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NOTE

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and medical devices
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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**

Delegations will find enclosed the tentatively agreed compromise text as regards Annex VII CLASSIFICATION CRITERIA of the proposed Regulation on medical devices. This compromise text, which is part of "Block1", is still subject to confirmation by the European Parliament and the Council. It is presented together with, respectively, the positions of the Council and the European Parliament at the start of the negotiations.

Block 1 consists of the following elements:

- Recitals (1) to (30), (32), (33) and (39b) of the proposed Regulation on medical devices	Set out in Addendum 1.
- Recitals (1) to (26) of the proposed Regulation on *in vitro* diagnostic medical devices	Set out in Addendum 2.
- Chapter I of both proposals and Annex XV of proposed Regulation on medical devices - definitions that are directly linked to chapters that are not in Block 1 are not included.	Set out in Addendum 3.
- Chapter II except Article 15 of both proposals	Set out in Addendum 4.
- Chapter V, Section I of both proposals	Set out in Addendum 5.
- Annex I of both proposals	Set out in Addendum 6.
- Annex II both proposals	Set out in Addendum 7.
- Annex III and IV of both proposals	Set out in Addendum 8.
- Annex VII of the proposed Regulation on medical devices	Set out in Addendum 9.
- Annex VII of the proposed Regulation on *in vitro* diagnostic medical devices	Set out in Addendum 10.

Explanation of the document layout

(Simplified, since this document only concerns MD)

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.

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***
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:	

Annex VII

CLASSIFICATION CRITERIA

I. SPECIFIC DEFINITIONS FOR THE CLASSIFICATION RULES

1. DURATION OF USE

1.1. 'Transient' means normally intended for continuous use for less than 60 minutes.

1.2. 'Short term' means normally intended for continuous use for between 60 minutes and 30 days.

1.3. 'Long term' means normally intended for continuous use for more than 30 days.

2. INVASIVE AND ACTIVE DEVICES

2.1. 'Body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma ~~or permanent tracheotomy~~.	**No EP amendment**
Comment:	
Compromise text: ***Council text***	

2.2. 'Surgically invasive device' means (a) an invasive device which penetrates inside the body through the surface of the body, ***including through mucus membranes of body orifices*** with the aid or in the context of a surgical operation; (b) a device which produces penetration other than through a body orifice.	**No EP amendment**
Comment:	
Compromise text: ***Council text***	

2.3. 'Reusable surgical instrument' means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures ***such as*** ~~for~~ cleaning, ***disinfection*** and/~~or sterilization~~ ***sterilisation*** have been carried out.	**No EP amendment**
Comment:	
Compromise text: ***Council text***	

2.4.	'Active therapeutic device' means any active ~~medical~~ device, whether used alone or in combination with other ~~medical~~ devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.	**No EP amendment**
Comment: "device" is in this Regulation a generic term including 'medical device'.		
Compromise text: ***Council text***		

2.5.	'Active device intended for diagnosis ***and monitoring***' means any active ~~medical~~ device, whether used alone or in combination with other ~~medical~~ devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.	**No EP amendment**
Comment:		
Compromise text: ***Council text***		

2.6. 'Central circulatory system' means the following blood vessels: *arteriae pulmonales*, *aorta ascendens*, *arcus aorta**e***, *aorta descendens* to the *bifurcatio aortae*, *arteriae coronariae*, *arteria carotis communis*, *arteria carotis externa*, *arteria carotis interna*, *arteriae cerebrales*, *truncus brachiocephalicus*, *venae cordis*, *venae pulmonales*, *vena cava superior*, *vena cava inferior*.

2.7. 'Central nervous system' means the brain, meninges and spinal cord.

2.8.	***'Injured skin or mucus membrane' means an area of skin or a mucus membrane presenting a pathological change or change following disease or a wound.***	**No EP amendment**
Comment:		
Compromise text: ***Council text***		

II. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES[1]

1. Application of the classification rules shall be governed by the intended purpose of the devices.

[1] It is noted that since automatic numbering was used in the Commission proposal, the numbering of the sections in Chapter II is not consistent with that in Chapters I and III. It is suggested to leave a correction of this to the legal-linguistic revision during which either Chapter II and III switch place and the sections in Chapter II are renumbered or the section numbering in both Chapters II and III is changed.

