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From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices
No. Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on **medical devices** and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 Proposal for a Regulation of the European Parliament and of the Council on **in vitro diagnostic medical devices** *- Presidency proposal for Annex VII of the two proposals*

Delegations will find enclosed proposals for texts for Annex VII of both proposals. These proposals are based on documents 16791/13 (IVD) and 5073/14 (MD) but contain further changes proposed by the Italian Presidency;

ANNEX VII

CLASSIFICATION Criteria

I. SPECIFIC DEFINITIONS FOR THE CLASSIFICATION RULES

1. DURATION OF USE [1]

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.~~ [2]

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[3];

b. a device which produces penetration other than through a body orifice.

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[1] IE PRES: There was no consensus among experts on whether classification should be based on the accumulated use of a device (Ref DS 1285/13 (FR)) and made the suggestion that 'Duration of Use' be better defined here with Implementing Rule number 6 in Section II deleted. Other experts suggested that these definitions were similar to those in the existing legislation and there was no need to change and to avoid unnecessary up-classifications that the accumulated use of a device should be considered by the Requirements in Annex I.

[2] IE PRES delete "*or permanent tracheotomy*" (Ref DS1295/13 (UK) and DS1343/13 (DE)).

[3] SE: insert "*or other interventional procedure"*(Ref DS 1366/13) to capture invasive devices used in other non-surgical procedures, however some experts expressed concern that it may risk up-classifying some devices unjustly.

2.3 'Reusable surgical instrument'[4] 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***[5] and~~/or~~r steriliz~~s~~ation have been carried out.

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.

2.5 'Active device' intended for diagnosis ***and monitoring***[6] 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.

2.6 'Central circulatory system'[7] 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.

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4 IE PRES: Many experts considered that a differentiation between reusable and single use surgical instruments was not justified. Experts at the meeting agreed to keep this definition with some adjustment to the text (see footnotes 5 & 6).

5 IE PRES: Experts agreed that appropriate procedures for the reuse of reusable surgical instruments were not limited to only cleaning and/or sterilisation.

6 IE PRES: Experts suggested this additional wording to make consistent with the text further on.

7 IE PRES: Experts suggested that this definition should include the heart. **Pcy:** this is covered by explicit mention under Rules 6, 7 and 8.

II. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES

1. Application of the classification rules shall be governed by the intended purpose of the devices.
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 are classified in their own right separately from the device with which they are used.
3. ~~Stand alone software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If stand alone software is independent of any other device, it is classified in its own right~~ **Software, which drives a device or influences the use of a device, falls automatically in the same class as the device.**
   Standalone software, which has a medical purpose as defined in article 2, point 1(1), is classified in its own right.[8][9]
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.

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8 Based on DE proposal

9 Pcy suggests to include the following definition:'Software stand alone' means a software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.
Alternative text is also possible: "Software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If the software is independent of any other device , it is classified in its own right."

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.**~~[10]

an uninterrupted actual use of the device for its intended purpose. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device. [11][12][13]

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.[14]

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.

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10 **IE PRES**: Some experts considered that the accumulated use of a device needs to be incorporated within the definition of 'duration of use' and suggested deleting implementing rule 6.

11 **DS 1295/13 UK**: wording on continuous use is unclear and suggested reverting to wording used in 93/42/EEC. Replace with '*an uninterrupted actual use of the device for its intended purpose. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device'*.

12 **DS 1343/13 DE**: Directive 93/42/EEC wording seems to be more appropriate

13 **Pcy** suggests to revert to the wording provided in directive 93/42/EEC; risk associated with the total exposure to a device may be better addressed within the Essential Requirements

14 IE PRES: Some experts suggested rewording *'.....providing the diagnosis which is the sole or primary basis for therapeutic decisions taken at the time of diagnosis'* as devices which allow for direct diagnosis (*i.e.* without seeking further confirmatory tests) should be differentiated from those which do not. However, the inclusion of this implementing rule was not clear to experts in general and it was felt that an impact assessment of this rule would be required in particular for software and active devices.

3.2 Rule 2

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.

In all other cases they are in class I, **except for blood bags, which are in class IIb**[15]**.**

3.3 Rule 3

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 intended to be used 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 IIb.[16]

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[15] DS 1295/13 UK: insert '*except for blood bags, which are in class IIb'*.

[16] FR: Replace with: *'All non-invasive devices consisting of substances or mixtures of substances coming into contact with cells, gametes, biological tissues, organs or embryos intended for implantation or administration into the body are in class III.'* Reservations from SE and UK on this text.
After the meeting, FR further suggested replacing with *'All devices consisting of a substance or a mixture of substances entering in direct contact in vitro with human cells, tissues or organs taken off the body or with human embryos before their implantation or administration into the body are in class III.'*

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 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.***

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.

