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From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices
No. prev. doc.:	17152/14 PHARM 103 SAN 495 MI 1016 COMPET 684 CODEC 2563
No. Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + 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

Delegations will find attached texts extracted from the consolidated footnoted text of the Proposal for a Regulation on medical devices prepared by the Italian Presidency and set out in document 17152/14. These texts are intended as bases for the examination of the Proposal at the meeting of the Working Party on 12 and 13 February 2015.

Annex A to this Note sets out the text of Chapter II.

Annex B to this Note sets out the text of definitions to be examined on 12 and 13 February.

Annex C to this Note sets out the text of Annex I to the Proposal.

Annex C to this Note sets out the text of Annex III to the Proposal.

Annex E to this Note sets out the text of Annex IV to the Proposal.

The footnotes in this document are identical to the corresponding footnotes in document 17152/14 but the footnote numbers differ since the software used to create this document can not handle independent numbering for each section.

Chapter II

Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement

Article 4

Placing on the market and putting into service

1. A device may be placed [1] on the market, ~~**made available**~~ or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.

3. Demonstration of conformity with the general safety and performance[2] requirements shall include a clinical evaluation in accordance with Article 49.

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[1] **DS 1075/14 LT** support the wording "*placed on the market*"; add "*made available*"; **UK** delete "*put into service*".

[2] **FR** delete "*performance*".

4. [3] [4] [5] [6]Devices that are manufactured and used within a single health institution shall be considered as being put into service[7]. The provisions regarding CE marking referred to in Article 18 and the obligations laid down in Articles 23 to 27 shall not apply to those devices, provided that manufacture ~~**and use**~~[8] of those devices occur **under a single quality management system and only within the facilities of that health institution**[9] ~~under the health institution's single quality management **system**~~[10] ~~**only within the facilities of that health institution under the health institution's single quality management system.**~~[11]

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[3] **DS 1710/1/13** Should "in-house" products comply with the proposed Regulations? **DK, IE, ES, HR, IT, CY LT, HU, MT, AT, PL, PT, SI, FI, SE, UK** agree with the regulation of in house medical devices. **DE, FR** do not agree.

[4] **DS 1710/1/13** Could "in house" medical devices defined in Article 4(4) of the MD proposal be exempted from certain legal obligations (Article 18 - CE marking of conformity; Chapter III - Articles 23 to 27- UDI and EUDAMED) if the manufacture and use of those "in-house" medical devices comply with the single Quality Management System of the health institution where they are (to be) used?
DK, IE, ES, HR, IT, CY, LT, HU, MT, AT, PL, PT, SI, FI, SE, UK agree with exemption from certain legal obligation (Article 18; chapter III – Articles 23 to 27) for in-house medical devices if the manufacture and use comply with the QMS of the Health institution.

[5] **DE** reservation. When devices are manufactured and used within a single health institution and there is practically no risk that they could be used on external patients, the principle of subsidiarity implies that they should be exclusively regulated at national level.

[6] **WD MDEV-61** 6 MS agree with the possibility to attain an adequate level of safety for in house MD only complying with the QMS of the health institution where the MDs are manufactured and used; 19 do not agree; 15 MS consider necessary to define more detailed conditions/provisions for in house MD in the MDR; 3 MS do not agree. Even if 16 MS agree on the text proposed in **DS 1059/14**, pages 31-32, during the Working Party on 11-12 November 2014 they considered that it is necessary that also in-house MD shall be subject to the conformity assessment procedure by a notified body.

[7] **14090/1/13** ft 5 **Cion** Article 42 has to be amended, in order to cover the concept of "*put into service*".

[8] **AT** delete "*and use*"; QMS only for the manufacture; **DE** support.

[9] **UK** suggestion (**DS 1059/14**). **DK**, **DE** support.

[10] **14090/1/13** ft 6 **BE, IT, AT, PT, UK** need to clarify the meaning of "single" health institution or institution under a "single" quality management system, namely by adding the necessary definitions (see DS 1730/13 ADD 1 for sub-contractors). For IVD (Art. 4(5)), **DE** suggested "*within the facilities of the health institution*" instead of "*health institution's single quality management system*". **DK** support.

[11] **DS 1059/14 IT**. **IE, NL, UK** support.

Health institutions shall keep a list of these devices available to the competent authority of the Member State on their territory of which they are established.[12]

[13]

In case the single health institution, partly or totally, outsources the internal manufacture of those devices to an external manufacturer all the provisions and obligations of this Regulation shall apply.[14]

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.[15]

Article5[16]

Distance sales

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation ~~at the latest~~[17] when the device is placed on the market[18].

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12 Similar suggestions from **HU** (**DS 1682/13**).

13 **DS 1068/14 IT** add "*anyway if the single health institution partially or totally committees the internal manufacture of those devices to an external manufacturer, those devices shall comply with the above provisions and obligations*".

14 This provision can be deleted following the new text proposed by **UK** (footnote 7).

15 **BG, CZ, UK** do not agree to use of delegated acts.

16 **DS 1710/1/13** 5 MS consider that the provisions on distance sales of medical devices should be more detailed; 10 do not agree; **DE, ES, HR, CY, MT, NL, PL, FI, SE, UK** consider sufficient the provisions on distance sales proposed by **Cion**; **IE, FR, IT, SI** do not agree.

17 **DS 1710/1/13 FR** suggests deleting "*at the latest*".

18 **HU** add "*made available*".

2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, **whether in return for payment or free of charge**[19], for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication**, directly or through intermediaries,** to a natural or legal person established in the Union shall comply with this Regulation.

3. ~~**Information society services as defined in Article 1(2) of Directive 98/34/EC offering a device to a natural or legal person established in the Union shall make easily available a copy of the EU declaration of conformity.**~~ **Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.**[20]

4. A Member State on grounds of protection of public health, may require from the information society services as defined in Article 1(2) of Directive 98/34/EC to cease its activity.[21]

~~**5. Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.**~~

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19 **DS 1682/13 BE** add "*whether in return for payment or free of charge*".

20 **DK, DE, NL, UK, Cion** do not support the wording of paragraph 3; **Pcy** reinstate paragraph 5 clearer than 3.

21 **DE, NL, UK** do not agree to paragraph 4.

Article 6

Harmonised standards

1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

2. The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance plan, clinical investigations, clinical evaluation or post-market clinical follow-up.

3. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products**, the references of which have been published in the Official Journal of the European Union**[22]**.**

[22] **14090/1/13** ft 8 **BE, FR, AT** add "*the references of which have been published in the Official Journal of the European Union.*". **DS 1682/13 FR; HU** add a reference to the national Pharmacopeia.

Article 7

Common ~~technical~~ specifications

1. Where no harmonized standards exist or where relevant harmonised standards are not sufficient, the Commission**, after having consulted the MDCG ~~and the MDAC~~**[23]**,** shall be empowered to adopt common ~~technical~~[24] specifications (~~CTS~~**CS**) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II ~~or~~, the clinical evaluation and post-market clinical follow-up set out in Annex XIII[25] **or the requirements regarding clinical investigation set out in Annex XIV**[26]. The ~~CTS~~**CS** shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).

2. Devices which are in conformity with the ~~CTS~~**CS** referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those ~~CTS~~**CS** or parts thereof.

3. Manufacturers shall comply with the ~~CTS~~**CS** unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.

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[23] **14090/1/13** ft 10 NL/DE: the role of the MDCG in their elaboration should be highlighted.

[24] **14090/1/13** ft 9 **IT, NL** scrutiny reservations. **Cion** this requires careful consideration since the term is used across sectors.

[25] **14090/1/13** ft 11 **PT** CTS should cover processes as well, e.g. the reprocessing of single use medical devices.

[26] **UK** add "*or the requirements regarding clinical investigation set out in Annex XIV*".

Article 8

General obligations of the manufacturer

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2. Manufacturers shall draw up **and keep up to date** the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.

   The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.[27]

3. Where compliance ~~of a device~~ with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 17, and affix the CE marking of conformity in accordance with Article 18.

3a. Manufacturers shall ensure compliance with the provisions of this Regulation throughout the entire lifetime of the devices he has made available on the market or put into service.

~~**4. Manufacturers shall comply with the obligations related to the UDI system referred to in Articles 24 and with the registration obligations referred to in Article 25.**~~[28]

[27] **BG** implementing acts instead of delegated acts.
[28] Provision already referred to in articles 24 and 25.

5. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any ~~supplement~~ **amendments and supplements**, issued in accordance with Article 45, available to the competent authorities for a period of at least ~~five~~ ~~**ten**~~ **five** years[29] after the last device covered by the declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

~~Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide,~~ **Upon** request by a competent authority, **the manufacturer shall provide the full technical documentation** ~~**and/**~~[30] **or** a summary technical documentation (STED)[31] [32] [33] ~~and grant access to the full technical documentation upon request~~**)**.

Manufacturer with registered place of business outside the Union, to allow the authorised representative to fulfill the tasks mentioned in Article 9, paragraph 3 shall ensure that the authorised representative has ~~**permanently available and**~~[34] **rapid access to the necessary documentation.**

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[29] **14090/1/13** ft 13 Instead of 5 years, **NL** suggested: '*the minimal life expectancy of the device after the last device covered by the declaration of conformity has been placed on the market*'. **Other delegations including Cion** considered that this wording would be a source of legal uncertainty. However, if considered too short, the period of 5 years could be reviewed. 5 years after the last device seems to be reasonable.

[30] **Cion** delete "*and/*".

[31] **DS 1710/1/13** Should the content of a summary of technical documentation be specified in the legislation? **DS 1710/1/13 DK DE IE ES FR MT PL PT SI FI SE UK** (12 delegations) consider that it is not necessary to specify the content of a STED; **HR, CY, IT, NL** (4 delegations) consider the content of a STED must be specified in the legislation.

[32] **14090/1/13** ft 14 **IT, AT, PT - DS 1075/14 LT** add "*including the elements set out in Annex II*".

[33] **14090/1/13** ft 15 **FR, NL, UK** scrutiny reservations.

[34] **DE** does not agree with the wording "*permanently available and rapid access*"; just one is necessary.

6. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or ~~CTS~~**CS** by reference to which conformity of a product is declared shall be adequately taken into account. ~~**Proportionate to the risk class and the type of device, manufacturers Manufacturers**~~ of devices, other than ~~**custom-made**~~[35] ~~or~~ investigational devices, shall ~~**institute**~~ **establish, document, implement**, maintain and **continually improve a quality management system** ~~**and keep up to date a quality management system**~~ that ~~shall address at least~~ **minimizes the possibility of non-conformance to the provisions of this regulation in** the ~~following aspects:~~ **most effective manner.**[36]

~~**The QMS consists of all parts and components of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It is managing the structure, responsibilities, procedures, processes and management resources to implement the needed principles and actions to achieve compliance with the provisions of this regulation.**~~

[35] **14090/1/13** ft 16 **BE, ES, FR, PT, SI, SE** custom made medical devices should not be excluded. **Cion** expressed reservations.

[36] **DS 1710/1/13** Do you agree that requirements on the quality management system as set out in Article 8(5) are sufficient? **HR, IT, CY, SI, FI, UK** agree that requirements on the QMS are sufficient; **BE, DK, DE, IE, ES, FR, PL, PT, SE** do not agree. **DS 1009/14** text added based on **DE** suggestion.