2.	If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories ***to a medical device*** are classified in their own right separately from the device with which they are used.	**No EP amendment**
Comment:		
Compromise text: ***Council text***		

3.	~~Stand-alone software,~~ ***Software,*** which 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.	**No EP amendment**
Comment:		
Compromise text: ***Council text***		

4. If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.

5. If several rules, or within the same rule several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and~~/or~~ sub-rule resulting in the higher classification shall apply.

6. In calculating the duration referred to in Chapter I, Section 1 continuous use means:
   (a) The entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior and after the period when the use is interrupted or the device removed.
   (b) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

7. A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition by itself or when it provides decisive information for the diagnosis.

III. CLASSIFICATION RULES

3. NON-INVASIVE DEVICES

3.1. Rule 1

All non-invasive devices are in class I, unless one of the rules set out hereinafter applies.

3.2. Rule 2	**No EP amendment**
All non-invasive devices intended for channelling or storing blood, body liquids***, cells*** or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in class IIa: - if they may be connected to an active medical device in class IIa or a higher class, - if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body ***cells and*** tissues***, except for blood bags, which are in class IIb***. In all other cases they are in class I.	
Comment:	
Compromise text: ***Council text***	

3.3. Rule 3	**No EP amendment**
All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or ***administration*** ~~infusion~~ into the body are in class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in class IIa. All non-invasive devices ***consisting of a substance or a mixture of substances*** intended to be used ***in vitro in direct contact with human cells, tissues or organs taken off from the human body or with human embryos before their implantation or administration into the body*** ~~for in vitro fertilisation (IVF) or assisted reproduction technologies (ART) which are liable to act with close contact on the inner or outer cells during the IVF/ART, such as washing, separating, sperm immobilising, cryoprotecting solutions,~~ are in class ***III*** ~~IIb~~.	
Comment:	
Compromise text: ***Council text***	

3.4. Rule 4 All non-invasive devices which come into contact with injured skin ***or mucous membrane*****:** - are in class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates, - are in class IIb if they are intended to be used principally ***for injuries to skin which have breached the dermis or mucous membrane*** ~~with wounds which have breached the dermis~~ and can only heal by secondary intent, - are in class IIa in all other cases, including devices principally intended to manage the micro-environment of ~~a wound~~ ***injured skin or mucous membrane.*** - are in class IIa in all other cases, including devices principally intended to manage the micro-environment of ~~a wound~~ ***injured skin or mucous membrane.*** ***This rule applies also to the invasive devices that come into contact with injured mucous membrane.***	**No EP amendment**
Comment: The second bullet point is double and is deleted by document 12040/15 ADD1 COR 1.	
Compromise text: ***Council text*** **3.4. Rule 4** All non-invasive devices which come into contact with injured skin ***or mucous membrane*****:** - are in class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates, - are in class IIb if they are intended to be used principally ***for injuries to skin which have breached the dermis or mucous membrane*** ~~with wounds which have breached the dermis~~ and can only heal by secondary intent, - are in class IIa in all other cases, including devices principally intended to manage the micro-environment of ~~a wound~~ ***injured skin or mucous membrane.*** - ~~are in class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound~~ ~~***injured skin or mucous membrane.***~~ ***This rule applies also to the invasive devices that come into contact with injured mucous membrane.***	

4. INVASIVE DEVICES

4.1. Rule 5 All invasive devices with respect to body orifices, other than surgically invasive devices ~~and~~ which are not intended for connection to an active medical device or which are intended for connection to ***a class I*** ~~an~~ active medical device ~~classified as class I~~: - are in class I if they are intended for transient use, - are in class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in ***the*** ~~a~~ nasal cavity, in which case they are in class I, - are in class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in ~~a~~ ***the*** nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in class IIa. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in class IIa or a higher class, are in class IIa.	**No EP amendment**
Comment: The changes to this rule are simply improvements of the wording. ***An additional comma*** *has been requested at the technical meeting on 19 February after "other than surgically invasive devices" in the first sentence.*	
Compromise text: ***Council text*** **4.1. Rule 5** All invasive devices with respect to body orifices, other than surgically invasive devices**,** ~~and~~ which are not intended for connection to an active medical device or which are intended for connection to ***a class I*** ~~an~~ active medical device ~~classified as class I~~: - are in class I if they are intended for transient use, - are in class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in ***the*** ~~a~~ nasal cavity, in which case they are in class I, - are in class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in ~~a~~ ***the*** nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in class IIa. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in class IIa or a higher class, are in class IIa.	

