in accordance with the manufacturer's instructions” by „put into service” (DS 1029/15).

²¹⁷ **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

²¹⁸ **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. **DE** opposes (DS 1029/15).

5. This Regulation shall not affect the application of Council Directive 96/29/Euratom, nor of Council Directive 97/43 2013/59/Euratom.²¹⁹
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 devices²²⁰ **may only be supplied on a medical prescription or that their application must be accompanied by specific professional counselling.**²²¹
- 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.*²²²
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 Regulation²²³

²¹⁹ Correction, following a suggestion in **DS 1416/14 AT**

²²⁰ **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.

²²¹ Suggestion from **DS 1416/14 AT**.

²²² **SE** suggestion during the WP meeting on 11-12 September 2014 (WD MDEV-57).

²²³ **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^{224, 225}, material or other article,²²⁶ **whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,**²²⁷ 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*²²⁸ process or state,
 - control or support of conception²²⁹,
 - ~~cleaning,~~²³⁰ ~~disinfection or sterilisation of any of the above-mentioned products,~~
 - ~~providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,~~²³¹

²²⁴ Pcy proposes to reinstate “reagent” following requests from ES, AT, PT Cion.

²²⁵ AT add “*or other product for in vitro use*” (DS 1029/15)

²²⁶ DS 1867/12 AT add “*including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products*”

²²⁷ Proposal from DE (DS 1029/15). ES, SE, UK, FR oppose. For complete DE proposals on Article 2.1.1 see DS 1029/15

²²⁸

²²⁹ DE propose to move this indent to the next sentence. (DS 1029/15)

²³¹ Alignment with the definition in the MD Regulation.

DE: delete “*blood and tissue donations*” (DS 1029/15)

- ~~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;~~^{232 233 234}

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.

235

²³² Following MD proposal

²³³ **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*”

²³⁴ **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

²³⁵ **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.~~^{236 237}

~~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.~~²³⁸

(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 or²³⁹ 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.

²³⁶ **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.*”

²³⁷ **IE, ES, LT, NL, PL, SK, UK, Cion** delete this subparagraph; **FR** suggests to change the text; **PT** support. **Pcy:** suggest addressing the issue in the context of custom-made devices.

²³⁸ Deletion following the addition of the new paragraph 1a in Article 1 of the MD Regulation.

²³⁹ **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~~^{240 241} by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically^{242 243} enable ~~or assist~~²⁴⁴ the *in vitro* diagnostic medical 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);***

~~(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;~~²⁴⁵

(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;

²⁴¹ ES add "*specifically*". AT, SE, PL Support

²⁴³ ES delete "*specifically*". SE Support

²⁴⁴ FR delete "*assist*" in order to avoid inclusion of laboratory generic use devices. AT, SE, BE support.

²⁴⁵ BE, FR, NL, AT, UK delete (3a).

- (6) 'companion diagnostic' means a device specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy;^{246 247 248}
- (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;

²⁴⁶ **FR, AT, Cion** use FDA definition as basis. **UK** use Parliament amendment 47 as basis. **DE** proposal in **DS 1029/15**, **FR** proposal in **DS 1007/14**.

²⁴⁷ **FR DS 1007/14** replace this definition by:

"'Companion diagnostic' means a device specifically ~~intended~~ designed to:

- *~~select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy~~ identify patients who are most likely to benefit from a corresponding medicinal product, or*
- *identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with a corresponding medicinal product, or*
- *monitor response to treatment by the corresponding medicinal product."*

²⁴⁸ **DE DS 1029/14** replace this definition by:

"'companion diagnostic' means a device specifically ~~intended~~ designed to:
~~select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy~~

- *identify patients who are most likely to benefit from the treatment with a corresponding medicinal product, or*
- *identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with a corresponding medicinal product."*

(8)²⁴⁹ '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.~~²⁵⁰

(8a) *'kit' means a set of components that are packaged*²⁵¹ *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;*²⁵²

(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;*²⁵³

(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 devices²⁵⁴;

(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;

²⁴⁹ NL delete (8).

²⁵⁰ CZ, DE, LT, PT delete "*The single procedure may involve several uses or prolonged use on the same patient*".

²⁵¹ NL replace "packaged" with "intended to be used"

²⁵² This is definition (13f) from document 12538/14. No changes have been done.

²⁵³ This is definition (13g) from document 12538/14. No changes have been done.

²⁵⁴ 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;²⁵⁵

(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 unacceptable risk~~ the absence of unacceptable ~~clinical~~²⁵⁶ risks, when using the device according to the manufacturer's instructions for use;²⁵⁷

(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;²⁵⁸

(12d) '*risk*' means the combination of the probability of occurrence of harm and the severity of that harm;²⁵⁹

²⁵⁵ 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.

²⁵⁶ **ES, PT, Cion** delete "*clinical*".

²⁵⁷ 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.

²⁵⁸ This is definition (13c) from document 12538/14. No changes have been done.

²⁵⁹ 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’;^{260 261 262}

²⁶⁰ This is definition (13e) from document 12538/14. No changes have been done.

