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NOTE

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and medical devices
No. prev. doc.:	12401/15 PHARM 40 SAN 301 MI 588 COMPET 426 CODEC 1251
No. Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on **medical devices** and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 Proposal for a Regulation of the European Parliament and of the Council on ***in vitro* diagnostic medical devices**

Delegations will find attached the revised addendum 3 to the 'Block 1' document (Chapter I Scope and definitions) setting out the state of discussion after the 1st trilogue on 13 October and technical meeting on 15 October 2015. Related comments and proposals are shaded in yellow.

Explanation of the document layout

X. This paragraph is neither changed by the European Parliament nor by the Council. It is written in plain text, which throughout the text means that it is identical to the Commission proposal and unless it is specifically pointed out it is the same for MD and IVD.

X. This slightly different paragraph is neither changed by the European Parliament nor by the Council. It is written in plain text, which throughout the text means that it is identical to the Commission proposal and since it is from the IVD proposal, it comes after the corresponding MD provision.

Where needed, provisions are preceded by indications **MD** or **IVD** to make clear to what proposal a certain text element belongs.

Where an Article or Section in the MD proposal directly corresponds to an Article or a Section in the IVD text but with another number, this is also indicated.

Please note that the numbering of paragraphs, sections and points is not always continuous since text elements that did not belong to the original Commission proposal have sometimes been deleted. As an example paragraph 1a might be followed by paragraph 1c. This is the result of deletions of text elements at a late stage. It was deemed that references might become incorrect if a renumbering was done at this stage.

Text that is amended by either the EP or the Council occurs in tables

Article Y Z. This paragraph is text from the MD proposal ***changed by the Council (added text in bold italics*** and deleted text in ~~strikethrough~~ compare EP text). ***Elements to note are highlighted in grey.***	**Amendment W** Article Y Z. This paragraph is text from the MD proposal ***changed by the European Parliament (added text in bold italics*** and deleted text in ~~strikethrough~~ compare Council text). ***Elements to note are highlighted in grey***
IVD - Article U T. This paragraph is text from the IVD proposal ***changed by the Council (added text in bold italics*** and deleted text in ~~strikethrough~~ compare EP text) and is different from the corresponding MD paragraph. ***Elements to note are highlighted in grey.***	IVD - Article U T. This paragraph is text from the IVD proposal ***changed by the EP (added text in bold italics*** and deleted text in ~~strikethrough~~ compare EP text) and is different from the corresponding MD paragraph. ***Elements to note are highlighted in grey***
Comment: This is the place for comments, e.g. to mention .what issue it concerns (for issues addressed in more than one place e.g. ingested products.	
Compromise text:	

Chapter I

Scope and definitions

Article 1

Scope

Article 1 1. This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with by medical devices and accessories to medical devices that are placed~~ ***concerning the placing on the market, making available*** on the market or put***ting*** into service ***of medical devices and accessories to medical devices for human use*** in the Union ~~for human use~~. ***This regulation also applies to clinical investigations on medical devices conducted in the Union.***	**Amendment 59:** Article 1 1. This Regulation establishes rules to be complied with by medical devices ~~and~~ accessories ***for human use,*** to medical devices ***and medical devices for aesthetic purposes*** that are placed on the market or put into service in the Union ~~for human use.~~
IVD - Article 1 1. This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with by medical devices and accessories to medical devices that are placed~~ ***concerning the placing on the market, making available*** on the market or put***ting*** into service ***of medical devices and accessories to medical devices for human use*** in the Union ~~for human use~~. ***This regulation also applies to performance studies on medical devices conducted in the Union.***	
Comment: Difference in ***Council text****with IVD consists of having "performance studies" instead of "clinical investigations". IVD differences highlighted in grey.* *Issue* ***aesthetic devices****, related to:* *- Amendment 60 (article 1(1b)) and Amendment 69 (article 2(1)(2a) - definition of aesthetic devices);* *- Article 1(1a), Article 1(1b), Article 2(1)(1) last paragraph, Annex I, Part I, Section 6; Annex I, Part III, Section 19.3(r), Annex V, Part A, Section 2.16, Annex XV*	
Compromise text: Council text	

Article 1 – continued ***1a.*** ***This regulation shall also apply to the groups of products without an intended medical purpose that are listed in Annex XV as from the date of entry into force of common specifications or the date of application of this Regulation, whichever is the latest, adopted pursuant to Article 7, taking into account the state of the art, and in particular existing standards for analogous devices with a medical purpose, based on a similar technology. The common specifications for a group of products listed in that annex shall address, at least, application of risk management and of the general safety and performance requirements set out in Annex I and clinical evaluation.*** ***The necessary common specifications shall be adopted as soon as possible following entry into force of this Regulation and at the latest so that they enter into force on the date of application of this Regulation.***	
*Issue **aesthetic devices**, related to:* *- Amendment 60 (article 1(1b)) and Amendment 69 (article 2(1)(2a) - definition of aesthetic devices);* *- Article 1(1), Article 1(1b), Article 1(c), Article 2(1)(1) last paragraph, Annex I, Part I, Section 6; Annex I, Part III, Section 19.3(r), Annex V, Part A, Section 2.16, Annex XV*	
Compromise text: *EP can accept the principle, but has questions related to scope and timing of application for common specifications. Also need to agree with COM on what is covered by CS (risk management only).*	

Article 1 - continued ***1b.*** For the purposes of this Regulation, medical devices***,*** ~~and~~ accessories to medical devices ***and products listed in Annex XV to which this Regulation applies pursuant to paragraph 1a*** shall hereinafter be referred to as 'devices'.	**Amendment 60:** Article 1(1) - second subparagraph For the purposes of this Regulation, medical devices ~~and,~~ accessories to medical devices ***and devices for aesthetic purposes*** shall hereinafter be referred to as 'devices'.
IVD - Article 1 - continued ***1a.*** 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'.	
*Comment: in IVD this is para 1a and sticks to Commission text. Differences in MD and IVD text highlighted in grey. Compare comments regarding **Aesthetic devices** under 1(1).*	
Compromise text: Council text	

Article 1 - continued ***1c.*** ~~The~~ ***Where justified in view of the similarity between a device with a medical purpose placed on the market and a product without a medical purpose in respect of their characteristics and risks, the*** Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in ***Article 1(1a)*** ~~the last subparagraph of number (1) of paragraph 1~~, ***by adding new groups of products*** ~~in the light of technical progress~~***, in order to protect the health and safety of users or other persons or other aspects of public health*** ~~and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks~~.	
Comment: Former article 2(2). No correspondence in IVD. Issue ***aesthetic devices****. See comments under 1(1).*	
Compromise text: Council text	

MD

2. This Regulation shall not apply to:

[All paragraphs of Article 1(2) completely different in IVD.]