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,[17]
- are reusable surgical instruments, in which case they are in class I,[18]
- are intended specifically for use in direct contact with the ***heart or central circulatory system or the***[19] 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,
- **are intended to** have a biological effect or are wholly or mainly absorbed in which case they are in class IIb,[20]
- 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,[21]
- are intended specifically for use in direct contact with the **heart or central circulatory system or the**[22] central nervous system, in which case they are in class III,

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17 **Pcy** It seems to be superfluous following the addition to third indent

18 IE PRES: Experts discussed that risk associated with reusable instrument should be based on its intended use rather than being the lowest risk class based on the fact that it is reusable. (ES, NL, PT, SE, UK, CION – in favour of deletion). DE/PL – against deletion stating that there have been no identified safety issues with having reusable surgical devices as class I.

19 Inclusion of the central circulatory system addresses the classification issues related to guidewires

20 IE PRES: Experts suggested adding '*are intended to*' for consistency. Post-meeting comments suggested retaining original text.

21 **Pcy** It seems to be superfluous following the addition to second indent

22 **Pcy** To have consistency with rule 6 regarding the inclusion of direct contact with central circulatory system

- are intended to supply energy in the form of ionizing radiation in which case they are in class IIb,
- **are intended to** 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.

4.4 Rule 8[23]

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, in which case they are in class III,
- are active implantable medical devices ***and their accessories*** ~~or implantable accessories to active implantable medical devices~~[24], in which case they are in class III,
- are breast implants, in which case they are in class III;
- are hip, knee, **hand, wrist, ankle, elbow**[25] 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 ancillary components such as screws, wedges, plates and instruments.***

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23 SE: all implantable devices should be class III. AT, FR, PT, SE in favour. Further analysis and caution suggested by ES, NL and UK. CION suggested that it may be logical but that further impact analysis would be required. (Ref DS1366/13).

24 PL: programmers for active implantable devices were already covered under rule 9.

25 IE PRES: Experts suggested adding 'hand, wrist, ankle'. FR: should 'elbow' joints be included. AT: small joint implants should be included as class III. NL: supported more general wording.

5. ACTIVE DEVICES

5.1 Rule 9[26]

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.

5.2 Rule 10

Active devices intended for diagnosis 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[27], in the visible spectrum,
- if they are intended to image *in vivo* distribution of radiopharmaceuticals,

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[26] FR: add *'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 III.*' DE/UK delegates opposed and questioned evidence basis for up-classification proposed. UK suggests that recent incidents have been a result of user issues.

[27] UK: add '*surface of the'* to ensure transillumination devices were appropriately covered. During the expert group meeting a number of experts had questioned whether this would lead to inappropriate classification of surgical or dental lights which illuminate more than the 'surface' of the patients body.

- ***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 central nervous system or diagnosis in clinical situations where the patient is in immediate danger, in which case they are in class IIb***[28]**.**

Active devices intended to emit ionizing radiation and intended for ~~**diagnostic or therapeutic**~~ interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in class IIb.

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. **29**

5.4 Rule 12

All other active devices are in class I.

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28 UK: insert wording as per GHTF Rule 10 (i)(a) and (b).

29 IE PRES: Text for new Rule 11a developed during expert meeting *'Active therapeutic devices intended to define therapeutic measures are in class IIa, unless there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring in which case they are in class IIb'.* Some experts did not believe there was sufficient evidence to support increasing the classification from Class IIb to Class III.

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[30] 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.[31]

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.

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[30] DE: Re-introduce '*which is liable to act*' from existing Directive. Supported by AT/PL. ES/FR/PT/UK supported Commission proposed text as it increases clarity for claimed 'sub-therapeutic' medicinal substances.

[31] IE PRES: FR (DS 1285/13), UK (DS 1295/13), AT (DS 1299/13), DE (DS 1343/13), DK (DS 1357/13), SE (DS 1366/13), PL (DS 1395/13) all have differing suggestions for amending this rule.

6.5 Rule 17

All devices manufactured utilising[32] 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.

~~**6.6 Rule 18**~~[33]

~~**By derogation from other rules, blood bags are in class IIb.**~~

6.7 Rule ~~19~~ 18[34]

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.

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32 NL: suggest inserting text in EN ISO 22442-1 - Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management may help to clarify – '*Animal tissues and their derivatives are used in the design and manufacture of medical devices to provide performance characteristics that have been chosen for advantages over non-animal based materials. The range and quantities of materials of animal origin in medical devices vary. These materials can comprise a major part of the device (e.g. bovine/porcine heart valves, bone substitutes for use in dental or orthopaedic applications, haemostatic devices), can be a product coating or impregnation (e.g. collagen, gelatine, heparin), or can be used in the device manufacturing process (e.g. tallow derivatives such as oleates and stearates, foetal calf serum, enzymes, culture media)*.'