~~The QMS shall address at least the following aspects:~~[37] [38] [39] [40] [41]

~~(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and management change;~~

~~(b) identification of applicable general safety and performance requirements and exploration of options to address these;~~

~~(c) the responsibility of the management;~~

~~(d) resource management, including selection and control of suppliers and sub-contractorssubcontractors;~~

~~(e) risk management according to section I.2 of Annex I;~~

~~(f) clinical evaluation, according to Art. 49 and Annex XIII, including post-market clinical follow-up;~~

~~(g) product realisation~~[42]~~, including planning, design, development, production and service provision;~~

~~(h) control of the UDI-Code assignments to all relevant devices ensuring consistency of information provided according to article 25;~~

~~(i) setting-up, implement and maintain a systematic post-market surveillance plan according to Art.xx;~~

~~(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;~~

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37 **14090/1/13** ft 17 **BE, ES, PT, UK** prefer not to mention the list of aspects to be taken into account, anyway referred in EN ISO 13485. **BE** suggested: "*..., shall establish, document, implement, maintain and continually improve the effectiveness of a quality management system ...*". **Cion** could be considered. **Pcy** considered that details shall be included in the standard (EN ISO 13485) and not in the Regulation.

38 **14090/1/13** ft 18 IE, NL, AT, RO add: "*(d) clinical evaluation; (e) complaint handling, vigilance investigation and reporting, (f) post-market surveillance and updates to risk management and clinical evaluation documentation; (g) management of corrective and preventative actions and verification of effectiveness.*" **Cion** changes could be considered.

39 **14090/1/13** ft 19 **PL** add: "*(e) documents and records control.*".

40 **14090/1/13** ft 20 **DK, AT** "*(e) processes for the continuous updating of the technical documentation.*"

41 **DS 1009/14 DE**.

42 **14090/1/13** ft 21 **DK** add "*including the clinical evaluation and the risk analysis*".

~~(k)~~ ~~processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;~~

~~(l)~~ ~~management of corrective and preventive actions and verification of their effectiveness;~~

~~(m)~~ ~~processes for monitoring~~[43] ~~and measurement of output, data analysis and product improvement.~~[44]

[43] **14090/1/13** ft 22 **DK** add "*including clinical vigilance and the risk analysis*".

[44] **AT** add translation procedure.

7.[45] ~~Proportionate to the risk class and the type of device, manufacturers~~[46] **Manufacturers** of devices, other than custom-made devices, shall ~~institute~~**implement** and keep up to date **~~a~~ the** ~~systematic procedure to collect and review experience gained from their devices placed on the market or put into service and to apply any necessary corrective action, hereinafter referred to as 'post-market surveillance plan'~~**post-market surveillance plan referred to in Chapter VII, section 0, article 60b**.[47] ~~**The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market clinical follow-up in accordance with Part B of Annex XIII. Where post-market clinical follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.**~~

~~**If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures and, where applicable, inform the notified body concerned**[48] **including immediate notification to Eudamed as established by Article 27**~~.

~~**The manufacturer shall draw-up an annual report setting out the results of post-market surveillance. That report shall be part of the technical documentation.**~~

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[45] **14090/1/13** ft 23 This paragraph should be examined at a later stage and harmonized with the provisions of chapter VII.

[46] **UK** reinstate the first sentence of the paragraph.

[47] **DE** replace this text by a reference to chapter VII.

[48] **DK** considers that for class I device it is not necessary to require assessment by a notified body.

8. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 19 of Annex I in an official Union language which can be easily understood by the intended user or patient. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user or patient[49]. The particulars on the label shall be easily legible, clearly comprehensible and indelible[50].

9. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform[51] **accordingly** the distributors and, where applicable, the authorised representative[52] ~~accordingly~~ **and the importers**. [53] **They shall also assume the costs of removal, repair or replacement of products deriving from these situations.** ~~**Where the device presents a risk, manufacturers shall immediately inform the competent authorities of the Member States in which theymade the device available**~~[54] ~~**and, where applicable, the notified body that issued a certificate for the device in accordance with Article 45, in particular, of the non-compliance and of any corrective action taken.**~~[55]

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[49] **14090/1/13** ft 24 **BE, PT** add "*The particulars on the label shall be easily legible, clearly comprehensible and indelible*". Note from the GSC: Article 13(1) of Regulation 1169/2011 on food information to consumers (OJ L 304, 22.11.2011) "*... easily visible, clearly legible and, where appropriate, indelible*".

[50] **DS 1710/1/13** Special provisions on marking.
Is it necessary to include a sentence like "*This is a medical device*" on the label and instructions for use of medical devices? 10 MS agree - 4 MS do not agree.

[51] **14090/1/13** ft 25 **BE** add "*the competent authorities*".

[52] **14090/1/13** ft 26 **HU** add "*and the importers*".

[53] **14090/1/13** ft 27 **IE, FR, IT, CY, AT, PT, SE** add: "*Where the device presents a risk, they shall immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question and the importer, giving details, in particular, of the non-compliance and of any corrective action taken.*". **DE, ES, Cion** it could be a repetition of the provisions already existing in other chapters (e.g. 61 and 62).

[54] **DS 1075/14 LT** replace "*made the device available*" with "*placed device on the market and/or put into service*".

[55] **Cion** maintain the last sentence of paragraph 9 since - it is from 768/2008.

10. Manufacturers shall, ~~**in response to a** reasoned~~ **upon** request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority[56]. ~~They~~ **The competent authority may make a request that the manufacturer provide ~~free~~ samples of the device free of charge[57] or, where impracticable, grant access to the device. Manufacturers** shall cooperate with that authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service[58] [59].
If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may suspend the ~~incriminated~~ involved device until its demonstration of conformity to the essential requirements[60].

11. Where manufacturers have their devices designed and manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 25.

[61]

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56 **14090/1/13** ft 28 **DE, IT, PL** scrutiny reservations; "*in an (any) official Union language which can be easily understood by that authority*" seems excessive.

57 **DE, FR** manufacturers shall keep available samples of the device free of charge.

58 **14090/1/13** ft 29 **BE, AT, PL, UK** add "*If the manufacturer fails to cooperate or if the information and documentation provided is incomplete or incorrect, the competent authority may suspend the incriminated device until its demonstration of conformity to the essential requirements.*".

59 **14090/1/13** ft 30 **PT** add: "*In case of bankruptcy, the manufacturer shall provide all the technical documentation of the devices for which he is responsible and all the marketing and PMS registries to the competent authority of the Member State in which he is established.*"

60 **DS 1075/14 LT** replace "*essential requirements*" with "*general safety and performance requirements*".

61 **14090/1/13** ft 31 **ES, FR, PT, SI** add: "*11. Manufacturers of medical devices shall have an insurance or equivalent financial guarantee to cover any damage to health due to safety problems of medical devices*". **DK, HU, NL, PL** national legislation applicable. **DE, IT, CY, UK** general rules on civil liability are enough.

12. **In case of bankruptcy of the manufacturer, the manufacturer or his authorised representative shall provide all the technical documentation and the post-market surveillance plan of devices which he has placed on the market or for which he has been designated by the competent authority of the Member State in which he is established.**[62]

13. **Manufacturers of medical devices shall have an insurance or equivalent financial guarantee to cover any damage to health due to safety problems of medical devices. They shall also assume the costs of removal, repair or replacement of products deriving from these situations.**[63] [64] [65] [66]

Article 9

Authorised representative

1. A manufacturer of a device that is placed on the Union market~~, or bears the CE marking without being placed on the Union market,~~ who does not have a registered place of business in a Member State ~~or does not carry out relevant activities at~~ a registered place of business in a Member State, shall designate a single authorised representative.

2. The designation shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.

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[62] Paragraph 12 has been deleted due the results of the questionnaire reported in **DS 1710/1/13**. Do you consider that the defined obligations of economic operators are appropriate? **DK, DE, ES, FR, HR, IT, HU, NL, PL, PT, SE, UK** consider the defined obligations of economic operators not appropriate; **IE, CY, MT, SI, FI** consider the defined obligations of economic operators appropriate.

[63] Sentence moved to paragraph 9, Article 8.

[64] **DS 1710/1/13** Should a liability insurance of the manufacturers be mandatory? 6 MS Agree - 7 MS do not Agree.

[65] **DS 1710/1/13** Should it (a liability insurance of the manufacturers) be regulated by the MD and IVD Regulations? 6 MS agree - 6 do not agree.

[66] **BG, DK, DE, IE, NL, UK** delete paragraph 13.

3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. **The authorised representative shall provide a copy of the mandate to the importer, pursuant to Article 11(2)(a), and, upon request, to the competent authority**[67]**.**

The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:

(aa) ensure that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer; [68]

(a) ~~keep~~ **keep ~~at his registered place of business~~**[69] **a copy of** the technical documentation,[70] the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any ~~supplement~~ **amendments and supplements** issued in accordance with Article 45 at the disposal of competent authorities for the period referred to in Article 8(4);

(ab) comply with the registration obligations laid down in Article 25(2), (4) and (5);

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[67] **14090/1/13** ft 32 **DE** delete "*The mandate shall be provided to the competent authority, upon request, and to the importer*" problems of confidentiality.

[68] **14090/1/13** ft 33 **UK** add "(aa) ensure that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer."

[69] **PT, UK** delete "*at his registered place of business*" to assure that technical documentation is the most updated.

[70] **DS 1075/14 LT** add "*STED*".

(b) in response to a ~~reasoned~~[71] request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device ***in an official Union language which can be easily understood by that authority***;[72] [73]

(ba) forward to the manufacturer any request by a competent authority[74] for samples, or access to a device and verify that the competent authority[75] receives the samples or gets access to the device;

(c) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;

(d) immediately inform the manufacturer about complaints and reports from healthcare professionals[76], patients and users about suspected incidents related to a device for which they have been designated;

(e) terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.

~~To allow~~ **for** ~~the authorised representative to fulfill the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has permanent immediate~~ **permanently available and rapid** ~~access to the necessary documentation in one of the official Union languages~~ **which can be easily understood by the authorised representative**~~.~~[77]

4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (2), (5), (6), (7) and (8).

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71 **14090/1/13** ft 34 **PL** opposed.

72 **DE** delete last sentence; **CZ, CY** support.

73 **ES** 9(3)(c) add "*in the language determined by the law of the Member State of that authority*"; this should apply for all the regulation; **CY, PT, UK** support.

74 **DE** which is the Authority? That of the Authorised representative? **ES, Cion** no; every authority of the European Union.

75 **14090/1/13** ft 35 **DE, IT, PL** scrutiny reservations; "*in an official Union language which can be easily understood by that authority*" seems excessive.

76 **DS 1075/14 LT** delete "*healthcare professionals*".

77 Sentence moved to article 8,paragraph 5.

5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

Article 10

Change of authorised representative

The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects:

(a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;

(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material**(s) or statement(s)**;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals[78], patients or users about suspected incidents related to a device for which he had been designated as authorised representative.

[78] **DS 1075/14 LT** delete "*healthcare professionals*".

Article 11[79]

General obligations of importers[80]

1. Importers shall place on the Union market[81] only devices that are in conformity with this Regulation.

2. ~~Before placing~~ **In order to place** a device on the market[82] importers shall ~~ensure~~ **verify** the following:

   (a) that the **device has been CE marked** **and that the declaration of** ~~appropriate~~ conformity **of the device has been drawn up and is still valid** ~~assessment procedure has been carried out by the manufacturer~~[83];

   (b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer **and that the authorised representative is notified of the devices that the importer is placing on the market**[84] [85];

   ~~(c) that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;~~[86]

   (d) ~~that the device bears the required CE marking of conformity;~~[87]

   (e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use ~~and EU declaration of conformity~~[88];

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79 In the wording of this article we referred to the definitions reported in Article 2 (definitions (16), (17) e (18)).