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

Article 1(2) - continued (b) medicinal products ***as defined in*** ~~covered by~~ Directive 2001/83/EC ~~and advanced therapy medicinal products covered by~~ ~~Regulation (EC) No 1394/2007~~. In deciding whether a product falls under Directive 2001/83/EC ~~or Regulation (EC) No 1394/2007~~ or under this Regulation, particular account shall be taken of the principal mode of action of the product.	
Issue **-** delineation towards medicinal products and advanced therapy medicinal products	
Compromise text: Council text	

Article 1(2) - continued ***(ba) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;***	
Issue **-** delineation towards medicinal products and advanced therapy medicinal products	
Compromise text: Council text	

Article 1(2) – continued (c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market ***or put into service*** ~~or used in accordance with the manufacturer's instructions~~, such blood products, plasma or cells, except for devices referred to in paragraph 4;	
No correspondence in IVD.	
Compromise text: *Council text*	

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

Article 1(2) – continued (e) transplants, tissues or cells of ~~human or~~ animal origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of ~~human or~~ animal origin, or their derivatives, which are non-viable or are rendered non-viable.	
No correspondence in IVD. See 1(2)(ea)	
Compromise text: *Council text*	

Article 1(2) - continued ~~However, human tissues and cells that are non-viable or are rendered non-viable and that have undergone only non-substantial manipulation, in particular those listed in Annex I of Regulation (EC) No 1394/2007, and products derived from such tissues and cells, shall not be considered devices manufactured utilising tissues or cells of human origin or their derivatives~~; ***(ea) transplants, tissues or cells of human origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;***	
No correspondence in IVD. See 1(2)(e)	
Compromise text: *Council text*	

Article 1(2) - continued (f) products, ***other than those referred to in points (c), (e) and (ea)***, 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***;	**Amendment 61:** Article 1(2) - continued (f) ***all*** products that contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable~~,~~ ***and that achieve their intended purpose by pharmacological, immunological or metabolic means***, including ***certain*** living micro-organisms, bacteria, fungi or virus;
No correspondence in IVD.	
Compromise text: Council text	

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

IVD

2. This Regulation shall not apply to:

[All paragraphs completely different compared to MD]

IVD Article 1 (a) products for general laboratory use ***or research-use only products*****,** unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;	
No correspondence in MD	
Compromise text: Council text	

(b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;

IVD Article 1(2) (c) ~~higher metrological order~~ ***internationally certified*** reference materials~~.~~***;*** ***(d) materials used for external quality assessment schemes;.***	
No correspondence in MD.	
Compromise text: Council text	

Article 1 - continued 3. Any device which, when placed on the market or ***put into service*** ~~used in accordance with the manufacturer's instructions~~ incorporates as an integral part an *in vitro* diagnostic medical device as defined in Article 2 of Regulation (EU) […/..] [on *in vitro* diagnostic medical devices] shall be governed by this Regulation~~, unless it is covered by Article 1(3) of that Regulation~~. The ~~relevant general safety and performance~~ requirements ~~set out in Annex I~~ of that Regulation shall apply ~~as far as the safety and performance of~~ ***to*** the *in vitro* diagnostic medical device part ~~are concerned~~	
IVD – Article 1 - continued 3. Any device which, when placed on the market or ***put into service*** ~~used in accordance with the manufacturer's instructions~~ incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices ~~without being an *in vitro* diagnostic medical device,~~ shall be governed by ~~this~~ ***that*** Regulation~~, provided that the principal intended purpose of the combination is that of an *in vitro* diagnostic medical device referred to in Article 2(2) of this Regulation~~. The ~~relevant general safety and performance~~ requirements ~~set out in Annex I to~~ ***of this*** ~~Regulation (EU) [Ref. of future Regulation on medical devices]~~ ***regulation*** shall apply ~~as far as the safety and performance of~~ ***to*** the ~~medical device part that is not an~~ *in vitro* diagnostic medical device ***part*** ~~are concerned~~.	
If mixed MD/IVD, primarily MD applies with IVD Regulation applying for IVD part. Therefore, Article 1(3) is also treated in IVD two-column.	
Compromise text: *Council text*	

Article 1 – continued 4. Where a device, when placed on the market or ***put into service*** ~~used in accordance with the manufacturer's instructions~~, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation. However, if the action of the medicinal substance is ***principal,*** not ancillary to that of the device, the product shall be governed by Directive 2001/83/EC ***or Regulation (EC) No 726/2004, as applicable***. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.	**Amendment 62:** Article 1 - continued 4. Where a device, when placed on the market or used in accordance with the manufacturer's instructions, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation ***following consultation with the national medicine agency or with the EMA***.
No correspondence in IVD	
Compromise text: Council text. However, PE insists on addition of last two lines. We will come back to this in the discussions on block 4.	

Article 1 – continued 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.	
No correspondence in IVD. Technical issue - intention to cover also centrally authorised products	
Compromise text: Council text	

Article 1 - continued ***5a.*** ***Where a device, when placed on the market or put into service, incorporates, as an integral part, tissues or cells of human origin or their derivatives covered by Directive 2004/23/EC with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation. In this case the provisions for donation, procurement and testing laid down in Directive 2004/23/EC shall apply.*** ***However, if the action of the tissues or cells or their derivatives is principal, not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by Directive 2004/23/EC. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.***	
No correspondence in IVD. Compare EP Amendment 63. Both amendments go into the same direction of applying legislation relevant to tissues or cells of human origin even if part of a MD.	
Compromise text: Council text	

	Amendment 63 Article 1 - continued ***5a.*** ***This Regulation shall not impede the continued application of measures within Directive 2002/98/EC and its five Daughter Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.*** ***Articles 10 (Personnel), 14 (Traceability), 15 (Notification of serious adverse events and reactions), 19 (Examination of donors) and 29 (Technical requirements and their adaptation to technical and scientific progress) of Directive 2002/98/EC ensure donor and patient safety and as such those existing standards shall be maintained.***
No correspondence in IVD. Compare EP Amendment 63. Both amendments go into the same direction of applying legislation relevant to tissues or cells of human origin even if part of a MD.	
Compromise text: EP insists. Can Council accept?	