4.2. Rule 6 All surgically invasive devices intended for transient use are in class IIa unless they: - are intended ***specifically*** to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III, - ~~are reusable surgical instruments, in which case they are in class I,~~ - are intended specifically for use in direct contact with the ***heart or central circulatory system or the*** central nervous system, in which case they are in class III, - are intended to supply energy in the form of ionising radiation in which case they are in class IIb, - have a biological effect or are wholly or mainly absorbed in which case they are in class IIb, - are intended to administer ~~medicines~~ ***medicinal products*** by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in class IIb.	**No EP amendment**
Comment: In the first trilogue of 13 October the EP expressed its concerns about the deletion of the second bullet point which, in their view, would classify simple tools (like scissors) in an unnecessary high class. They want the second bullet point reintroduced with the addition of "inactive" in front of "surgical instruments". *After several rounds of discussion, the tentative compromise proposed for Rule 6 is below (see Coreper 7053/16 and WK 212/2016).* ***Agreed in trilogue on 7 April.***	
Compromise text: **4.2. Rule 6** All surgically invasive devices intended for transient use are in class IIa unless they: - are intended ***specifically*** to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III, - <u>are reusable surgical instruments, in which case they are in class I,</u> - are intended specifically for use in direct contact with the ***heart or central circulatory system or the*** central nervous system, in which case they are in class III, - are intended to supply energy in the form of ionising radiation in which case they are in class IIb, - have a biological effect or are wholly or mainly absorbed in which case they are in class IIb, - are intended to administer ~~medicines~~ ***medicinal products*** by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in class IIb.	

4.3. Rule 7 All surgically invasive devices intended for short-term use are in class IIa unless they: - are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III, - are intended specifically for use in direct contact with the ***heart or central circulatory system or the*** central nervous system, in which case they are in class III, - are intended to supply energy in the form of ionizing radiation in which case they are in class IIb, - have a biological effect or are wholly or mainly absorbed in which case they are in class III, - are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in class IIb.	**No EP amendment**
Comment:	
Compromise text: ***Council text***	

4.4. Rule 8 All implantable devices and long-term surgically invasive devices are in class IIb unless they: - are intended to be placed in the teeth, in which case they are in class IIa, - are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III, - have a biological effect or are wholly or mainly absorbed, in which case they are in class III, - are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer ~~medicines~~ ***medicinal products***, in which case they are in class III, - are active implantable ~~medical~~ devices or ***their accessories*** ~~implantable accessories to active implantable medical devices~~, in which case they are in class III, - are active implantable ~~medical~~ devices or ***their accessories*** ~~implantable accessories to active implantable medical devices~~, in which case they are in class III, - are breast implants, in which case they are in class III; - are ~~hip, knee or shoulder~~ total and partial joint replacements, in which case they are in class III, with the exception of ancillary components such as screws, wedges, plates and instruments, - are spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are in class III ***with the exception of components such as screws, wedges, plates and instruments***.	**No EP amendment** **Amendment 303** - are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III, ***with the exception of sutures and staples.***
Comment: At the technical meeting on 19 February the EP stated that they would like to keep this amendment. The Presidency proposed that instead of citing sutures and staples, the word "specifically" should be used, as in other rules. The EP would agree to withdraw its amendment if the Council accepted the Presidency proposal to add "specifically" after "are intended to be used". The initial tentative compromise proposed for Rule 8 can be found in WK 213/2016. After several rounds of discussion, the Presidency decided it will stick to Council text. ***This rule is part of the package of the well-established technologies that will be discussed on 11 May.*** ***EP agreed at the trilogue on 11 May to keep Council text.*** ***See next page***	

Compromise text:

4.4. Rule 8

All implantable devices and long-term surgically invasive devices are in class IIb unless they:

- are intended to be placed in the teeth, in which case they are in class IIa,
- are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III,
- have a biological effect or are wholly or mainly absorbed, in which case they are in class III,
- are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer ~~medicines~~ ***medicinal products***, in which case they are in class III,
- are active implantable ~~medical~~ devices or ***their accessories*** ~~implantable accessories to active implantable medical devices~~, in which case they are in class III,
- are active implantable ~~medical~~ devices or ***their accessories*** ~~implantable accessories to active implantable medical devices~~, in which case they are in class III,
- are breast implants ***or surgical meshes***, in which case they are in class III;
- are ~~hip, knee or shoulder~~ total and partial joint replacements, in which case they are in class III, with the exception of ancillary components such as screws, wedges, plates and instruments,
- are spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are in class III ***with the exception of components such as screws, wedges, plates and instruments***.

5. ACTIVE DEVICES

5.1. Rule 9 All active therapeutic devices intended to administer or exchange energy are in class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in class IIb. All active devices intended to control or monitor the performance of active therapeutic devices in class IIb, or intended directly to influence the performance of such devices are in class IIb. ***All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are in class IIb.*** All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable ~~medical~~ devices are in class III.	**No EP amendment**
Comment:	
Compromise text: ***Council text***	

5.2. Rule 10 Active devices intended for diagnosis ***and monitoring*** are in class IIa: - if they are intended to supply energy which will be absorbed by the human body, except for devices ~~used~~ ***intended*** to illuminate the patient's body, in the visible spectrum, - if they are intended to image *in vivo* distribution of radiopharmaceuticals, - if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of ***the*** central nervous system ***or diagnosis in clinical situations where the patient is in immediate danger***, in which case they are in class IIb. Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic ***radiology, including*** interventional radiology ***devices*** ~~including~~ ***and*** devices which control or monitor such devices, or which directly influence their performance, are in class IIb.	**No EP amendment**
Comment: The EP accepted the Council text at the technical meeting on 19 February. However, the Presidency asked the Commission to clarify if there is no missing reference to a class at the end of the first bullet point. The Commission agreed to check, but stated that this is most probably class I.	
Compromise text: **5.2. Rule 10** Active devices intended for diagnosis ***and monitoring*** are in class IIa: - if they are intended to supply energy which will be absorbed by the human body, except for devices ~~used~~ ***intended*** to illuminate the patient's body, in the visible spectrum***, in which case they are in class I***, - if they are intended to image *in vivo* distribution of radiopharmaceuticals, - if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of ***the*** central nervous system ***or diagnosis in clinical situations where the patient is in immediate danger***, in which case they are in class IIb. Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic ***radiology, including*** interventional radiology ***devices*** ~~including~~ ***and*** devices which control or monitor such devices, or which directly influence their performance, are in class IIb.	

5.2a. Rule 10a (new)	**No EP amendment**
Comment: *Following the discussions in the CWP the presidency would like to propose a new classification rule to avoid misclassification of independent software. See WK 210/2016.* ***During the technical meeting on 29 March the EP tentatively agreed to the new software rule. Agreed at the technical meeting on 13 May.***	
Compromise text: **5.2a. Rule 10a (new)** ***Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, is in class IIa, except if such decisions have an impact that may directly or indirectly cause:*** - ***the death or an irreversible deterioration of the state of health, in which case it is in class III;*** - ***a serious deterioration of the state of health or a surgical intervention, in which case it is in class IIb.*** ***Software intended to monitor physiological processes is in class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, in which case it is in class IIb.*** ***All other software is in class I.***	

Annex VII - continued **5.3. Rule 11** All active devices intended to administer and/or remove ~~medicines~~ ***medicinal products*****,** body liquids or other substances to or from the body are in class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in class IIb.	**No EP amendment**
Comment: This change is simply a correction of terminology.	
Compromise text: ***Council text***	

5.4. Rule 12

All other active devices are in class I.

6. SPECIAL RULES

6.1. Rule 13

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, with action ancillary to that of the devices, are in class III.

6.2. Rule 14

All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in class IIb, unless they are implantable or long term invasive devices, in which case they are in class III.