80 **14090/1/13** ft 37 **BE, CZ, DE, IE, ES, IT, NL, AT, PT, SE, UK** importers do not have the same responsibilities as manufacturers.

81 **DS 1075/14 LT** add "*and/or put into service*".

82 **DS 1075/14 LT** add "*and/or put into service*".

83 **14090/1/13** ft 38 **PL** opposed to the deletion. **BE, CZ, DE, IE, ES, IT, NL, AT, PT, SE, UK** importers do not have the same responsibilities as manufacturers. **Cion** 11(2)(a) the same of that is in article R4 of decision 768/2008.

84 **DS 1682/13 UK** suggested the addiction.

85 **DE** there is no need to inform the authorised representative.

86 **14090/1/13** ft 39 **CZ, DE, ES, IT, LV, UK** suggested deleting the whole point c), in order to clearly delineate responsibilities between importer and authorised representative. **FR, PL, PT, Cion** opposed; deleted following the inclusion of point 11(2)(aa).

87 **14090/1/13** ft 40 **FR** add "*and is accompanied by the required EU declaration of conformity*". **Cion** the EU declaration of conformity must exist (see point c)) but needs not accompany each device.

88 **DE** does not agree on declaration of conformity accompanying the device; **SE, Cion** support.

(f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 24;[89]

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market[90] until it has been brought into conformity and shall inform the manufacturer and **~~and, where applicable,~~** his authorised representative. ~~to that effect, as well as~~**, ~~of any suspected non-conformities and,~~ Where the importer consider or has reason to believe that the device presents a risk, he shall also inform** the competent authority of the Member State in which he is established.[91]

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or ~~**where that is not possible for practical reasons,**~~ on its packaging or~~**, where impracticable,**~~ in a document accompanying the device.[92] They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall ~~ensure~~ **verify**[93] that the device is registered in the electronic system in accordance with Article 25(2~~).)~~**)**[94]**, ~~comply with their obligations laid down in paragraphs 3 to 5 of that Article~~ and shall add their details to that registration. Importers shall also verify that the registration includes details on the authorised representative and, if appropriate, inform the ~~relevant~~ authorised representative or the manufacturer ~~if it is not the case.~~**[95]

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89 **14090/1/13** ft 41 **DE, IT, LV** delete point 2(e).

90 **DS 1075/14 LT** add "*and/or put into service*".

91 **14090/1/13** ft 42 **FR** would delete the whole sub-paragraph, as it is inconsistent with Article 11(1) and would create confusion between the obligations of manufacturers and importers.

92 **DE, ES, FR** concerns on this provision; **AT** does not agree but clarity is necessary; **Cion** the same in R4 paragraph 3 of decision 768/2008.

93 **14090/1/13** ft 43 **PL** opposed. **Cion** expressed reservations on the change.

94 **14090/1/13** ft 44 **FR, AT, PL, PT** the obligation to register the device in the electronic system should appear in the general obligations of the manufacturers and authorised representatives.

95 **14090/1/13** ft 45 **PL** opposed. **CZ, IT** scrutiny reservations.

5. Importers shall ensure that, while a device is under their responsibility[96], storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I **and shall comply with the conditions set by the manufacturer, where available**.

6.[97] ~~When deemed appropriate~~ **~~Where a risk has been identified~~** ~~with regard to the risks presented by a device, importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products~~[98]**~~,~~ and** ~~investigate complaints and.~~ **~~They~~ Importers shall** keep a register[99] of complaints, of non-conforming products and of product recalls and withdrawals, and ~~shall keep~~**provide** the manufacturer, authorised representative and distributors ~~informed of such monitoring~~[100] **with any information requested by them**[101]**, in order to allow them to carry out sample testing of marketed products**[102] **and investigate complaints**.

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96 **14090/1/13** ft 46 **FR, IT, NL, AT** how can a medical device be under the responsibility of one operator rather than another?

97 **NL** consider **DS 1017/14**.

98 **14090/1/13** ft 47 **CZ, DE, IT, AT, PT, SE** delete "*carry out sample testing of marketed products*"; these are manufacturers' responsibilities. **FR** opposed.

99 **14090/1/13** ft 48 **BE, IE, FR, PT** add "*for all devices*".

100 **14090/1/13** ft 49 **CZ, DE, IT, AT** delete "*and shall keep the manufacturer, authorised representative and distributors informed of such monitoring" already provided for in 11(8)*".

101 **DS 1017/14 NL**.

102 **14090/1/13** ft 47 **CZ, DE, IT, AT, PT, SE** delete "*carry out sample testing of marketed products*"; these are manufacturers' responsibilities. **FR** opposed.

7. Importers who consider or have reason to believe that a device which they have ~~placed~~[103] **~~made available~~**[104] **placed** on the market is not in conformity with this Regulation shall immediately inform the manufacturer and**, where applicable**[105]**,** his authorised representative ~~and, if~~**. Where** appropriate, ~~take~~**importers shall co-operate with the manufacturer ~~and, where applicable~~, his authorised representative ~~or~~ and the competent authorities to ensure that** the necessary corrective action to bring that device into conformity, withdraw or recall it **is taken**. **Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 4 , giving details, in particular, of the non-compliance and of any corrective action taken**[106]**.**

8[107]. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have ~~placed~~**~~made available~~**[108] **placed** on the market shall immediately forward this information to the manufacturer and his authorised representative[109]**~~, as well as the competent authorities~~**[110] **~~of the Member States where he is aware that the device has been made available~~**.

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[103] **14090/1/13** ft 50 **DE** replace with "*made available and Article 2(21) amended accordingly: 'importer' means any natural or legal person established within the Union who makes a devices from a third country available on the Union market*". **CZ** opposed.

[104] **DS 1075/14 LT** replace "*made available*" with "*placed on the market and/or put into service*".

[105] **14090/1/13** ft 51 Alignment with 12(4).

[106] **14090/1/13** ft 52 **ES, FR, PT** opposed to the deletion. **Cion** expressed reservations regarding deletion since this provision is from decision 768/2008.

[107] To be reviewed following the results of questionnaire on vigilance matter.

[108] **DS 1075/14 LT** replace "*made available*" with "*placed on the market and/or put into service*".

[109] **14090/1/13** ft 53 **DE** delete "*his authorised representative*".

[110] **14090/1/13** ft 54 **ES, IE, PT** only serious incidents should be reported to the competent authority, in order to avoid excessive administrative burden.

9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity ~~at the disposal of the market surveillance authorities and ensure that the technical documentation~~ **and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45**[111] ~~, can be made available to those authorities, upon request. By written mandate, the importer and the authorised representative for the device in question may agree that this obligation is delegated to the authorised representative~~[112]~~.~~ **and a copy of mandate between the manufacturer and authorised representative at the disposal of the market surveillance authorities.**

10. ~~Importers shall, in response to a request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. This obligation shall be considered fulfilled when~~**The national authority may make a request that** the authorised representative for **importer provide free samples of** the device in question provides**or, where impracticable, grant access to** the required information[113] **device**~~.~~[114] Importers shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have placed on the market. **Importers, upon request of a competent authority, shall provide free samples of the device or, where impracticable, grant access to the device.**

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111 **FR** reinstate "*and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45*"; **ES, AT** support; **DE** not support.

112 **14090/1/13** ft 55 **FR, PT** opposed to the deletion. **Cion** expressed reservations regarding deletion.

113 **14090/1/13** ft 57 **BE, ES, FR, LV, PT** add "*and samples*".

114 **14090/1/13** ft 56 **ES, FR, LV** opposed to the deletion. **BE** scrutiny reservation. Instead, these delegations would add: "*The national authority may also request that the importer provide, for the purposes of analysis and for justified reasons, free samples of the devices.*".

Article 12[115]

General obligations of distributors

1. **In the context of their activities,** ~~W~~ **w**hen making a device available on the market, distributors shall act with due care in relation to the requirements applicable **and make available on the market only those devices that are in conformity with this Regulation**.[116]

2. Before making a device available on the market distributors shall verify that the following requirements are met:

   (a) the ~~**product**~~ **device** ~~bears the required CE marking of conformity~~ **has been CE marked and that the declaration of conformity of the device has been drawn up and is still valid**[117] [118]; ~~**and is accompanied by the required EU declaration of conformity**~~[119]**;**

   (b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(~~**7x**~~ **8**) ~~**and by the EU declaration of conformity**~~[120];

   (c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 24 and Article 11(3) respectively.[121]

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115 In the wording of this article we referred to the definitions reported in Article 2 (definitions (16), (17) e (18)).

116 **DE** delete paragraph 1.

117 **AT** This means that distributor shall open the parcel? It is not desirable; ask for a more general task.

118 **FR** suggests "*verify that the declaration of conformity is still valid*"; PT support.

119 **14090/1/13** ft 58 **ES, FR, PT, SE** add "*and that the required declaration of conformity is available*".

120 **DE** delete "*and by the EU declaration of conformity*"; **CZ, PT, SE, Cion** support.

121 **14090/1/13** ft 59 **DE** delete point (c) as the distributor is not able to verify it. **FR, PT** opposed.

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity**. Where the device presents a risk, the** **The distributor shall** and inform the manufacturer and, where applicable, his authorised representative**, and** the importer. ~~to that effect, as well as~~**of any suspected non-conformities and, if the device presents a risk, he shall also inform** **Where the distibutor consider or has reason to believe that the device presents a risk, he shall also inform** the competent authority of the Member State in which he is established.[122]

3. Distributors shall ensure that, while a device is under their responsibility[123], storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I[124] **and shall comply with the conditions set by the manufacturer, where available.**

[122] **14090/1/13** ft 60 **FR** would delete the whole sub-paragraph, as it is inconsistent with the obligation to put on the market only devices that are in conformity with the requirements of this Regulation.

[123] **14090/1/13** ft 61 **FR, IT, NL, AT** how can a medical device be considered to be under the responsibility of one operator rather than another?

[124] **14090/1/13** ft 62 **FR, NL** opposed to the new wording. **Cion** would prefer to keep initial wording and add "*and shall comply with the conditions set by the manufacturer, where available.*".

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer ~~and make sure~~**. Where appropriate, distributors shall co-operate with the manufacturer and, where applicable his authorised representative and the importer, and with** ~~any~~ **competent authorities to ensure** that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. **Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, and, where applicable, the notified body that issued a certificate for the device in accordance with Article 45**[125]**, giving details, in particular, of the non-compliance and of any corrective action taken**[126]**.**

5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward[127] this information to the manufacturer and, where applicable, his authorised representative[128]**,** ~~**as well as the competent authorities of the Member States in which they are aware that device has been made available.**~~[129] **They shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative informed of such monitoring and provide them with any information upon their request**.[130]

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125 **14090/1/13** ft 63 **IE; ES, PT** only serious risks should be reported to the competent authority and the notified bodies, in order to avoid excessive administrative burden.

126 **14090/1/13** ft 64 **IE** opposed to the deletion.

127 **14090/1/13** ft 65 **AT** upon request.

128 **14090/1/13** ft 66 **ES, PT** serious incidents should be notified to the competent authority of the Member State where they occurred. **CZ** opposed.

129 **DE** reinstate the obligation to report serious incident directly to competent authorities; **ES, PT, SE** support.