Article 1 – continued 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~~.	
Identical text and change in IVD Article 1(4).	
Compromise text	

Article 1 – continued 7. This Regulation shall not affect the application of Council Directive ~~96/29/Euratom nor of Council Directive 97/43~~***2013/59***/Euratom	
Identical text and change in IVD Article 1(5). Technical issue - update since new Directive adopted.	
Compromise text	

No Council amendment	**Amendment 64 and IVD amendment 41** Article 1 - continued ***7a. The regulation of medical devices at Union level shall not interfere with the freedom of Member States to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.***
Corresponding to IVD Amendment No 41, referring to IVDs instead.	
Presidency proposal: Accept EP amendment subject to verification by the Council Legal Service and possible redrafting.	

Article 1 - continued 8. This Regulation shall not affect national laws ~~which require~~ ***concerning the organisation, delivery or financing of health services and medical care, such as, the requirement*** that certain ***medical*** devices may only be supplied on a medical prescription***, the requirement that only certain health professionals or health care institutions may dispense or apply certain medical devices or that their application must be accompanied by specific professional counselling***.	
No Council amendment	**IVD amendment 41** Article 1 – continued 6. This Regulation ***provides that certain devices may only be supplied on a medical prescription but*** it shall not affect national laws which require that certain ***other*** devices may also only be supplied on a medical prescription. ***Direct to consumer advertising of devices classed as prescription only by this Regulation shall be illegal.*** ***- The following devices may only be supplied on a medical prescription:*** ***1) Class D devices;*** ***2) Class C devices in the following categories:*** ***(a) devices for genetic testing;*** ***(b) companion diagnostics.*** ***- By derogation, justified by the attainment of a high level of public health protection, Members States may maintain or introduce national provisions allowing special class D tests to also be available without a medical prescription. In that case, they shall duly inform the Commission.*** ***- The Commission shall be empowered to adopt delegated acts in accordance with Article 85 to decide that other class C tests may only be supplied on a medical prescription after consultation with stakeholders.***
MD Article 1(8) Corresponds to IVD Article 1(6). *EP has not amended the corresponding MD text, but has amended the IVD text*	
Compromise text: To be discussed at the IVD trialogue	

Article 1 - continued ***8a. This Regulation shall be without prejudice to national law regarding public access to official documents and regarding freedom of the press and freedom of expression in other media.***	
Identical with IVD Article 1(6a)	
Compromise text: Council text	

Article 1 - continued ~~9.~~ ~~References to a Member State in this Regulation shall be understood as 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.~~	
Corresponds to IVD Article 1(7) - also deleted there.	
Compromise text: Council text	

Article 2

Definitions

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

[IVD - no paragraph numbering in Article 2.]

Definitions related to devices:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:	**Amendment 65 and IVD Amendments 42 and 43** (1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific ***direct or indirect*** medical purposes of:
– diagnosis, prevention, monitoring, treatment or alleviation of disease, – diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability, – investigation, replacement or modification of the anatomy or of a physiological ***or pathological*** process or state, – ~~control or support of conception~~, – ~~disinfection or sterilisation of any of the above-mentioned products,~~ – ***providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,***	**Amendment 66 and IVD Amendments 42 and 43 - continued** – diagnosis, prevention, monitoring, ***prediction, prognosis*** treatment or alleviation of disease, **IVD Amendments 42 and 43 - continued** ***– providing information concerning direct or indirect impacts on health,***
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. ***Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.***	
~~The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.~~	**Amendment 67** The implantable or other invasive products, ***as well as products using external physical agents,*** intended to be used for human beings, which are listed ***on a non-exhaustive basis*** in Annex XV, shall be considered medical devices ***for the purposes of this Regulation***, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.

IVD

(1) ‘medical device’ means ***'medical device' as defined in Regulation (EU) No [Reference to the future Regulation on medical devices].*** ~~any instrument, apparatus, appliance, software, implant, reagent material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:~~

- ~~diagnosis, prevention, monitoring, treatment or alleviation of disease,~~
- ~~diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,~~
- ~~investigation, replacement or modification of the anatomy or of a physiological process or state,~~
- ~~control or support of conception,~~
- ~~disinfection or sterilisation of any of the above-mentioned products.~~

~~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.~~

EP amended the definition of medical devices differently for the MD and IVD regulation. IVD amendments only (as they partially took MD text) highlighted in grey.

Compromise text - include AM 66 ('prediction, prognosis') .

(1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, ***prediction, prognosis*** treatment or alleviation of disease
- investigation, replacement or modification of the anatomy or of a physiological ***or pathological*** process or state,
- ***providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,***

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

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

IVD Article 2

(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:

[No correspondence in MD for this definition]

IVD - Article 2 - definition (2) - continued – concerning a physiological or pathological ***process or*** state; – concerning a congenital abnormality;	**IVD Amendment 44** - concerning ~~a~~ congenital ~~abnormality~~ ***physical or mental impairments,,;***
No correspondence in MD	
Compromise proposal: Accept the EP amendment.	

– concerning the predisposition to a medical condition or a disease;

– to determine the safety and compatibility with potential recipients;

– to predict treatment response or reactions;

– to define or monitor therapeutic measures.

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

No Council amendment	**IVD Amendment 45** Article 2 - definition (2) continued with subparagraph (2) ***In vitro diagnostic medical devices used for DNA-testing shall be subject to this Regulation.***
*No correspondence in MD. **Issue**: genetic testing. Does this belong to Article 1 instead ?*	
Presidency proposal: Accept the EP amendment.	

Article 2(1) - continued (2) 'accessory to a medical device' means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable ~~or assist~~ the device(s) to be used in accordance with its/their intended purpose(s) ***or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)***;	**Amendment 68** Article 2(1) - continued (2) ***'***accessory to a medical device***'*** means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable ~~or assist~~ the device(s) to be used in accordance with its/their intended purpose(s); ***or to specifically assist the medical functionality of the medical device(s) in view of its/their intended purpose(s);***
Corresponds to IVD Article 2 definition (3). Same change by both Institutions. *EP has made no amendment to the corresponding IVD definition.*	
Compromise proposal: Council text. EP can withdraw this amendment.	