33 IE PRES: delete Rule 18 due to amendment of rule 2.

34 IE PRES: Several delegations (DE/PL/NL) suggest the issue is complex and required further consideration by experts. ES support text. UK acknowledge complexity but support COM proposal. Some questioned the text due to a lack of relevant definitions and suggested that consideration be given to the potential risks associated with differing materials release into the body, not all would justify a Class III classification.

~~**6.8 Rule 20 19**~~[35]

~~**All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class III.**~~

6.9 Rule ~~21 20~~ 19[36]

Devices that are composed of substances or combination of substances **presented as one of the pharmaceutical dosage forms of the European Pharmacopoeia**, intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are ~~**class III**~~**:**

- **in class III if they, or their products of metabolism, are systemically absorbed by the human body,**
- **in class IIb if they, or their products of metabolism, are locally dispersed but not absorbed by the human body.**

[35] IE PRES: DE/NL/PL/SE/UK not in favour of a specific rule to cover these devices suggesting a lack of evidence of a major safety issue. During the Expert meeting, FR indicated it had requested this inclusion due to national policy that risk to donors should be minimised and so maximum provision should be provided to devices used in donation.

[36] IE PRES: ES/PL/SE/UK delete the rule as these products are considered to be medicinal products. AT/DE/DK/FR/PT support CION text.

New Rule X [37,38]

All invasive devices with respect to body orifices, other than surgically invasive devices which are intended to administer medicinal products by means of a delivery system via the pulmonary route are in class IIa, unless their mode of operation has an essential impact on the efficacy and safety of the administered medicines and those are intended to treat severe diseases. In this case they are in class IIb.

[39][40]

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[37] DE: New rule capturing devices which may impact on the efficacy and safety of drugs administered to treat severe diseases such as asthma/COPD. (Ref DS1343/13).

[38] IE PRES: General agreement for its inclusion amongst experts, however, an impact assessment may be required to realise what products would be affected by the inclusion of this rule.

[39] IE PRES: A number of experts agreed in principle with the introduction of a new rule to capture AED given their criticality, public use and incidents of recalls. However, several experts suggested that the issues with these devices are primarily user related and not device related and therefore would not support the increase in classification which this rule would result in. DE revised the text for this new rule after the Expert Meeting *'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'*.

[40] Pcy considers that the increase in classification would not correctly address the safety of automatic external defibrillators

ANNEX VII[41]
CLASSIFICATION CRITERIA

1. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES

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

1.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.

1.3. Accessories are classified in their own right separately from the device with which they are used[42].

1.4. ~~Standalone s~~Software, which drives a device or influences the use of a device, falls automatically in the same class as the device. ~~If s~~Standalone software ~~is independent of any other device, it~~ is classified in its own right. [43,44]

1.5. Calibrators intended to be used with a device shall be classified in the same class as the device.

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41 BE: suggested text for Article 39 and Annex I (section 17.2) of the Proposal (ref DS 1258/13)

42 FR: further consideration needs be given to determine how accessories differed from 'instruments'

43 BE: replace text with '*Software which is incorporated in a devices or which is a medical device in itself, including software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, is classified in its own right. Where this medical device software drives a device, it falls automatically in the same class as the device.*

A 'software module' means software that is associated with a specific application for the user. The boundaries and the interfaces of a module is identified by the manufacturer'

44 DE: Confusion with regard to the term 'standalone software' should be avoided. Also, definition of "medical device" in the Commission Proposal should be modified to make clear that software which has to be implemented in a devices with therapeutic or diagnostic function and which is sold separately from the device is considered as a medical device. Need to avoid general operating software (like windows, Mac OS etc.) being considered as medical device.

DE: replace text of 1.4 with *'Software, which is distributed separately from the device but which drives a device or influences the use of a device, falls in the same class as the device. Standalone software is classified in its own right.'*

1.6. ~~Standalone~~ Control materials with quantitative or qualitative assigned values intended for one specific analyse or multiple analyses shall be classified in the same class as the device.

1.7. The manufacturer shall take into consideration all the rules in order to establish the proper classification for the device.

1.8. Where a device has multiple intended purposes stated by the manufacturer, which place the device into more than one class, it shall be classified in the higher class.

1.9. If several classification rules apply to the same device the rule resulting in the higher classification shall apply.

1.10. Each of the rules applies to first line assays, confirmatory assays and supplemental assays.

2. CLASSIFICATION RULES

2.1. Rule 1

Devices intended for the following purposes are classified as **class D**:

- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion ~~or transplantation~~***, transplantation or cell administration***.
- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or ***suspected high*** ~~currently undefined~~ risk of propagation.
- ***Devices intended to be used to determine the infectious load of a life-threatening disease where its monitor is critical in the process of patient management.***

This rule applies to first line assays, confirmatory assays and supplemental assays.