130 **SE** does not agree on this register.

6. **~~Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the authorised representative for the device in question, where applicable, provides the required information~~**[131] **~~[132].~~**
Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. **~~The competent authority may also request that the distributor provide, free samples of the device or, where impracticable, grant access to the device.~~Distributors, upon request of a competent authority, shall provide free samples of the device or, where impracticable, grant access to the device.**

[131] **14090/1/13** ft 67 **IE, HR, AT, PT, SE** add "*Distributors shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and verify that the technical documentation and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45, can be made available to those authorities by the authorised representative, upon request.*"

[132] **Cion** reinstate the first sentence since it is from decision 768/2008.

Article 13[133]

Person responsible for regulatory compliance

1. Manufacturers shall have ~~available within~~ **permanently and continuously at** their ~~organisation~~[134] **disposal,** at least one ~~qualified~~ person[135] ~~**responsible**~~ **in charge for regulatory compliance activities**[136] who possesses expert knowledge in the field of medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:

   (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~**a course of study recognized**[137] **as** equivalent ~~course of study, in natural sciences,~~ **by the Member States concerned, in** medicine, pharmacy, engineering or another relevant ~~discipline~~[138] sciences, and at least two years of professional experience in regulatory affairs or in quality management systems relating to ~~medical~~ devices;

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133 Article 13. Person responsible for regulatory compliance
Do you consider that any of the qualification requirements for "*qualified persons*" are not appropriate or clear? Please specify and provide an alternative wording.
5 MS Agree - 7 MS do not agree.

134 **14090/1/13** ft 68 **BE, DE, ES, FR, AT, PT** "*1. The Manufacturers shall, immediately upon commencement of his/her activities, appoint within their organization at least one qualified person who is sufficiently reliable and possesses the expert knowledge necessary for the fulfilment of the persons functions as the person responsible for regulatory compliance in the field of medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:*" The main argument in favour of such a strict requirement would be that the qualified person should know the manufacturer's organization. **DE** added that it is essential to define the qualified person's task.
DK, EE, LV, NL, SE, UK there is no need for the qualified person, with knowledge in the field of medical devices, to be an employee of the manufacturer organisation, as long as he/she would be permanently and continuously at the manufacturer's disposal.
Cion recognises that requiring that the qualified person would be an employee could be a too heavy burden. Suggested taking into account the wording of Directive 2001/83/EC ("*at his disposal*") on the same issue.

135 **14090/1/13** ft 69 **BE, UK** the name of the qualified person should be included in the EUDAMED.

136 **NL** manufacturer is responsible for regulatory compliance.

137 **DE** the equivalence is not clear; **BG** support.

138 **14090/1/13** ft 70 Delegations recognised that this description of the diplomas must be aligned with

(b) five years of professional experience in regulatory affairs ~~or~~[139] related to devices including experience in quality management systems ~~relating to medical devices~~.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate[140] their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

~~This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises~~[141] ~~as defined by Commission Recommendation 2003/361/EC~~[142]~~.~~

2. The ~~qualified~~ person **~~responsible~~ in charge for regulatory compliance activities** shall at least be responsible for ensuring the following matters:[143]

(a) that the conformity of the devices is appropriately ~~assessed~~ **checked in accordance with the quality management system under which these devices are manufactured** before a **product**[144] **~~batch~~** is released[145];

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) **that the post-market surveillance obligations ~~according~~ in accordance with Article 8(7) are complied;**

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139 **14090/1/13** ft 71 **BE, FR, PT** the qualified person must be competent in risk assessment and in demonstrating conformity with the essential requirements, as well as in quality management. Therefore, 5 years of cumulative experience in both fields seems crucial.

140 **14090/1/13** ft 72 **SK** it is not clear to whom this demonstration must be done. **Cion** clarified that it should be done to a competent authority, upon request.

141 **14090/1/13** ft 73 **DE, PT** micro-enterprises should not be exempted. **Cion** expressed reservations.

142 OJ L 124, 20.5.2003, p. 36.

143 **NL** details are not necessary; **DE** does not agree; tasks have to be clear.

144 **DE** suggest "*product release*"; **BG, ES, Cion** support.

145 **14090/1/13** ft 75 **IE, ES, FR** "*(a) that the conformity of the devices is appropriately assessed checked in accordance with the quality system under which these devices are manufactured, before a batch is released;*" **DS 1682/13** text added based on **IE** suggestion.

(d) **~~that the existing information concerning risks connected to devices is collected and evaluated and the necessary measures are co-ordinated as well as~~** that the reporting obligations in accordance with Articles 61 to 66 **~~concerning risks related to devices~~** are fulfilled[146] [147];

(e) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued;

(f) **~~collection and evaluation of existing information concerning risks connected to medical devices and co-ordination of the necessary measures. He/she is responsible for the fulfilment of reporting obligations in so far as they concern risks related to devices~~**[148] [149].

3. The ~~qualified~~ person **responsible for regulatory compliance** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

[146] **UK, Cion** letter d is not clear.

[147] **14090/1/13** ft 76 **BG, DK** opposed to the obligations added, as too large. **DS 1682/13** text updated based on **DE** suggestion.

[148] **DS 1682/13** text added based on **DE** suggestion. **UK, Cion** it is not clear.

[149] **14090/1/13** ft 77 **DK** opposed.

4.[150] Authorised representatives shall have ~~available within~~ **permanently and continuously at** their ~~organisation~~ **disposal** at least one ~~qualified~~ person ~~**responsible**~~ **in charge for regulatory compliance activities** who possesses expert knowledge regarding the regulatory requirements for medical[151] devices in the Union. The expert knowledge shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ **a course of study recognised as** equivalent[152] **by the Member States concerned,** ~~course of study,~~ in ~~law~~[153], ~~natural sciences,~~ medicine, pharmacy, engineering or another relevant ~~discipline~~[154] **sciences**[155], and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical[156] devices;

(b) five years of professional experience in regulatory affairs or in quality management systems relating to medical[157] devices.

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150 **AT** delete paragraph 4; **PT** does not agree.

151 **Pcy** reinstate to avoid confusion with IVD.

152 **DE** "*equivalence*" is not clear; **BG** support.

153 **14090/1/13** ft 78 **CZ, IT** do not see the need for the qualification in law. **Pcy** changes following changes in paragraph 1.

154 **14090/1/13** ft 70 Delegations recognized that this description of the diplomas must be aligned with

155 **Pcy** changes following changes in paragraph 1; the qualified person of the authorised representative should be able, inter alia, to deal with technical documentation.

156 **Pcy** reinstate to avoid confusion with IVD.

157 **Pcy** reinstate to avoid confusion with IVD.

Article 14

Cases in which obligations of manufacturers apply to importers, distributors or other persons

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers[158] if he does any of the following:

   (a) makes available on the market a device under his name, registered trade name or registered trade mark[159] [160], **except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation**;

   (b) changes the intended purpose of a device already placed on the market or put into service;

   (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

   The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (19) of Article 2(1), assembles or adapts a device already on the market to its intended purpose for an individual patient.

2.[161] For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

   (a) provision, including translation[162], of the information supplied by the manufacturer in accordance with Section 19 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State;

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158 **14090/1/13** ft 79 **BG, DK, IT** it should be clearly explained that there should be a new evaluation, a new procedure. **Cion** confirmed that this is the intended meaning.

159 **14090/1/13** ft 80 **ES** distributor may add his trade mark to the one of the manufacturer?

160 **AT** the scope of this paragraph is not clear; **ES** presented written suggestion (**DS 1329/14**) concerning private label since a distributor or an importer that has a private label agreement (registered trade mark) shall not assume the responsibility of the manufacturer; **PT, UK** support **ES** suggestion.

161 **14090/1/13** ft 81 **BE, SE** consider that there is a safety risk; would prefer deleting this paragraph.

162 **14090/1/13** ft 82 **NL** there is a danger of misuse when the translations contain mistakes.

(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where ~~that is not possible~~ **impracticable**, on its packaging or in a document accompanying the device[163].

He shall ensure that he has in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.

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[163] **14090/1/13** ft 83 Following a linguistic remark from **DE**, the text could read:
"*A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is not possible, on its packaging or, in exceptional cases, in a document accompanying the device:*
– *the activity carried out,*
– *his name, registered trade name or registered trade mark,*
– *the address at which he can be contacted and his the location can be where he is established.*"

4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate[164], issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

[164] **14090/1/13** ft 84 **DK, ES, UK** which kind of certificate?

Article 15[165] [166] [167] [168] [169] [170] [171]

Single-use ~~**Reprocessing of medical**~~ *devices and their reprocessing*[172] [173] [174]

0. Save where prohibited by Member States under national law, the reprocessing and further use of single-use devices shall be permitted only in accordance with this article.

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[165] **14090/1/13** ft 85 **CZ, FR, IT, PL, RO, SE** opposed to reprocessing.
DK, EE, AT, PT, SK, UK support **Cion** proposal. **DK** "*in house*" reprocessing should be excluded. **PT** see EP amendment. **DE, NL** reprocessing for all products – MS may establish their requirements.

[166] **DE** suggestion:

"*Article 15 – Reprocessing of Medical Devices*

1. *Member States shall adopt and publish provisions governing the proper reprocessing of medical devices at the latest two years following the entry into force of the present Regulation. To this end, they shall stipulate in particular the use of suitable validated procedures, the success of which is guaranteed in a verifiable manner and which do not pose a danger to the safety of patients, users and third parties.*
2. *A Member State may maintain or introduce national provisions that prohibit the reprocessing of specific medical devices and/or the making available of specific reprocessed devices within its territory in so far as it considers this necessary for reasons that are to be specified.*
3. *Member States shall inform the Commission and the other Member States of the national provisions taken pursuant to (1) and (2).*"

CZ support.

[167] **DS 1710/1/13** Should it be permitted to reprocess medical devices placed on the market as "*single use*"? **DK, DE, IE, ES, HR, CY, HU, NL, PT, SI, UK** support reprocessing.
FR, IT, MT, PL, FI, SE do not agree.

[168] Do you agree that reprocessing of single use medical devices should be regulated at EU level? **DK, IE. ES, HR, CY, HU, PL, PT, SI, UK** agree; **DE** does not agree.

[169] Do you agree with the definitions proposed in Article 2(27) of the MD proposal? 9 MS agree - 1 MS does not agree.

[170] Do you agree with the provisions set out in Article 15 and in particular Article 15(6) of the MD proposal? 6 MS agree - 5 do not agree.

[171] Do you agree with the provisions of Article 15(4) by which the Commission shall establish and regularly update a list of categories or groups of single-use devices for critical use which may be reprocessed? 9 MS agree - 3 do not agree.

[172] **Pcy** proposes to reinstate the title from the **Cion** proposal.

[173] **DS 1040/14 DE** suggestion

"*Article 15 Reprocessing of Single –use Medical Devices*

A Member State may maintain or introduce national provisions that prohibit the reprocessing of single use medical devices.

The making available on the market of reprocessed single-use medical devices is prohibited. The reprocessing of a medical device for another party and then returning it to them is not considered to be making available on the market."

[174] Doc. **MDEV-61** 17 MS agree with the text proposed in option A; 6 MS do not agree; 4 MS agree with option B. **BE, BG, EE, IE, ES, FR, HR, CY, LT, LU, HU, MT, AT, PL, PT, SI, SK** agree with the text proposed.