No Council amendment	**Amendment 69** Article 2(1) - continued ***(2a) 'device for aesthetic purposes' means any instrument, apparatus, appliance, software, implant, material, substance or other article, intended by the manufacturer to be used, alone or in combination, for the purposes of modifying the physical appearance of human beings, without any therapeutic or reconstructive intent, by implanting it in the human body, attaching it to the surface of the eye or using it to induce a tissue or cell reaction on external or non-external parts of the human body.*** ***Tattooing products and piercings shall not be considered devices for aesthetic purposes.***
*Issue **aesthetic devices**, **See: 1(1)***	
Compromise text: Amendment rejected.	

	Amendment 70
Article 2(1) - continued (3) 'custom-made device' means any device specifically made in accordance with a written prescription of ~~a doctor of medicine, of a dental practitioner or of~~ any ~~other~~ person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient. However, mass-produced devices which need to be adapted to meet the specific requirements of ~~a doctor of medicine, a dental practitioner or~~ any ~~other~~ professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of ~~doctors of medicine, dental practitioners or~~ any ~~other~~ authorised person shall not be considered to be custom-made devices;	Article 2(1) - continued (3) 'custom-made device' means any device specifically made ~~in accordance with~~ ***by an appropriately qualified person exclusively to meet a specific patient's individual requirements and needs. In particular a 'custom-made device' may be produced on the basis of*** a written prescription of a doctor of medicine, of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics~~, and is intended for the sole use of a particular patient.~~ However, mass-produced devices which need to be adapted to meet the specific requirements of a doctor of medicine, a dental practitioner or any other professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of doctors of medicine, dental practitioners or any other authorised person shall not be considered to be custom-made devices;
No correspondence in IVD.	
Compromise proposal: (3) 'custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient ***exclusively to meet their individual requirements and needs***. However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;	

Article 2(1) - continued (4) 'active device' means any device, the operation of which depends on ~~a source of electrical energy or any~~ ***a*** source of ~~power~~ ***energy*** other than that ~~directly~~ generated ***by the human body for that purpose or*** by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices. ~~Stand alone software shall be considered an active device;~~	**Amendment 71** Article 2(1) - continued (4) 'active device' means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated ***by the human body or*** by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices. **Amendment 72** ~~Stand alone software shall be considered an active device;~~
No correspondence in IVD	
Compromise text: *Council text.* *Commission asks to reconsider deletion of "Stand alone software shall be considered an active device" which has the consequence that standalone software is classified as class I in all cases. Commission will send a note to EP and Council.*	

IVD Article 2 - continued (4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons;	**IVD Amendment 46** Article 2(1) - continued (4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons, ***including testing services offered to lay persons by means of information society services;***
No correspondence in MD	
Presidency proposal: *(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons,* ***including devices used for testing services offered to lay persons by means of information society services;***	

MD Article 2(1)

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

– to be totally introduced into the human body or

– to replace an epithelial surface or the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be considered an implantable device;

[No correspondence in IVD]

IVD Article 2

(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 ***by a health professional***; *(addition accepted by EP)*

[No correspondence in MD]

(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;

IVD Article 2 - continued (6) 'companion diagnostic' means a device ***which is essential for the safe and effective use of a corresponding medicinal product to:*** - ***identify patients who are most likely to benefit from the medicinal product, or;*** - ***identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with the medicinal product, or;*** - ***monitor response to treatment by the medicinal product for the purpose of adjusting treatment to achieve improved safety or effectiveness;*** ~~specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy~~;	**IVD Amendment 46 – continued** Article 2 - continued (6) 'companion diagnostic' means a device specifically intended ~~to select~~ ***for and essential to the selection of*** patients with a previously diagnosed condition or predisposition as ***suitable or unsuitable*** ~~eligible~~ for a ~~targeted~~ ***specific*** therapy ***with a medicinal product or a range of medicinal products***;
No correspondence in MD. To be discussed at the 3rd trilogue.	
Compromise text:	

(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;

Article 2(1) - continued (8) 'single-use device' means a device that is intended to be used on an individual patient during a single procedure. ~~The single procedure may involve several uses or prolonged use on the same patient;~~	**Amendment 73** Article 2(1) - continued (8) ′single-use device′ means a device that is intended to be used on an individual patient during a single procedure ***and which has been tested and demonstrated to be impossible to reuse***.
Corresponds to same IVD number, but no EP amendments of this definition in the IVD Regulation. *Issue* ***reprocessing***,	
Compromise text: To be discussed at 2nd trilogue.	

Article 2(1) – continued ***(8a)*** ***'falsified device' means any device with a false presentation of its identity, and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights.***	
Comment: Corresponds to IVD Article 2 definition (8a). See Chapter II, EP Chapter VI, Amendment 98, Article 5(2b)	
Compromise text: Council text	

IVD Article 2 – continued ***(8aa)*** ***'kit' means a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof;***	
Comment: Changed number No correspondence in MD	
Compromise text: Council text	

No Council amendment	**Amendment 74** Article 2(1) ***(8a)*** ***'reusable device' means a device that is suitable for reprocessing and that is intended to be used on multiple patients or during multiple procedures;***
Comment: No correspondence in IVD. Compare Article 2(1)(8).	
Compromise text:	

Article 2(1) ~~(9)~~ ~~'single-use device for critical use' means a single-use device intended to be used for surgically invasive medical procedures;~~	**Amendment 75** Article 2(1) ~~(9)~~ ~~'single-use device for critical use' means a single-use device intended to be used for surgically invasive medical procedures;~~
Comment: No correspondence in IVD. Same change	
Compromise text: Deletion agreed. Same changes by the Council and the EP.	

Article 2(1) - continued ***(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;***	
Comment: No correspondence in IVD.	
Compromise text: Council text	

Article 2(1) - continued ***(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;***	
Comment: No correspondence in IVD.	
Compromise text: Council text	

Article 2(1) - continued (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;	**Amendment 354** Article 2(1) - continued (10) 'intended purpose' means the use for which the device is intended according to the ~~data supplied by the manufacturer on the~~ ***clinical evaluation, to be reflected in the conformity certificate, the product*** label, in the instructions for use ~~or~~ ***and if applicable*** in promotional or sales materials or statements;
Corresponds to IVD Article 2 definition (9), *No EP amendments of this definition in the IVD Regulation.*	
Compromise text: Parliament insists on reference to clinical investigation in which the claims are demonstrated.	