²⁶¹ **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."*

²⁶² **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 unacceptable 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)²⁶³ 'manufacturer' means the natural or legal person who manufactures or fully refurbishes²⁶⁴ a device or has a device designed, manufactured or fully refurbished²⁶⁵, and markets that device under his name or trademark²⁶⁶, ***regardless of whether these operations are carried out by that person himself or on his behalf by a third party.***²⁶⁷

~~***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.***~~²⁶⁸

²⁶³ Pcy replace with the 98/79/EC definition.

²⁶⁴ ES Delete: "or fully refurbishes".

²⁶⁵ ES Delete: "or fully refurbished".

²⁶⁶ ES Delete: "or trademark".

²⁶⁷ 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.

²⁶⁸ Following MD proposal.

For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already²⁶⁹ 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;²⁷⁰

- (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*²⁷¹, 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*²⁷² purpose is the care or treatment of patients or the promotion of public health²⁷³;
- (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;

²⁶⁹ **ES** Replace the introductory part of this sentence with: "*It will also be considered manufacturer whoever fully refurbishes* a device already ...".

²⁷⁰ Cion proposal reinstated following interventions by **NL**, **UK** and **Cion**.

²⁷¹ **DS 1189/13 IT** add "*located outside the European Union*".

²⁷² Following MD proposal - **HU** Delete "*primary*". **NL**, **Cion** reinstate *primary*. **UK** suggests to include also research; **IE**, **NL** support;

²⁷³ **ES** Delete: "*or the promotion of public health*".

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;

~~(24a)²⁷⁴ *“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.*~~^{275 276 277}

(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 supports²⁷⁸ the scientific validity and performance for the use of a device as intended by the manufacturer;

²⁷⁴ Following MD Proposal

²⁷⁵ **DS 1937/13 FR** add definition of “state of the art”.

²⁷⁶ **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.’*."

²⁷⁷ **BE, DK, DE, ES, LT, SE, UK, Cion** delete this definition

²⁷⁸ **BE** Replace "that supports" with "supported by".

- (29) 'scientific validity of an analyte' means the association of an analyte to a clinical condition or a physiological state;
- (30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable²⁷⁹, 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;

²⁷⁹ **BE** Delete ", *where applicable*,".

- (37) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;
- (38) 'diagnostic specificity' means the ability of a device to recognize the absence of a target marker associated with a particular disease or condition;
- (39) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;
- (40) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;
- (41) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;
- (42) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;
- (43) 'likelihood ratio' means the likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state;
- (44) 'calibrators and control materials' means any substance, material or article intended by the manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended purpose of that device;
- (45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical performance study;

- (45a) *'equivalence' means the ability of two or more devices, with the same intended purpose, to have ~~similar~~ ~~identical~~ ~~similar~~²⁸⁰ 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 clinically significant difference in the performance of the devices.*²⁸¹
- (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;

²⁸⁰ **ES, NL Cion** object to “*identical*”; **PT** suggests to consider similar technical characteristics and the same biological and clinical characteristics, following MEDDEV.

²⁸¹ **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 available²⁸² or put into service for the purpose of identifying any need to immediately apply any necessary **corrections, corrective or preventive actions.²⁸³**

(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;

²⁸² Following MD proposal - **DK** add “made available”.

²⁸³ **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,²⁸⁴
- serious public health threat;²⁸⁵

(52a)²⁸⁶ '*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;^{287 288}

(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~~²⁸⁹;

²⁸⁴ 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

²⁸⁵ UK Add "- foetal distress, foetal death or a congenital abnormality or birth defect;".

SE support

²⁸⁶ Definition from GHTEF/SC/N4/2012 Edition 2

²⁸⁷ 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."

²⁸⁸ PT add the second paragraph of the definition of 'serious public health threat' given in MEDDEV 2.12-1, rev. 8.

²⁸⁹ 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**²⁹⁰ 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;~~²⁹¹

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];

²⁹⁰ **6804/14 DE** add "check and to ensure that ~~products~~ devices".

²⁹¹ **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 products²⁹²

1. ~~*The Without prejudice to Article 2(2) of Directive 2001/83²⁹³, at a duly substantiated request of a Member State,²⁹⁴ the Commission may shall²⁹⁵, at the request of a Member State or on its own initiative and following consultation with the MDCG and interested parties,²⁹⁶*~~ 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,²⁹⁷ 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.

²⁹² Following MD Proposal Definition from GHTEF/SC/N4/2012 Edition 2.

²⁹³ Following MD Proposal - Pcy proposal in response to issue raised by BE and DK.

²⁹⁴ DE not agree on the wording "at a duly substantiated request"; AT support

²⁹⁵ FR Replace: "may" with "shall". UK Against. DE, AT add a deadline for acting.

²⁹⁶ UK Replace: "on its own initiative" by "and following consultation with the MDCG and interested parties".

²⁹⁷ DK, ES, SE, Cion delete "through MDCG referred to in Article 80(d)".