1. Any natural or legal person[175] [176] who reprocesses a single-use device to make it suitable for further use **~~to be made available on the market~~**[177] within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation. **~~The in-house manufacture obligations' exemptions of Art. 4(4) shall apply.~~**[178]

2. Only single-use devices that have been placed **or put into service**[179] on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be reprocessed**~~, subject to any national provisions adopted in accordance with paragraph 3~~**.

3. In the case of reprocessing of single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out.

4. The Commission, by means of implementing acts, shall establish and regularly update a list of categories or groups of single-use devices for critical use which may be reprocessed in accordance with paragraph 3[180]. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).[181]

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175 **14090/1/13** ft 86 **EE, ES, IT,AT** add "*including health institutions as specified in Article 4(4)*".

176 **DS 1068/14 IT** add "including health institutions as specified at Art. 4(4)"

177 **DS 1068/14 IT** replace "*a device to make it suitable to be made available on the market" with "a single use device to make it suitable for further use*".

178 **DS 1068/14 IT** delete "*The in-house manufacture obligations' exemptions of Art. 4(4) shall apply*".

179 **Cion** add "*or put into service*".

180 **ES** negative list could be better; AT, UK support; **Cion** does not agree.

181 **NL, SK, UK** opposed to this paragraph.

5. The name and address of the legal or natural person referred to in paragraph 1 and the other relevant information in accordance with Section 19 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device **~~enabling the health professional to suitably apprise the patient that a reprocessed medical device will be used on him~~**.

~~3. For the purposes of this Article, and with a view to ensuring the safety of patients, users and third parties, MS may adopt provisions governing the proper reprocessing and use of medical devices, having regard, in particular to the utilisation of suitably validated procedures, the success of which can be verified.~~

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

6.[182] A Member State may maintain or introduce **stricter** national provisions **restricting or** prohibiting, within its territory, on grounds of protection of public health ~~specific to that Member State~~ the following:

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available **~~on the market~~** **and further use**[183] of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of the national provisions and the grounds for introducing them **~~pursuant of (3) & (4)~~**. The Commission shall keep the information publicly available.

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[182] **14090/1/13** ft 88 **NL** opposed as lets too much flexibility to the MS. **FR** this flexibility is essential.

[183] **Cion** support.

Article 16[184] [185]

~~*Implant card*~~ ***~~Patient implant card and information leaflet~~*** ***Information to be supplied to the patient with an implanted device***[186]

1. The manufacturer[187] of an implantable device shall provide together with the device ~~an~~ implant card ~~**and an information leaflet**~~ **the following:**~~-~~[188]

   (a) **information allowing the identification of the device, including the device name, serial number, batch code or lot number, the Unique Device Identification, as well as the name and address of the manufacturer;**[189]

   (b) **information on the medical examinations that the patient should avoid**[190] **or warn those performing them;**

   (c) **any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;**[191]

   (d) **any information about the expected lifetime of the device and any necessary follow-up;**

   (e) **any other information to assure a safe use of the device by the patient.**

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[184] Article 16. Implant card. Do you consider that an implant card should be provided with all categories of implantable devices? 8 MS agree - 8 MS do not agree.

[185] **DE, NL, AT, UK** do not agree with too many details in the provision and ask for a more general provision.

[186] **14090/1/13** ft 89 **DK, NL** both must be permanently updated, through the access to the information contained in EUDAMED. The information in the card must contain the composition of the devices, should certain components be incompatible with other substances and be the cause of allergies. **Cion** the information on composition and allergies should rather be included in the leaflet.

[187] **14090/1/13** ft 90 **DE** too much information is a burden for the manufacturer.
UK all the information should be provided by the health institution.

[188] **14090/1/13** ft 95 **BE, IE** all the information to be supplied to patients in accordance to section 19 of Annex I.

[189] **14090/1/13** ft 93 **DE, NL** add: *the product name, batch code or lot number and name and address of the manufacturer*".

[190] **14090/1/13** ft 94 **AT** list of the medical examinations that the patient should avoid.

[191] **14090/1/13** ft 96 **DE** replace with "*information that must be noted to avoid certain risks in connection with the device.*".

1a. **The above mentioned information** ~~which~~ shall be made available to the particular patient who has been implanted with the device**, by means of a card, a leaflet or any other means that can allow a rapid access to the information and shall be written in a way that is readily understood by a lay person**. **The information shall be given at least in the official language or, where applicable, languages of the Member State(s) where the device is put into service.**

1b. **The Commission, by means of implementing acts, shall establish a list of categories or groups of devices to which this Article shall not apply.**[192] **These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88 (3).**[193]

~~2.~~ ~~This~~ **The** ~~card~~**, which shall have the size of an identification card, to be permanently carried by the patient,** ~~shall contain the following:~~

~~(a) the information allowing identification of the device, including the~~ **device name, serial number, batch code or lot number, the** ~~Unique Device Identification, as well as the name and address of the manufacturer;~~

~~**(b)** fields for entries to be made post-implantation by the health institution, specifying the patient's name, the date of implantation and the name of the responsible person as well as the institution carrying out the implantation;~~

~~**(c)** list of the medical examinations that the patient should avoid or warn those performing them.~~

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[192] **DE, AT** prefer positive list; **FR** prefer negative list.

[193] This paragraph has been inserted on request of **DK, DE, ES, NL, UK** that asked for a positive list.

3. **The information leaflet shall contain the following information:**

(a) **the device name, as well as the name and address of the manufacturer;**

(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;

(c) any information about the expected lifetime of the device and any necessary follow-up.

4. The information **in the implant card and the information leaflet** shall be written in a way that is readily understood by a lay person. **Both documents shall be at least in the official language and or, where applicable, languages of the Member State(s) where the device is made available on the market or put into service. The content of all language versions must be identical.**

Article 17

EU declaration of conformity

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall **accompany the device and** be translated[194] into **the** **an** official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.

[194] **14090/1/13** ft 97 **PL, PT** who should be responsible for the translation?

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress[195].

Article 18

CE marking of conformity

1. Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity[196], ~~as presented in Annex IV~~ **~~accompanied by the indication "medical device", in accordance with Annex xx~~**.[197]

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided[198].

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195 **14090/1/13** ft 98 **DE, IT** opposed, as no technical progress could be foreseen in this area. **Cion** the content would be amended only if needed.

196 **14090/1/13** ft 99 **BE, DK, FR, IT, SE** "*accompanied by the indication 'medical device'*" or **SE** by a symbol with that meaning. **PT** would transfer such a requirement to the labelling (annexes).

197 **NL, UK** do not agree with adding "*accompanied by the indication "medical device", in accordance with Annex xx*"; **CZ, HU** agree with giving the information but not necessarily in association with the CE mark; **Pcy** consider that it is better to transfer the request to Annex I, point 19.

198 **14090/1/13** ft 100 **DK**: it is not the best option to let the manufacturer choose where to affix the CE marking.

4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 42. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.

6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.

Article 19

Devices for special purposes

1. Member States shall not create any obstacle to the following devices:

   (a) investigational devices which are supplied to a doctor of medicine, a dental practitioner or an authorised person for the purpose of clinical investigation[199] if they meet the conditions laid down in Articles 50 to 60 and in Annex XIV;

   (b) custom-made devices which are[200] made available on the market if they comply with Article 42(7) and Annex XI.

   Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 54.

2. Custom-made devices shall be accompanied by the statement referred to in Annex XI which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

   Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been[201] made available in their territory.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided **~~that such devices are not used on participants and the expression "demonstration devices" is visibly affixed on those devices~~**[202] a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.

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199 **14090/1/13** ft 101 **DE** the different medical "titles" of the qualifications should be reviewed.
200 **DS 1075/14 LT** add "*placed or*".
201 **DS 1075/14 LT** add "*placed or*".
202 **BE, NL, UK, Cion** delete the added words.

Article 20

Systems and procedure packs

1. Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:

   (a) other devices bearing the CE marking;

   (b) *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU)[203] **[…/…]with the exemption of devices for self-testing;**

   (c) other products which are in conformity with the legislation applicable to those products[204] **only when they are used within the medical procedure or their presence in the system or procedure pack is justified**.

2. In the statement, the person referred to in paragraph 1 shall declare the following:

   (a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions;

   (b) that he packaged the system or procedure pack and supplied relevant[205] information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

   (c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

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[203] **14090/1/13** ft 102 **BE, ES, AT** add "*with the exception of devices for self-testing;*".
DE opposed.

[204] **14090/1/13** ft 103 **ES, PL** add "*only when they are used within the medical procedure or their presence in the system or procedure pack is justified*".

[205] **14090/1/13** ft 104 **SE** how to define "relevant"?

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market **in his own name** shall, at his choice, follow one of the procedures referred to in Annex VIII or in Part A of Annex X. The application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.

4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, **or where the sterilisation has not been carried out in accordance with the manufacturer's instructions** the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 42.

5. The systems or procedure packs referred to in paragraph 1shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraph 1and 3 as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 19 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.

Article 21

Parts and components

Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device ~~without significantly changing its performance or safety characteristics~~, shall ensure that the article does not adversely affect the safety and performance of the device. ~~Substantiating~~ **Supporting** evidence[206] shall be kept available to the competent authorities of the Member States.

~~An article that is intended specifically to replace a part or component of a device and that significantly changes~~[207] ~~the performance or safety characteristics of the device shall be considered a device.~~

Article 22[208]

Free movement

Without prejudice to Article 15, Member States shall not refuse, prohibit or restrict the[209] making available or putting into service within their territory of devices which comply with the requirements of this Regulation.

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206 **14090/1/13** ft 105 **DE** which kind of evidence?

207 **14090/1/13** ft 106 **PL, PT** who will establish that the changes are significant?

208 **14090/1/13** ft 107 **NL** add provisions on promotion, in line with Article 94 of Directive 2001/83/EC. **FR** promotion should be dealt at national level.

209 **DS 1075/14 LT** add "*placing on the market*".

~~Article 22a~~[210] [211]

~~Promotion~~

~~1. Where medical devices are being promoted, no gifts, pecuniary advantages or benefits in kind may be supplied, offered, promised or accepted, unless they are inexpensive and relevant to the practice of medicine.~~

~~2. Hospitality at events for purely professional and scientific purposes or at sales promotion events shall always be strictly limited to the main objective of the event and to what is strictly necessary to attend said event.~~

~~3. Services rendered by healthcare professionals as part of the marketing or promotion of medical devices, shall be based on a written agreement detailing at least the exact nature of the services and remuneration. Remuneration shall be proportionate to the services rendered.~~

~~4. Existing measures and trade practices in Member States relating to prices, margins and discounts shall not be affected by paragraphs 1, 2 and 3. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I.~~

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[210] Advertising of medical devices
Do you see a need for specific provisions at EU level for the advertisement of medical devices? If the answer is positive, please specify which kind of provisions and justify.
6 MS Agree - 9 MS do not agree.

[211] **DS 1710/1/13 DK, IE, HR, IT, MT, PL** agree with a specific provision at EU level for the advertisement of medical devices. **DE, FR, CY, HU, NL, PT, SI, FI, UK** do not agree. If the answer is positive (to regulate advertisement at EU level), should they be subject to the present Regulations?
3 MS agree - 2 MS do not agree.

ANNEX B

Definitions to be examied in the meeting of the Working Party on 12 and 13 February 2015.

(7) 'generic device group' means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(8) 'single-use device' means a device that is intended to be used[212] on an individual patient during a single procedure.
~~The single procedure may involve several uses or prolonged use on the same patient;~~[213]

(9) 'single-use device for critical use' means a single-use device intended to be used for ~~surgically~~[214] invasive medical procedures;

[215]

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[212] **IE** suggest to add "*on a continuous basis*".