(11) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

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

(13) 'Unique Device Identification' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

[Correspond to IVD Article 2 definitions 10, 11 and 12]

No Council amendment	**IVD Amendment 48:** Article 2 - continued ***(12a) 'novel device' means:*** - ***a device which incorporates technology (the analyte, technology or test platform) not previously used in diagnostics, or;*** - ***an existing device which is being used for a new intended purpose for the first time;***
Comment: This EP amendment is not included in MD. ***Issue:*** *Scrutiny*	
Compromise text : To be further discussed with scrutiny issue	

No Council amendment	**IVD Amendment 49:** Article 2 - continued ***(12b) 'device for genetic testing' means an in vitro diagnostic medical device the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development;***
Issue: *genetic testing*	
Compromise text : To be further discussed at the 3rd trilogue.	

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

[No correspondence in IVD]

Article 2(1) - continued ***(14a) 'derivative' means a "non-cellular substance" extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case shall not contain any cells or tissues;***	
Comment: No correspondence in IVD.	
Compromise text: Council text	

(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;

[No correspondence in IVD]

Article 2(1) - continued	
(15aa) ***‘particle’,*** for the purposes of the definition of nanomaterial ***in paragraph 1(15)***, ~~‘particle’, ‘agglomerate’ and ‘aggregate’ are defined as follows: ‘particle’~~ means a minute piece of matter with defined physical boundaries;	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;
Comment: No correspondence in IVD. The Council change is just a split in order not to have definitions within definitions.	
Compromise text: Council text	

Article 2(1) - continued	
(15ab) ‘agglomerate’***, for the purposes of the definition of nanomaterial in paragraph 1(15),*** 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;	‘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;
Comment: No correspondence in IVD. The Council change is just a split in order not to have definitions within definitions.	
Compromise text: Council text	

Article 2(1) - continued	
(15ac) ‘aggregate’***, for the purposes of the definition of nanomaterial in paragraph 1(15),*** means a particle comprising of strongly bound or fused particles;	‘aggregate’ means a particle comprising of strongly bound or fused particles;
Comment: No correspondence in IVD. The Council change is just a split in order not to have definitions within definitions.	
Compromise text: Council text	

Article 2(1) - continued ***(15a) 'performance' means the ability of a device to achieve its intended purpose as claimed by the manufacturer;***	**Amendment 79** Article 2(1) - continued ***(31a) '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;***
IVD Article 2 – continued (30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting the intended purpose of the device;	**and IVD amendment 55** Article 2 - continued (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~~ ***attainment of technical capabilities,*** analytical ***performance*** and, where applicable, the clinical performance supporting the intended purpose of the device;
EP definition of performance completely different in MD, not taken over from IVD. *Very many issues with performance / clinical performance. See also Council MD definition (37c) and IVD definition (32)*	
Compromise text: Council text. EP can withdraw amendments 79 MD and 55 IVD..	

Article 2(1) – continued ***(15b) 'safety' means the absence of unacceptable risks, when using the device according to the intended purpose given by the manufacturer;***	
Comment: Corresponds to IVD Article 2 definition (15a)	
Compromise text: EP rejects the Council text as it does not see a need for such definition.	

Article 2(1) – continued ***(15d) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;***	
Comment: Corresponds to IVD Article 2 definition (15aa)	
Compromise text: Council text	

Article 2(1) – continued ***(15e) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;***	
Comment: Corresponds to IVD Article 2(1) definition (15b)	
Compromise text: Council text	

Article 2(1) – continued ***(15f)*** ‘***compatibility‘ is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:*** ***-*** ***perform without losing or compromising the ability to perform as intended, and/or*** ***-*** ***integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or*** ***-*** ***be used together without conflict/interference or adverse reaction.***	
Comment: Corresponds to IVD Article 2 definition 15c	
Compromise text: Council text	

Article 2(1) – continued ***(15g)*** ***‘interoperability’ is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to*** ***-*** ***exchange information and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or*** ***-*** ***communicate with each other, and/or*** ***-*** ***work together as intended.***	
Comment: Corresponds to IVD Article 2 definition 15d	
Compromise text: Council text	

Definitions related to the making available of devices:

Article 2(1) - continued (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;	**Amendment 76** Article 2(1) - continued (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;
IVD – Article 2 – continued (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;	
Comment: The Council has made no amendment to the Commission texts in MD and IVD. *Corresponds to IVD Article 2(1) definition 13, but there "a device for performance evaluation", IVD differences highlighted in grey.* *EP amended the MD text, but not the corresponding IVD text.*	
Compromise text: Council text. EP can withdraw this amendment.	

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

IVD article 2

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

(18) 'putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

IVD article 2

(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;

[MD (17) and (18) correspond to IVD definitions 14 and 15; IVD differences highlighted in grey]

No Council change	**IVD Amendment 50:** Article 2 - continued ***(15a) 'Information Society service' means any service, normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services;***
Comment This EP amendment is not included in MD.	
Compromise text: Amendment rejected. EP may withdraw it.	

Definitions related to economic operators, users and specific processes:

Article 2(1) - continued (19) 'manufacturer' means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark.	**No EP amendment for MD, but IVD Amendment 51** Article 2- continued (16) 'manufacturer' means the natural or legal person ~~who manufactures or~~ ***with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under that person's own name, regardless of whether those operations are carried out by that person or on that person's behalf by a third party. The obligations of this Regulation to be met by manufacturers also apply to natural or legal persons who assemble, package, process,*** fully ~~refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device~~ ***refurbish or label one or more ready-made products and/or assign to them their intended purpose as devices with a view to their being placed on the market*** under ~~his~~ ***that person's own*** name or trademark.
Corresponds to IVD Article 2 definition (16) *EP amendment of IVD but not MD for Article 2(1) definition (19)*	
Compromise text: Council text	

Article 2(1) – continued ***(19a)*** ***'fully refurbishing',*** for the purposes of the definition of manufacturer, ~~fully refurbishing is defined as~~ ***means*** the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;	
Comment: Corresponds to IVD Article 2 definition (16a)	
Compromise text: Council text	

Article 2(1) – continued (20) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, ***located outside the European Union*** to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;	
Comment: Corresponds to IVD Article 2 definition (17).	
Compromise text: Council text	

(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;

[MD (21) and (22) Correspond to IVD Article 2 definitions (18) and (19).]