All assays for the clinical diagnosis and monitoring of infection by HIV 1/2, Hepatitis C virus, Hepatitis B virus and HTLV I/II devices should be classified as Class D. Assays for the clinical diagnosis of Hepatitis B virus are taken to include the following infectious disease markers: Hepatitis B surface antigen (HBsAg), Hepatitis B core total antibodies (anti-HBc total) and Hepatitis B virus nucleic acid detection (HBV NAT). [45]

[45] DE: To avoid a situation by which misinterpretation of the new rules would end up in a wrong classification of devices which were on the list A of Annex 2 98/79EG this clarification is needed.

2.2. Rule 2[46]

Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as **class C,** except when intended to determine any of the following markers:

– ABO system [A (ABO1), B (ABO2), AB (ABO3)];

– Rhesus system [RH1 (D), ***RHW****1*, RH2 (C), RH3 (E), RH4 (c), RH5 (e)];

– Kell system [Kel1 (K)];

– Kidd system [JK1 (Jka), JK2 (Jkb)];

– Duffy system [FY1 (Fya), FY2 (Fyb)]

in which case they are classified as **class D.**

2.3. Rule 3

Devices are classified as **class C** if they are intended for:

(a) detecting the presence of, or exposure to, a sexually transmitted agent;

(b) detecting the presence in cerebrospinal fluid or blood of an infectious agent ~~with a risk of limited propagation~~ ***without a high risk of propagation****;*

(c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested, or to the individual's offspring;

(d) pre-natal screening of women in order to determine their immune status towards transmissible agents;

(e) determining infective disease status or immune status, if there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

(f) ~~selection of patients, *i.e.* (i)~~ Devices intended to be used as companion diagnostics; ~~or~~

(fa) ~~(ii)~~ Devices intended to be used for disease staging ***for critical conditions where an erroneous result may have a negative impact on patient management***; ~~or~~

(fb) ~~(iii)~~ Devices intended to be used in screening***,*** ~~for or in the~~ diagnosis***, or staging*** of cancer~~.~~***;***

[46] SE: all devices covered under Rule 2 should be in class D.

(g) human genetic testing;

(h) monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an ~~imminent~~ life-threatening situation for the patient or for the patient's offspring;

(i) management of patients suffering from a life-threatening ~~infectious~~ disease ***or condition****;*

(j) screening for congenital disorders in the foetus.

(k) Screening for congenital disorders in newborn where failure to detect and treat such disorders could lead to life-threatening situations or severe disability.

2.4. Rule 4 [47,48]

(a) Devices intended for self-testing **or for near-patient testing** are classified **in their own right** ~~as class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are~~ **and are at minimum classified as** Class B.

~~(b) Devices intended for blood gases and blood glucose determinations for near-patient testing are class C. Other devices that are intended for near-patient testing shall be classified in their own right.~~[49] - [50]

[47] SE: rule should be amended so that all self testing devices are Class C.

[48] NL: add *'devices intended to be operated by users that are not laboratory professionals, should be classified as class B unless the devices has specific critical characteristics that require classification in a higher risk class'*

[49] BE: clarify/amend Rule 4 to avoid confusion with Rule 3(j) – (original Rule 3(h)) and the potential for misclassification of other products as a result. (DS 1258/13).

[50] DE: clarification and consistency (DS 1393/13)

2.5. Rule 5

The following devices are classified as **class A**:

(a) reagents or other articles which possess ***no critical*** ~~specific~~ characteristics, intended by the manufacturer ***to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s)***; ~~to make them suitable for *in vitro* diagnostic procedures related to a specific examination;~~ ***and which are not critical components in the in vitro diagnostic procedure for achieving the intended purpose(s)***; [51] [52]

(b) instruments intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures;

(c) specimen receptacles.

2.6. Rule 6

Devices not covered by the above-mentioned classification rules are classified as **class B**.

2.7. Rule 7

Devices which are controls without a quantitative or qualitative assigned value are classified as **class B**.

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[51] DE: Rule 5 should include only:
- products for general laboratory use that qualify as IVD device
- accessories which possess no critical characteristics
- buffer solutions, washing solutions which fall in the scope of the IVD Regulation

Since Rule 5 is preceding Rule 6 there would be the danger to classify separately commercialized reagents or other products with specific characteristics, such as antibodies, chemical reagents which critically influences assay, catalysts, specific stains, specifically coated plates or tubes or specific microbiological culture media as class A. (DS 1393/13)

[52] AT: not in favour of this text insertion.