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

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

[215] ~~**DS 1868/12 FR** add:~~
~~"*"Aesthetic devices" means: Any instrument, apparatus, appliance, implant, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings to provide a desired change in visual appearance, without therapeutic or reconstructive purpose, by its total introduction into the human body, by placing it in contact with the surface of the eye or by inducing cell or tissue modifications, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.*~~
~~*Tattoos and body piercing are not considered as aesthetic devices.*~~"

216 217

(9a) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose within a unique procedure;[218]

(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;[219]

(10) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;

(11) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices[220];

(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;

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216 **DS 1733/13 (FR), DS1205/14 FR** add the following definition:
" *'Falsified medical device' means any device with a false presentation:*
- *of its identity, including its packaging and labelling, its name, its design and manufacturing characteristics and, if appropriate, its components or its expiry date*
- *of its origin, referring to its manufacturer, its country of manufacture or its country of origin and, if appropriate, of that of its various components, or*
- *of its history, incorporating its CE marking certificates and documents relating to CE marking procedures, its technical documentation, its traceability, or to authorisations issued by non-EU countries.*

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights."

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

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

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

220 **ES** replace the end of the definition by: "… or on the *sales* packaging;". **PT** support.

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

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

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

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

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

Definitions related to the making available of devices:

(16) ‘making available on the market’ means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

221 222

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221 **DS 1367/13 BE** add the following definitions:

"*(16a) 'performance' means any technical characteristics, any effects and any benefit of the device when used for the intended purpose and in accordance with the instructions of use.*

(16b) 'safety' means the avoidance of risk (or harm) caused by the device or associated with its use.

(16c) 'benefit' means the device's positive impact on health based on clinical data; referred to as clinical efficacy when based on clinical investigations and as clinical effectiveness when based on clinical experience after placing on the market. Benefit can also mean a positive impact on patient management or public health, for example for diagnostics.

(16d) 'risk' (or harm) means the device's negative impact on the overall health based on clinical investigations, other clinical data and vigilance reports. For diagnostics, the risk from false-positive or false-negative results should also be considered.

(16e) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose.

(16f) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.

(16g) 'system' means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose."

222 **DS 1519/13 IT** add the following definitions:

"*(16a) 'benefit' means the positive effect on health, evaluated upon valid scientific clinical evidence, obtained using a medical device for the intended purpose and in accordance with the instructions of use*

(16b) 'safety' means reasonable assurance, evaluated upon valid scientific clinical evidence, that a medical device, when used for the intended purpose and in accordance with the instructions of use, provides positive effect on health outweighed the probable risks and is freedom from inacceptable risk. Safety also means avoidance of risk caused by a medical device or its use in users or other subjects

(16c) 'risk' means the combination of the probability of occurrence of harm and severity of that harm

(16d) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the medical device for the intended purpose, when used in accordance with the instructions of use."

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

(18) 'putting into service' means the stage at which a device, other than an investigational device[223], has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

Definitions related to economic operators, users and specific processes:

(19) 'manufacturer' means the natural or legal person ~~***with responsibility for the design,***~~ ~~who~~ manufactures ***or fully refurbishes***[224] ~~***, packaging and labelling of***~~ a device ~~***before it is placed on the market***~~ or has a device designed,[225] ~~***or***~~ manufactured or fully refurbished,[226] and markets that device[227] under his ~~***own***~~ name or trademark[228] [229]***, regardless of whether these operations are carried out by that person himself or on his behalf by a third party***.[230]

~~***The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.***~~[231]

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223 **DS 1416/14 AT** delete "*other than an investigational device*". **PT** support.
224 **ES** Delete: "*or fully refurbishes*".
225 The highlighted text is reinstated.
226 **ES** Delete: "*or fully refurbished*".
227 The highlighted text is reinstated.
228 The highlighted text is reinstated.
229 **ES** Delete: "*or trademark*".
230 **DS 1189/13 IT** add "*regardless of whether these operations are carried out by that person himself or on his behalf by a third party*". This sentence would clarify that manufacturers can produce medical devices or alternatively can have their medical devices produced by a third party on their behalf.
231 **DE** replace with the 93/42/EEC definition. **DK** support (**DS 1403/14**).

For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already[232] 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;[233] [234]

(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***[235]***,*** to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(21) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;

(22) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;

(23) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(24) 'health institution' means an organisation whose primary[236] purpose is the care or treatment of patients or the promotion of public health[237];

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

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

233 **NL, UK, Cion** reinstate Cion proposal.

234 The highlighted text is reinstated.

235 **DS 1189/13 IT** add "*located outside the European Union*";

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

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

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

(27) ‘reprocessing’ means the process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used device;

ANNEX I[238] [239]

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS[240]

I. General requirements

1. Devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose~~, taking into account the generally acknowledged state of the art~~. They shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety***, taking into account the generally acknowledged state of the art***[241] [242].

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238 The text of this annex is based on DS 1536/14. The only changes compared to that document are reformatting and correction of obvious errors.

239 A lot of different terminology is being used to indicate requirements for risk reduction, e.g. "reduce as far as possible", "reduce as far as possible and appropriate", "eliminate", "minimize", "shall not present any risk", "reduce to a minimum". It was suggested that the same terminology should be used wherever possible throughout Annex I. **NL** support.

240 It was suggested to find alternative wording for "to reduce as far as possible the risk" as there would be no end point to risk reduction (e.g. "reduce risks as much as possible until the intended benefit risk balance has been achieved" or "reduce risks as much as possible without adversely affecting the evaluated benefit risk balance"). **SE** share these concerns; **Pcy** suggest the following to harmonize the text: "reduce as far as possible and appropriate the risk".

241 It was suggested that the term "state of the art" should be clarified. It was suggested to discuss whether 'state of the art" should be connected just with the risk benefit of the device or with its performance as well. It should be discussed and decided in CWP. Do we mean "medicine practises" as well? **DE** consider that reduce the risk could imply a negative effect on efficacy; **PT** support; **NL** support.

242 **BE, ES** revert to the Cion proposal; **Cion** support new formulation of paragraph 1.

~~This shall include:~~[243]

- ~~reducing as far as possible the risk of use error due to ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and~~
- ~~consideration of the technical knowledge, experience, education and training, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).~~

~~*1a.*~~[244] ~~*The manufacturer has to establish, implement, document and maintain a risk management process*~~[245] [246]~~**. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.**~~

~~**The risk management process must include:**~~

~~*(a)*~~ ~~*identification and analysis* **identify of known or** *reasonably* **foreseeable hazards and estimate the associated risks arising from the intended use and** *reasonably* **foreseeable misuse;**~~

~~*(b)*~~ ~~*elimination and reduction of risks according to clause 2;*~~

~~*(c)*~~ ~~*proliferation*~~[247] ~~*of training to users.*~~[248]

[249]

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243 It was suggested to move those bullets into new Section (new Section 2b).

244 **UK** merge paragraphs 1a and 2; **ES** support.

245 **DE** move 1a to article 8.

246 It was suggested to discuss and decide which place (Annex or Article) is more suitable for such general provision.

247 **ES** against the term "*proliferation*".

248 **IE** reservation on training of users.

249 **IE** add wording that imply a continuous management of the information concerning the risks, included the information from the market; **AT** support.

2.[250] The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks~~, the manufacturer shall manage the risks so that the residual risk~~ associated with each hazard as well as the overall residual risk ~~is judged acceptable. The~~**, the** manufacturer shall **establish, implement, document and maintain a continuous risk management process to allow** ~~apply the following principles in the priority order listed~~:

(a) **to** identify **and analyse** known or **reasonably** foreseeable hazards and estimate the associated risks arising from the intended use and reasonably foreseeable misuse;

(b) **to** eliminate **or ~~the~~ reduce** risks as far as possible ~~through inherently safe design and manufacture~~ **and appropriate**;

(c) **where appropriate, to implement** ~~reduce as far as possible the remaining risks by taking~~ adequate protection measures, including alarms **, in relation to risks that cannot be eliminated**; and

(d) **to** provide **information for safety (warnings/precautions/contraindications) and, where appropriate,** training to users**.**

The manufacturer shall ~~and/or~~ inform users of any residual risks.

~~The solutions *risk control measures* adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.~~ ~~To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.~~ *~~In selecting the most appropriate solutions, Tthe~~* ~~manufacturer shall apply the following principles in the priority order listed:~~

~~(a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;~~

~~(b)(a) eliminate *or reduce* risks as far as possible and appropriate through inherently safe design and manufacture *construction*;~~

[250] **DK**, **DE** revert to the Cion proposal on clause 2.

~~(c)~~*~~(b)~~* ~~reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and~~ *~~where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated~~*~~;~~

~~(d)~~*~~(c)~~* *~~provide information for safety (warnings/precautions/contraindications) and, where appropriate training to users.~~*

2b. In eliminating or reducing risks[251] related to use error the manufacturer shall apply the following principles:

- ***reducing as far as possible the risks related to the ergonomic features of the device[252] and the environment in which the device is intended to be used (design for patient safety), and***
- ***consideration of the technical knowledge, experience, education and training and, where applicable, the medical and physical conditions of intended users (design for lay, professional, disabled or other users).***

3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of ~~*intended*~~[253] use and has been properly maintained in accordance with the manufacturer's instructions. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.[254]

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251 **UK** Same terms should be used; **Pcy** proposal: "*reduce risks as far as possible and appropriate*".

252 **DS 1439/14 BE** add "*the interpretation of the result*".

253 **Cion** delete "*intended*" since it is specified "*normal*".

254 Last sentence reinstated. **ES, PT**, **Cion** against deleting last sentence; it is important mentioning the lifetime of the device.

4. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by[255] ~~***during***~~ transport and storage **conditions**[256] (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

5. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the ***evaluated***[257] benefits to the patient[258] of the achieved performance of the device during normal conditions of use.

5a. Demonstration of conformity with the general safety and performance requirements must include a clinical evaluation in accordance with Article 49 **and Annex XIII.**[259] [260]

~~***6a.***~~[261] ~~***Any claims of the manufacturer with regard to the patient benefit(s) of a device must clearly address specified, clinically relevant outcomes to the target group(s), including, where appropriate, specification of efficacy and effectiveness, where these patient benefits and the inherent risks, harms and side effects shall be acceptable against the state of the art in medicine and be demonstrated by clinical evidence according to article 49 and Annex XIII.***~~

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255 Reinstated word.

256 **Cion**: negative effects on the devices could come to light even after the transport and storage

257 **DK** delete "*evaluated*".

258 **AT** add "*based on the risk/benefit determination and the state of art in medicine*";
DS 1455/14 FR, AT add "achieved, under consideration of the state of the art in medicine".

259 **DS 1455/14 FR, AT** add "*and Annex XIII*".

260 **Cion** better move the paragraph to chapters.

261 It was suggested for CWP to decide regarding the need of such provision. **DK, ES, AT, SE, Cion** delete paragraph 6a; **BE** support the added paragraph.

6.[262] For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, the general requirements set out in Sections 1 and 5[263] shall be understood that the device, when used under the conditions and for the purposes intended, shall not present any risk or only the minimum acceptable risks related to the product's use which is consistent with a high level of protection for the safety and health of persons[264].