Article 2(1) – continued (23) ‘economic operators’ means the manufacturer, the authorised representative, the importer**,** ~~and~~ the distributor ***and the person referred to in Article 20 (1) and 20 (3);***	
IVD Article 2 – continued (20) ‘economic operators’ means the manufacturer, the authorised representative, the importer**,** and the distributor ;	
Comment: Corresponds to IVD Article 2 definition (20),	
Compromise text: *Council text*	

Article 2(1) - continued (24) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;	**Amendment 77 and Amendment 52 in IVD** Article 2(1) - continued (24) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients ~~or the promotion of public health~~ ***and which has the legal capacity to carry out such activities***; ***commercial laboratories which provide diagnostic services shall not be considered to be health institutions***;
Comment: Corresponds to IVD Article 2 definition (21) *EP amendment for IVD is different than for MD, differences highlighted in grey.*	
Presidency proposal: (24) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients ~~or~~ **and** the promotion of public health;	

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

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

[MD (25) and (26) correspond to IVD Article 2 definitions (22) and (23)]

Article 2(1) - continued (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;	**Amendment 78** Article 2(1) - continued (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; ***routine device maintenance service activities are not included in this definition;***
Comment: No correspondence in IVD. Compare Article 2(1)(8).	
Compromise text	

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;

[Corresponds to IVD Article 2(1) definition (24)]

Article 2(1) - continued (29) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;	**IVD Amendment 28** Article 2(1) - continued (25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including ~~calibration~~, testing, certification and inspection;
Comment: Corresponds to IVD Article 2 definition (25). *EP has not amended the MD, but amended the IVD text.*	
Compromise text: *Council text. EP can withdraw this amendment.*	

(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;

[MD (30) and (31) correspond to IVD Article 2 definitions (26) and (27)]

Definitions related to clinical evaluation and clinical investigations:

Article 2(1) - continued (32) 'clinical evaluation' means ~~the assessment and analysis of~~ ***a systematic and planned process to continuously generate, collect, analyse and assess the*** clinical data pertaining to a device in order to verify the safety and performance of the device when used as intended by the manufacturer;	**Amendment 82** Article 2(1) - continued (32) 'clinical evaluation' means the assessment and analysis of clinical data pertaining to a device in order to verify the safety ~~and~~ performance ***and clinical benefits*** of the device when used as intended by the manufacturer;
Comment: No correspondence in IVD.	
Compromise text	

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

[No correspondence in IVD]

No Council change	**Amendment 83** Article 2(1)(33) - continued ***Clinical investigations for medical devices, where made compulsory in accordance with this Regulation, shall include clinical investigations in the appropriate target population and well-controlled investigations.***
Comment: No correspondence in IVD	
Compromise text	

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

[No correspondence in IVD]

IVD - Definitions related to clinical evidence:

IVD Article 2

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

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

[No correspondence in MD]

IVD Article 2 - continued (33) '~~clinical~~ performance study’ means a study undertaken to establish or confirm the clinical performance of a device;	
Comment: No correspondence in MD	
Compromise text	

IVD Article 2 - continued (35) 'performance evaluation' means the assessment and analysis of data to establish or verify the *scientific validity*, the analytical and, where applicable, the clinical performance of a device;	IVD Amendment 56 Article 2 - continued (35) ′performance evaluation′ means the assessment and analysis of data to establish or verify ~~the~~ *that the device performs as intended by the manufacturer, including the technical,* analytical and, where applicable, the clinical performance of a device;
Comment: No correspondence in MD	
Compromise text	

IVD Article 2 - continued (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;	
Comment: No correspondence in MD	
Compromise text	

IVD Article 2

(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;

[No correspondence in MD]

Article 2(1) – continued (35) 'clinical investigation plan' means ~~the~~ ***a*** document~~(s)~~ ***that describes*** ~~setting out~~ the rationale, objectives, design***, methodology, monitoring, statistical considerations*** and ***organisation*** ~~proposed analysis, methodology, monitoring, conduct and record-keeping~~ of ***a*** ~~the~~ clinical investigation;	
IVD – Article 2 – continued (34) 'clinical performance study ***plan*** ~~protocol~~' means ~~the~~ ***a*** document(s) ~~setting out~~ ***that describes*** the rationale, objectives, design ***methodology, monitoring, statistical considerations*** and ***organisation*** ~~and proposed analysis, methodology, monitoring, conduct and record-keeping~~ of the clinical performance study;	
Corresponds to IVD Article 2(1) definition (34), but there reference to performance evaluation, IVD differences highlighted in grey.	
Compromise text	

Article 2(1) - continued (36) 'clinical data' means the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following: – clinical investigation(s) of the device concerned, – clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated, – ~~published and/or unpublished~~ reports ***published in peer reviewed scientific literature*** on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated**,** – ***other clinical data coming from the post-market surveillance system, in particular the post-market clinical follow-up;***	**Amendment 84** Article 2(1) - continued (36) 'clinical data' means ***all*** the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following:
Comment: No correspondence in IVD	
Compromise text	

Article 2(1) - continued (37) 'sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation**,** ***for the*** ~~and~~ management ***and for setting up the financing*** of ~~a~~ ***the*** clinical investigation;	**Amendment 86 and same IVD amendment 60** Article 2(1) - continued (37) 'sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation and management**,** ***conduct or financing*** of a clinical investigation;
IVD Article 2 – continued (45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation ~~and~~ ***for the*** management ***and for setting up the financing*** of ~~a~~ ***the*** ~~clinical~~ performance study;	
Comment: Corresponds to IVD Article 2 definition (45), but there reference to performance study; IVD differences highlighted in grey *EP same amendment for IVD.*	
Compromise text	

No Council change	**Amendment 87** Article 2(1) - continued ***(37a) 'conformity assessment' means, in relation to a clinical study, the checking by the authorities responsible of the relevant official documentation, facilities and records and of the existence of sufficient insurance cover. Such checking may be carried out on the premises of the sponsor and/or the research establishment or wherever the authority responsible may deem checks to be necessary.***
Comment: See definition in Article 2(1)(28)	
Compromise text	

Article 2(1) - continued ***(37a) 'subject' means an individual who participates in a clinical investigation;***	
IVD Article 2 - continued ***(37a) 'subject' means an individual who participates in a performance study whose specimen(s) undergo in-vitro-examination by a device for performance evaluation and/or by a control;***	
Comment: Corresponds to same IVD number (37a) in Article 2, but there reference to performance study, IVD difference highlighted in grey.	
Compromise text	

Article 2(1) - continued ***(37b) 'clinical evidence' means the clinical data pertaining to a 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;***	**No EP amendment for MD, but IVD amendment 54** Article 2 - continued (28) 'clinical evidence' means the ~~information that supports~~ ***data, positive and negative, supporting the evaluation of*** the scientific validity and performance for the use of a device as intended by the manufacturer;
Comment: Corresponds to IVD article 2 definition (28) with Council amendments. IVD text only – as it was deleted – is highlighted in grey and introduced in the MD part.	
Compromise text	