6.3. Rule 15 All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in class IIb. All devices intended specifically to be used for disinfecting or sterilising medical devices are in class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are in class IIb. This rule does not apply to devices that are intended to clean ~~medical~~ devices other than contact lenses by means of physical action only.	**No EP amendment**
Comment: "device" is in this Regulation a generic term including 'medical device'.	
Compromise text: ***Council text***	

6.4. Rule 16 Devices specifically intended for recording of diagnostic images generated by X-ray~~, MRI, ultra-sound or other diagnostic devices~~ are in class IIa.	**No EP amendment**
Comment:	
Compromise text: ***Council text***	

6.5. Rule 17 All devices manufactured ~~utilising~~ ***incorporating or consisting of*** tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable are in class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable that are intended to come into contact with intact skin only.	**No EP amendment**
Comment:	
Compromise text: ***Council text***	

~~**6.6. Rule 18**~~ ~~By derogation from other rules, blood bags are in class IIb.~~	**No EP amendment**
Comment:	
Compromise text: ***Council text***	

No Council amendment **6.7. Rule 19** All devices incorporating or consisting of nanomaterial are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.	**Amendment 304** All devices incorporating or consisting of nanomaterial ~~are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot~~ ***deliberately intended to*** be released into the ~~patient's or user's~~ ***human*** body ~~when the device is used within its intended purpose~~ ***are in class III***.
Comment: This text has been agreed in Coreper on 2 December 2015 (14471/15) and tabled at the trilogue of 3 December. The EP communicated that they don't accept it at the trilogue of 17 February 2016. At the technical meeting on 19 February the EP stated that this will be taken up again in trilogue discussions. *After several rounds of discussion, the tentative compromise proposed for Rule 19 is below (see Coreper 7053/16 and WK 212/2016).* ***Agreed in trilogue on 7 April.***	
Compromise text: **6.7. Rule 19** All devices incorporating or consisting of nanomaterial are: - in class III ***if they present a high or medium potential for internal exposure*** ~~unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose~~***;*** - ***in class IIb if they present a low potential for internal exposure;*** - ***in class IIa if they present a negligible potential for internal exposure.***	

~~**6.8. Rule 20**~~ ~~All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class III.~~	**Amendment 305** ~~All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class III.~~
Comment: Both EP and Council have deleted this rule.	
Compromise text: ***Rule 20 remains deleted*** ~~**6.8. Rule 20**~~ ~~All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class III.~~	

6.9. Rule 21 Devices that are composed of substances or combination***s*** of substances ***that are*** intended to be ~~ingested, inhaled or administered rectally or vaginally~~ ***introduced into the human body via a body orifice, or applied on skin*** and that are absorbed by or ***locally*** dispersed in the human body are***:*** ***-*** in class III ***if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose,*** ***- in class III if they are intended to be introduced into the gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body,*** ***- in class IIb in all other cases, except if they are applied on skin, in which case they are in class IIa.***	**Amendment 306** ~~Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are in class III.~~
Comment: This compromise proposal was agreed (WK 183/2015) in the Working Party of 14 December. The EP has not accepted this at the trilogue of 17 February. At the technical meeting on 19 February the EP stated that this will be taken up again in trilogue discussions. *After several rounds of discussion, the tentative compromise proposed for Rule 21 is below (see Coreper 7053/16 and WK 212/2016).* ***Agreed in trilogue on 7 April.***	
Compromise text: 6.9. **Rule 21** Devices that are composed of substances or combination***s*** of substances ***that are*** intended to be ~~ingested, inhaled or administered rectally or vaginally~~ ***introduced into the human body via a body orifice, or applied on skin*** and that are absorbed by or ***locally*** dispersed in the human body are***:*** ***-*** in class III ***if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose,*** ***- in class III if they ~~are~~ achieve their intended purpose ~~to be introduced into act~~ in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body,*** ***- in class IIb in all other cases, except if they are applied on skin, in which case they are in class IIa, or*** ***- if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities, in which case they are in class IIa.***	

6.10. Rule 22 ***All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are in class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product and those that are intended to treat life threatening conditions, in which case they are in class IIb.***	**No EP amendment**
Comment:	
Compromise text: ***Council text***	

6.11. Rule 23 ***Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determinates the patient management by the device are in class III, such as closed loop systems or automated external defibrillators.***	**No EP amendment**
Comment:	
Compromise text: ***Council text***	