II. Requirements regarding design and construction

7. Chemical, physical and biological properties

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

(a) the choice of materials ***and substances*** used, particularly as regards toxicity and, where appropriate, flammability;

(b) the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the ***device and, where relevant, absorption, distribution, metabolism and excretion***[265];

(bb) the impact of processes on material properties;

(c) where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand;

(d) the ~~choice~~ ***mechanical properties*** of the materials used, reflecting, where appropriate, matters such as ***strength, ductility, fracture resistance*** ~~hardness~~, wear ***resistance*** and fatigue ***resistance*** ~~strength~~;

(e) surface properties;

(f) confirming that the device meets any defined chemical and/or physical specifications.

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

[263] **AT** add reference to Section 2b.

[264] CWP to decide on the scope. It was not decided which safety requirement should apply to such products. **SE** delete paragraph 6.

[265] **DS 1518/2014 PT, UK** joint suggestion on substances to be introduced into the human body.

7.2. The devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed and to the duration and frequency of exposure.

7.3. The devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their ~~normal~~ ***intended*** use ~~or during routine procedures~~; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these medicinal products and that both the performance of the medicinal products and of the devices are maintained in accordance with their respective indications and intended use.

7.4. [266] [267] [268]The devices shall be designed and manufactured in such a way as to reduce[269] as far as possible and appropriate the risks posed by substances ***or particles, including wear debris, degradation products, processing residues,*** that may ~~leach, or leak~~ ***be released*** from the device[270]. Special attention shall be given to substances ***or particles*** which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006[271], and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[272].

[273]

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266 **DK** supports Cion proposal.

267 It was suggested to discuss these provisions in CWP. Do we need to define the limits? Should "particle" be included (check with the REACH regulation)? Which MD should be subject to the labelling requirements?

268 **DS 1328/14 SE** suggestions for changes to section 7.4; **DK** against.

269 **DS 1930/13 NL** modify "*to a level as low as reasonably practicable* ~~*as far as possible and appropriate*~~".

270 **DS 1928/13 UK** add "*and from wear debris generated during normal conditions of use*"; **UK** suggests additional wording to make explicit that manufacturers should be taking into account the effect of wear debris, which has been a major issue with metal-on-metal hip replacements.

271 OJ L 353, 31.12.2008, p. 1.

272 OJ L 136, 29.5.2007, p. 3.

273 **DS 1568/13 BE** add "*General and systematic assessment of medical devices on the risk from above listed dangerous substances shall be based on Common Technical Specifications (or Harmonised standard) developed by the Commission by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88 (3). When establishing the implementing acts, the Commission shall take into account the risk of migration of leaching and leaking substances from medical devices and the risk of exposure for the different classes of medical devices. The requirements of the chemical risk assessment as defined under the REACH regulation shall be taken as basis for the analysis. The Commission shall carry out a study to develop recommendations for identifying adequate specifications within … (to be defined in agreement with the Commission) years after entry into force of this Regulation.*". **IE, AT, PL, PT** support. **DK**, **DE**, **UK** not consider the need to add all the dangerous substances.

[274]If devices, or parts thereof, that are intended

– to be invasive devices and to come into contact with the body of the patient ~~for short- or long-term~~, or

– to (re)administer medicines, body liquids or other substances, including gases, to/from the body, or

– to transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

contain, in a concentration of 0.1% ***or above***[275] by mass[276] of the plasticised[277] material ***of the devices or parts thereof as mentioned*** ~~or~~ above[278], phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing phthalates.[279]

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274 **DS 1929/13 DE** replace the rest of this section with:
"*If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.*".

275 **DS 1930/13 NL** add "*or above*".

276 It was suggested to check which term is more suitable: mass/weight?

277 **DS 1568/13 BE** delete "*plasticised*" and "*phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008*" and add "*taking into consideration the sum of these classified substances, hazardous substances as defined under alinea 1 of point 7.4,*"; **PT** support.

278 **DS 1937/13 FR** delete "*in a concentration of 0.1% by mass of the plasticised material or above*".

279 **DS 1937/13 FR** add "*The tubes intended to be used in the treatment of children or treatment of pregnant or nursing women, shall not contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008. Moreover,*"

If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

7.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate risks posed by the unintentional ingress ~~or egress~~ of substances into ~~or from~~ the device taking into account the device and the nature of the environment in which it is intended to be used.

7.6. The devices shall be designed and manufactured in such a way as to reduce ~~to a minimum~~ **as far as possible and appropriate** the risks linked to the size and the properties of particles ~~used~~ ***which are released into the patient's or user's body, unless they come into contact with the intact skin only.*** Special ***attention shall be given to nanomaterials*** ~~care shall be applied when devices contain or consist of nanomaterial that can be released into the patient's or user's body~~.

8. Infection and microbial contamination

8.1. The devices and manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible **and appropriate** the risk of infection to patients, users and, where applicable, other persons. The design shall:

~~(a) allow easy handling,~~

~~and, where necessary~~,

(b) reduce as far as possible and appropriate any microbial leakage from the device and/or microbial exposure during use,

(c) prevent microbial contamination of the device or ***its content such as*** specimen***s or fluids***.

8.2. Devices labelled as having a ~~special microbiological~~ ***specific microbial*** state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.[280]

8.3. Devices delivered in a sterile state shall be designed, manufactured and packaged ~~in a non-reusable pack, and/or~~ according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened ***at the point of use***. ***These measures shall ensure that the integrity of the sterile packaging is clearly evident to the final user.***

8.4. Devices labelled ~~either~~ as sterile ~~or as having a special microbiological state~~ shall have been processed, manufactured, ***packaged*** and, ~~if applicable,~~ sterilised by appropriate, validated methods.

8.5. Devices intended to be sterilised shall be manufactured ***and packaged*** in appropriate~~ly~~ ***and*** controlled ~~(e.g. environmental)~~ conditions ***and facilities***.

8.6. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

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[280] It was suggested to decide regarding the need of such provisions. If yes, labelling requirements (Section 19) should be amended accordingly.

8.7. The labelling of the device shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition ***additional to the symbol used to indicate that a product is sterile***.

x.x. Where applicable, the device is designed to facilitate its disinfection, cleaning, decontamination and/or resterilisation (e.g. endoscopes).[281]

9. Devices incorporating a substance considered to be a medicinal product and devices composed of substances or combination of substances <u>that are absorbed by or locally dispersed in the human body</u> ~~intended to be ingested~~[282]~~, inhaled or administered rectally or vaginally~~[283]

9.1. In the case of devices referred to in the first subparagraph of Article 1(4), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, shall be verified ~~by analogy~~[284] with the methods specified in Annex I to Directive 2001/83/EC, as laid down in the applicable conformity assessment procedure in this Regulation.

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[281] This new requirement is meant to respond to the difficulties concerning the cleaning of endoscopes, encountered in practice. The risk of nosocomial infections is particularly high with this type of devices. Consequently, a particular attention shall be paid to this issue. It is suggested to include additional provision. Needed to decide where and improve the wording.

[282] It was decided to discuss regulation of ingested product in CWP.

[283] **DS 1937/13 FR** Change as follows "*Devices incorporating <u>as an integral part, when placed on the market or used in accordance with the manufacturer's instructions,</u> ~~a substance considered to be~~ a medicinal product and devices composed of substances or combination of substances ~~intended to be ingested, inhaled or administered rectally or vaginally~~*".

[284] The meaning of "*by analogy*" is not clear.

9.2. Devices that are composed of substances or combination of substances **that are** intended to be ~~ingested,~~[285] ~~inhaled or administered rectally or vaginally~~ **introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane** and that are absorbed by or **locally** dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC **including consideration of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as laid down in the applicable conformity assessment procedure in this Regulation**.[286]

[285] It was decided to discuss regulation of ingested product in CWP.

[286] **DS 1518/2014 PT, UK** joint suggestion on substances to be introduced into the human body.

10. Devices incorporating materials of biological origin[287]

10.1. For devices manufactured utilising tissues or cells, or their derivatives, of human origin which are ***non-viable or rendered non-viable*** covered by this Regulation in accordance with point (e) of Article 1(2) the following applies:[288] [289]

(a) Donation, procurement and testing of tissues and cells of human origin used for the manufacture of devices shall be made in accordance with Directive 2004/23/EC.

(b) [290]The processing, preservation and any other handling of those tissues and cells shall be carried out so as to provide ~~optimal~~ safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

(c) It shall be ensured that the traceability system for devices manufactured utilising those human tissues or cells is complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC[291].[292]

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287 It was suggested to decide regarding the meaning of "biological origin"

288 **DS 1930/13 NL** Reference should be made under a) to directive 2006/17/EC, and under b) and c) to directive 2006/86/EC. It should be considered whether the reference to directive 2002/98/EC is still necessary (probably yes).
- COMMISSION DIRECTIVE 2006/17/EC of 8 February 2006, implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells
- COMMISSION DIRECTIVE 2006/86/EC of 24 October 2006, implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

289 It was suggested to consider which references should be made. Reference should be made under a) to directive 2006/17/EC, and under b) and c) to directive 2006/86/EC.

290 **IE, AT** add "*appropriate sourcing*".

291 OJ L 33, 8.2.2003, p. 30.

292 Text from Cion proposal reinstated. **DK, IE, FR, AT, PT, Cion** reinstate Section 10.1. c).

10.2. For devices manufactured utilising tissues or cells, or their derivatives, of animal origin which are non-viable or rendered non-viable the following applies:

(a) Where feasible taking into account the animal species, tissues and cells of animal origin shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained ***by manufacturers and notified bodies***.

(b) Processing, preservation, testing and handling of tissues, cells and substances of animal origin shall be carried out so as to provide ~~optimal~~ safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, ***except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device.***

(c) In the case of devices manufactured utilising tissues or cells of animal origin as referred to in Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin[293], the particular requirements laid down in that Regulation shall apply[294].

10.3. For devices manufactured utilising other non-viable biological substances[295] the following applies:

In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide ~~optimal~~[296] safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

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[293] OJ L 212, 9.8.2012, p. 3.

[294] ~~Council Directives 90/385/EEC and 93/42/EEC will be repealed. Commission Regulation (EU) No 722/2012 should be considered, instead of this reference in the new Regulation.~~

[295] It was suggested to decide regarding the meaning of "*biological origin*".

[296] DE delete "*optimal*".

11. ~~Interaction of devices with their environment~~ *Construction and environmental properties*

11.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated[297] on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer***, electrical*** or mechanical coupling, shall be designed and constructed in such a way as to ***avoid***[298] ~~minimize all possible risks from incorrect~~ ***mis***connection.

11.2. Devices shall be designed and manufactured in such a way as to remove or ~~***minimize***~~ reduce as far as possible and appropriate[299]:

(a) the risk of injury***,*** ~~to the patient, user or other persons~~ in connection with their physical ***features, including the volume/pressure ratio, dimensional*** and ***where appropriate*** ergonomic features;

~~(b) the risk of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used;~~

(c) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;

(d) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

(e) the risk associated with the possible negative interaction between software and the ***IT***[300] environment within which it operates and interacts;

~~(f) the risks of accidental ingress of substances into the device;~~[301]

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297 There was a suggestion to add "*shall be justified and indicated*". Also it should be checked with the requirements stated in Section 19.

298 **Cion** Sometimes it is not possible for the manufacturer avoid misconnection.

299 Highlighted text reinstated following a **Cion** request.

300 Cion against adding "*IT*".

301 **DK, PT** reinstate 11.2.(f).