Article 2(1) - continued ***(37c) 'clinical performance' means the ability of a device to achieve its intended purpose as claimed by the manufacturer, including any direct or indirect medical effects on humans as well as the clinical benefit on patients resulting from the technical or functional, including diagnostic characteristics of a device, when used as intended by the manufacturer;***	**Amendment 79** Article 2(1) - continued ***(31a) '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;***
IVD Article 2 - continued (32) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological ***or pathological process or*** state in accordance with the target population and intended user;	
Comment: Very many issues with performance! Definition of clinical performance in MD and IVD is very different, but same term used. *See also the definition of performance Article 2(1) MD definition (15a) and IVD definition (30).* *EP definition in MD a mix of both "performance" and "clinical performance"; while EP definition in IVD specific to performance.*	
Compromise text.	

Article 2(1) - continued ***(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;***	**Amendment 80** Article 2(1) - continued ***(31b) 'benefit' means the positive health impact of a medical device based on clinical and non-clinical data;***
Comment: No correspondence in IVD. See Article 2(1)(31b)	
Compromise text.	

IVD Article 2 - continued

[No correspondence in MD for 38 - 43]

(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;

No Council change	IVD Amendment 58 Article 2(1) - continued *(43a) 'calibrator' means a measurement standard used in the calibration of a device;*
Comment: No correspondence in MD	
Compromise text	

No Council change	IVD Amendment 59 Article 2 - continued (44) '~~calibrators and~~ control materials~~'~~ means ~~any~~ *a* substance, material or article intended by ~~the~~ *its* manufacturer ~~either to establish measurement relationships or~~ *to be used* to verify the performance characteristics of a device ~~in conjunction with the intended purpose of that device~~;
Comment: No correspondence in MD	
Compromise text	

Article 2(1) – continued ***(37h) 'investigator' means an individual responsible for the conduct of a clinical investigation at a clinical investigation site;***	
Comment: No correspondence in IVD.	
Compromise text	

Article 2(1) - continued ***(37k) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation;***	
IVD Article 2 - continued ***(45a) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular performance study after having been informed of all aspects of the performance study 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 performance study;***	
Comment: Corresponds to IVD Article 2 definition (45a), but there reference to performance study, IVD differences highlighted in grey.	
Compromise text	

Article 2(1) - continued ***(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;***	**Amendment 88 and amendment IVD 57** Article 2(1) - continued ***(37b) 'ethics committee' means an independent body in a Member State, consisting of health-care professionals and non-medical members including at least one well-experienced, knowledgeable patient or patient representative. Its responsibility is to protect the rights, safety, physical and mental integrity, dignity and well-being of subjects involved in clinical investigations / interventional clinical performance studies and other clinical performance studies and to provide public assurance of that protection in full transparency. In cases of such investigations / studies involving minors, the ethics committee shall include at least one healthcare professional with paediatric expertise;***
Comment: Corresponds to IVD Article 2 definition (45b). *EP made same amendment to IVD, but reference to performance evaluation and interventional studies. Differences in IVD text highlighted in grey.*	
Compromise text	

Article 2(1) - continued (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;	
IVD – Article 2 – continued (46) 'adverse event' means any untoward medical occurrence, ***inappropriate patient management decision,*** 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 ***study*** ~~evaluation~~;	
Comment: Corresponds to IVD Article 2(1) definition (46). ***Council text****with no changes compared to Commission proposal. Differences in IVD text highlighted in grey.*	
Compromise text	

Article 2(1) - continued (39) 'serious adverse event' means any adverse event that led to any of the following:	**1.**
IVD Article 2 – continued – ***a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or in the death of the individual's offspring,***	
– death,	
IVD Article 2 – continued – serious deterioration in the health of the ~~subject~~ ***individual being tested or the recipient of tested donations or materials***, 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, ***(v) chronic disease***, – foetal distress, foetal death or a congenital abnormality or birth defect;	**Amendment 89 and IVD amendment 61** Article 2(1)(39) - continued (iii) hospitalisation or ~~extending the duration of~~ ***prolongation of patient*** hospitalisation, **Amendment 90** Article 2(1)(39) - continued – foetal distress, foetal death or a congenital ~~abnormality~~ ***physical or mental impairments*** or birth defect;
Comment: Corresponds to IVD Article 2 definition (47), with the exception of the parts highlighted in grey under the "IVD Article 2(1)" lines. The Commission proposal has been only partly modified, but because single definition it has been very difficult to not put the text also in the table.	
Compromise text	

Article 2(1) - continued (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;	**Amendment 91 and IVD amendment 62** Article 2(1) - continued (40) 'device deficiency' means any inadequacy in the identity, quality, ~~durability,~~ ***stability***, reliability, safety or performance of ~~an investigational~~ ***a*** device, ***as defined in points 1 to 6 of this paragraph***, including malfunction, ~~use errors~~ or inadequacy in the information supplied by the manufacturer;
IVD Article 2 - continued (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;	
Comment: Corresponds to IVD Article 2 definition (48), but in IVD reference to a device for performance evaluation. Different EP amendment for IVD then for MD, MD not included in IVD and vice-versa. IVD amendment text highlighted in grey.	
Compromise text	

Article 2(1) – continued Definitions related to ***post-market surveillance,*** vigilance and market surveillance:	
Comment: Same change of title in IVD.	
Compromise text	

Article 2(1) – continued ***(40a) 'post market surveillance' means all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.***	
Comment: Corresponds to IVD Article 2(1) definition (48a)	
Compromise text	

Article 2(1) – continued ***(40b)*** ~~(48)~~ ***'market surveillance' means the activities carried out and measures taken by public authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;***	
Comment: Corresponds to IVD Article 2(1) definition (48b). This definition has been introduced by the Council also in IVD.	
Compromise text	

(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;

[MD (41) and (42) correspond to IVD Article 2 definitions (49) and (50) respectively.]

Article 2(1) – continued (43) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market ***including use-error due to ergonomic features,*** any inadequacy in the information supplied by the manufacturer and any ~~unexpected~~ undesirable side-effect;	
IVD Article 2 - continued (51) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market ***including use-error due to ergonomic features***, any inadequacy in the information supplied by the manufacturer and any ~~unexpected~~ ~~undesirable effect~~ ***harm as a consequence of the medical decision, action taken or not taken on the basis of information or result(s) provided by the device***;	
Comment: Corresponds to IVD Article 2(1) definition (51), IVD differences highlighted in grey.	
Compromise text	

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

– death of a patient, user or other person,

– temporary or permanent serious deterioration of the patient's, user's or other person's state of health,

– serious public health threat;

[Corresponds to IVD Article 2 definition (52)]

Article 2(1) – continued ***(44a) 'serious public health threat' means any event type, which could results in imminent risk of death, serious deterioration in state of health, or serious illness that may require prompt remedial action, and that may cause significant morbidity or mortality in humans or that is unusual or unexpected for the given place and time;***	
Comment: Corresponds to IVD Article 2 definition (53)	
Compromise text	

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

(46) ‘field safety corrective action’ means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

[MD (45) and (46) correspond to IVD Article 2 definitions (53) and (54) respectively.]

No Council change	**No EP amendment in MD, but IVD amendment 64** Article 2(1) - continued (55) ‘field safety notice’ means the communication sent by the manufacturer to users***, waste disposal operators*** or customers in relation to a field safety corrective action;
Comment: Corresponds to IVD Article 2(1) definition (55), no EP amendment of MD, but EP amendment on IVD.	
Compromise text	

Article 2(1) ~~(48) ‘market surveillance’ means the activities carried out and measures taken by public authorities to ensure that products 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;~~	
Comment: Moved to Article 2(1) definition (40b), used to correspond to IVD Article 2 definition (56)	

No Council change	**IVD amendment 63** Article 2 - continued ***(48a) 'inspection' means an official review, carried out by a competent authority, of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by that authority to be related to a clinical performance study and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;***
Comment: EP amendment on inspections only in IVD.	
Compromise text	

No Council change	**Amendment 92 and IVD amendment 65** Article 2(1) - continued ***(48a) 'unannounced inspection' means an inspection conducted without advance notice;***
Comment: EP amendment on both MD and IVD the same text. MD Article 2(1) definition (48a) corresponds to IVD Article 2 definition (56a)	
Compromise text	

Definitions related to standards and other technical specifications:

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

[Corresponds to IVD Article 2 definition (57)]

Article 2(1) - continued (50) 'common ~~technical~~ specifications' ***(CS)*** means a document other than a standard that prescribes technical ***and/or clinical*** requirements that provide a means to comply with the legal obligations applicable to a device, process or system.	
Comment: Corresponds to IVD Article 2 definition (58)	
Compromise text	

Article 2 – continued ~~2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in the last subparagraph of number (1) of paragraph 1, in the light of technical progress and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks.~~	
*Comment: Has become Article 1**(1c)**; No correspondence in IVD*	
Compromise text	

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.

[No correspondence in IVD]

Article 3
Regulatory status of products

Article 3 1. ~~The~~ ***Without prejudice to Article 2(2) of Directive 2001/83 at a duly substantiated request of a Member State the*** Commission ~~may~~ ***shall,*** ~~at the request of a Member State or on its own initiative~~ ***after consulting the MDCG,*** by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).	**Amendment 93 and amendment 66 of IVD** Article 3 1. The Commission may ***on its own initiative or shall***, at the request of a Member State ~~or on its own initiative~~, by means of implementing acts~~,~~ ***on the basis of the opinions of the MDCG and the MDAC referred to in Articles 78 76 and 78a 76a respectively***, determine whether or not a specific product, or category or group of products, ***including borderline products,*** falls within the definitions of 'in vitro medical device' or 'accessory to a an in vitro diagnostic medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88 84 (3).
1. ~~The~~ ***Without prejudice to Article 2(2) of Directive 2001/83, at a duly substantiated request of a Member State, the*** Commission ~~may~~ ***shall,*** ~~at the request of a Member State or on its own initiative~~ ***after consulting the MDCG,*** by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 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).	
Comment: Corresponds to Article 3(1) in IVD, just reference to MD/IVD different and reference to article concerned at the end of the para. IVD differences highlighted in grey. *The same amendment for EP as well, only reference to devices and articles different.* *See Article 3(1a)*	
Compromise text: Council text for MD. *But, on IVD, the reference to the medicinal products directive is not pertinent. Therefore, the IVD text should read:* Commission ***shall, after consulting the MDCG,*** by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 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).	

Article 3 - continued ***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.***	

Comment: Corresponds to Article 3(1a) in IVD. See Article 3(1)
Compromise text: Council text

Article 3 - continued 2. The Commission shall ensure the sharing of expertise between Member States**,** in the fields of medical devices, *in vitro* diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.	**Amendment 93 and IVD amendment 66** Article 3 - continued ~~2.~~ ~~The Commission shall ensure the sharing of expertise between Member States in the fields of medical devices, in vitro diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.~~
IVD Article 3 - continued 2. The Commission shall ensure the sharing of expertise between Member States**,** in the fields of *in vitro* diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.	
Comment: Corresponds to Article 3(2) in IVD, just order of medical devices, in-vitro medical devices changed. The EP has deleted Article 3(2) in both MD and IVD.	
Compromise text	

ANNEX XV

LIST OF *GROUPS OF* PRODUCTS *WITHOUT AN INTENDED MEDICAL PURPOSE* ~~COVERED BY THE LAST SUBPARAGRPAH OF THE DEFINITION OF 'MEDICAL DEVICE'~~ REFERRED TO IN ~~NUMBER (1) OF~~ ARTICLE *1* ~~2~~(1*a*)	
Comment:	
Compromise text:	

1. Contact lenses ***or other articles intended to be introduced into or onto the eye***;	
Comment:	
Compromise text:	

2. ~~Implants~~ ***Products intended to be totally or partially introduced into the human body through surgically invasive means*** for ***the purpose of*** ~~modification~~ ***modifying the anatomy*** or fixation of body parts ***with the exception of tattooing products and piercings***;	
Comment:	
Compromise text:	

3. ***Substances, combinations of substances, or articles intended to be used for facial*** ~~Facial~~ or other dermal or mucous membrane ~~fillers~~ ***filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing***;	
Comment:	
Compromise text:	

4. Equipment ***intended to be used to reduce, remove or destroy adipose tissue, such as equipment*** for liposuction***, lipolysis or lipoplasty***;	
Comment:	
Compromise text:	

~~5. Invasive laser equipment intended to be used on the human body;~~	
Comment:	
Compromise text:	

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

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.	
Corresponds to	
Compromise text:	