(g) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given[302];

(h) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

11.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices whose intended ***use*** ~~purpose~~ includes exposure to or use in association with flammable ***or explosive*** substances or substances which could cause combustion.

11.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance~~, where such is necessary to achieve the performances intended,~~ can be done safely ***and effectively***.

11.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such ~~as~~ ***a*** way that the interoperability ***and compatibility***[303] ***are*** ~~is~~ reliable and safe.

11.6. Any measurement, monitoring or display scale shall be designed in line with ergonomic principles, taking account of the intended ***users and the environmental condition in which the devices are intended to be used*** ~~purpose of the device~~.

11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or ~~of any~~ ***related*** waste substances by the user, patient or other person. ***To that end***, ***manufacturers shall investigate and test procedures and measures by which their devices can be safely disposed after use. These procedures shall be described in the instruction for use.***

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[302] It was suggested to look for better place for this requirement.

[303] New definitions needed (interoperability, compatibility).

12. Devices with a diagnostic or measuring function

12.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose~~, based on appropriate scientific and technical methods~~. The limits of accuracy shall be indicated by the manufacturer **taking into account the generally acknowledged state of the art**[304].

12.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC[305].

13. Protection against radiation[306]

13.1. General

(a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted ***hazardous*** radiation shall be reduced as far as possible and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.[307]

(b) The operating instructions for devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user[308] and on ways of avoiding misuse and of ~~eliminating~~ **reducing** the risks inherent ~~in~~ **to** installation **as far as possible and appropriate**[309].[310]

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304 **AT** add to take into consideration the state of the art.

305 OJ L 39, 15.2.1980.

306 Definition of "*radiation*" is needed.

307 **DS 1929/13 DE** delete "*any emitted*" and "*and appropriate*".

308 **DS 1928/13 UK** add "*and other persons*".

309 **DS 1930/13 NL** suggests the following text "~~*eliminating*~~ *reducing the risks inherent to* ~~*in*~~ *installation to a level as low as reasonably practicable.*"

310 **DS 1937/13 FR** add "*Information regarding the acceptance testing, the performance testing and the acceptance criteria shall also be specified, as well as the maintenance procedure*".

13.2. Intended radiation

(a) Where devices are designed to emit hazardous~~, or potentially hazardous,~~ levels of visible and/or invisible[311] radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters[312] within an acceptable tolerance.[313]

(b) Where devices are intended to emit ~~potentially~~ hazardous, visible and/or invisible[314] radiation, they shall be fitted, where possible[315], with visual displays and/or audible warnings of such emissions.

13.3. Unintended radiation

Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible and appropriate.

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311 It was suggested to delete words "*visible and/or invisible*" in case new definition of "radiation" will include them. **DS 1929/13 DE, AT** replace "*visible and/or invisible*" with "*ionizing and/or not ionizing*".

312 **DS 1930/13 NL** modifying "~~*variable parameters*~~ *variables*".

313 **DS 1928/13 UK** modify as follows:

"~~*(a)*~~ *Where devices are designed to emit hazardous, or potentially hazardous, levels of* ~~*visible and/or invisible*~~ *radiation* ***and/or electromagnetic fields*** ~~*necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission*~~*, it shall be possible for the user to control the emissions.* ***Such devices shall be fitted, where reasonably practicable, with visual displays and/or audible warnings of such emissions and*** ~~*Such devices*~~ *shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.*

~~*(b) Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions*~~".

314 It was suggested to delete "*visible and/or invisible*" in case new definition of „radiation" will include them.

315 Delete "*where possible*" and add "*except in exceptional case*" at the end of the sentence".

13.4. Ionising radiation

(aa) **Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Council Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.**[316]

(a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, ~~where possible~~ **except in exceptional cases**[317], the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.[318] [319]

(b) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.

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316 **DS 1937/13 FR** add new: "The design and manufacture of medical devices emitting ionizing radiation shall take into account the requirements of the Council Directive *[add the reference]* laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation." **AT** support.

317 **DS 1928/13 UK** would welcome a discussion on the rationale for changing '*where practicable*' in the current essential requirements to '*where possible*' in section 13.4.(a) as it will have implications for equipment design.

318 **DS 1929/13 DE** change as follows:
"*(a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where ~~possible~~ practicable, the quantity, geometry and ~~energy distribution (~~or quality~~)~~ of radiation emitted can be varied and controlled taking into account the intended use.*".

319 **DS 1937/13 FR** change as follows:
"*(a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, ~~where possible,~~ the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use, except in exceptional cases, and to allow the user to have appropriate information of quantity of radiation produced by the equipment during the procedure and have knowledge, at the end of the procedure, of relevant parameters for assessing the patient dose.*" **AT** support.

(c) Devices emitting ionising radiation, intended for ~~therapeutic radiology~~ **radiotherapy**[320] shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam characteristics in terms of type of radiations, energy and, where appropriate, energy distribution[321].

[322]

[320] **DS 1928/13 UK** change as follows:
"*(c) Devices emitting ionising radiation, intended for ~~therapeutic radiology~~ **radiotherapy** shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam characteristics in terms of type of radiations, energy and, where appropriate, energy distribution.*" **AT** support.

[321] **DS 1929/13 DE** change as follows:
"*(c) Devices emitting ionising radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam ~~characteristics~~ ~~in terms of~~ type ~~of radiations,~~ and energy and, where appropriate, the quality of radiation ~~energy distribution.~~*".

[322] **DS 1937/13 FR** add new point:
"*(d) The operating instructions for devices emitting ionizing radiation shall give detailed information as to the acceptance testing to carry out before the first use, the performance testing to carry out thereafter on a regular basis or after any maintenance procedure, and the acceptance criteria to be met, which have been defined by the manufacturer.*".

14. ~~Software incorporated in devices and standalone software~~[323] *Electronic programmable systems*[324] *Devices that incorporate electronic programmable systems*

14.1. Devices that incorporate ~~***an***~~ electronic programmable systems, ~~including software, or standalone software that are devices in themselves,~~[325] shall be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.

14.2. For devices that incorporate software or for ~~standalone~~ software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, verification and validation.

14.3. ~~Software referred to in this Section that are intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise).~~ ***The manufacturer shall describe minimum requirements on hardware, IT networks characteristics and IT security measures, including protection against hacking, necessary to run the software as intended.***

15. Active devices and devices connected to them

15.1. For active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.

15.2. Devices where the safety of the patients depends on an internal power supply shall be equipped with a means of determining the state of the power supply ***and warning if the capacity of the power supply becomes critical***.

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[323] UK reinstate the title from Cion proposal.
[324] Definition of "*electronic programmable system*" is needed.
[325] **Cion** reinstate "*including software, or standalone software that are devices in themselves*".

15.3. Devices where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.

15.4. Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

15.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.

15.6. Devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

15.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed ~~and maintained~~[326] as indicated by the manufacturer.

16. Protection against mechanical and thermal risks

16.1. Devices shall be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

16.2. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

[326] **Cion** Reinstate "*and maintained*".

16.3. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

16.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle shall be designed and constructed in such a way as to minimise all possible risks.

16.5. Errors likely to be made when fitting or refitting, or connecting or reconnecting, certain parts before or during use which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.[327]

The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.[328] [329]

16.6. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

[327] Making misconnections impossible would require a mechanical coding of connections which is currently not possible and which would cause extraordinary costs for the health systems of MS. Deletion since already covered in 11.1.

[328] **Cion** reinstate section 16.5 since it is from the machinery directive.

[329] Section 16.5 is reinstated following the Cion request.

17. Protection against the risks posed to the patient or user by supplied energy or substances

17.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to assure the safety of the patient and of the user.

17.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

17.3. The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.

18. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

18.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.

18.2. Devices for use by lay persons shall be designed and manufactured in such a way as to

- ensure that the device is easy to use by the intended user at all stages of the procedure, and[330]
- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results[331].

18.3. Devices for use by lay persons[332] shall, where reasonably[333] possible, include a procedure by which the lay person

- can verify that, at the time of use, the device will perform as intended by the manufacturer, and
- if applicable, is warned if the device has failed to provide a valid result.

III. Requirements regarding the information supplied with the device[334]

19. Label and instructions for use[335] [336]

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330 **DS 1929/13 DE** "- *ensure that the device is, if necessary after appropriate training and information, ~~easy~~ safely and accurately to use by the intended user at all stages of the procedure, and*".

331 **DS 1930/13 NL** replace "*as far as possible*" by "*to a level as low as reasonably practicable*".

332 **DS 1929/13 DE** Why only for devices for lay persons? What is reasonably possible?

333 **DS 1937/13 FR** replace "*reasonably*" with "*technically*".

334 **ES** sometimes information is not supplied by the device.

335 **DS 1568/13 BE**: add "*and leaflet*".

336 **DS 1698/13 NL**: add "*and patient leaflet*".

19.1. General requirements regarding the information supplied by the manufacturer[337]

Each device shall be accompanied by[338] the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:

(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.

(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging[339] for each unit, and/or on the packaging of multiple devices.

Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided[340] **free of charge**.[341]

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337 "*19.1 General requirements regarding the information supplied ~~by the manufacturer~~ with the device*

(a) The medium, format, content, legibility, and location of the label, instructions for use and patient leaflet shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use and the patient leaflet shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.".

338 **PT** asks for clarifying that is the manufacturer that shall supply information.

339 **ES** better mention "*sales packaging*".

340 **PT** asks that further copies of IFU shall be supplied free of charge.

341 **DS 1929/13 DE** Requirements on electronic labelling are not adequately introduced into the regulation. **SE** support.

"~~(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices. Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided.~~" **PT** against.

(c) ~~For devices of class I and IIa~~[342]~~, instructions for use are not needed~~[343] ~~or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.~~[344] **By way of exception, no such instructions for use are needed for devices in class I or IIa if they can be used safely without any such instructions.**[345] [346]

(d) Labels shall be provided in a human-readable format ~~but~~ **and** may[347] be supplemented by machine-readable ~~forms~~ **information**, such as radio-frequency identification (RFID) or bar codes.

(e) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent and under the conditions set out in Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices[348].

(f) Residual risks which are required to be communicated to the user and/or other person[349] shall be included as limitations, contraindications, precautions or warnings in the information supplied by the manufacturer.

[350]

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342 **DS 1929/13 DE** "*(c) ~~For devices of class I and IIa,~~ iInstructions for use are not needed or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.*".

343 **DS 1937/13 FR** *"(c) For devices of class I and IIa, instructions for use may be abbreviated or are not needed ~~or may be abbreviated~~ if the device can be used safely and as intended by the manufacturer without any such instructions for use.*". **Cion** support.

344 **DS 1930/13 NL** Only in exceptional cases it should be allowed not to include instructions for use.

345 **DS 1951/13 CZ** "*(c) For devices of class I and IIa, instructions for use are not needed or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use. The rationale of the manufacturer shall be based on risk assessment.*".

346 **CZ, DK, DE, ES, FR, NL, AT** ask for modifying the text.

347 **DS 1929/13 DE** "*(d) Labels shall be provided in a human-readable format **and** ~~but~~ may be supplemented by machine-readable ~~forms~~ **information**, such as radio-frequency identification (RFID) or bar codes.*". **Cion** support

348 OJ L 72, 10.3.2012, p. 28.

349 **DS 1930/13 NL** "*(f) Residual risks which are required to be communicated to the user and/or other person according to the results from the risk analysis for that device shall be included as limitations, contraindications, precautions or warnings in the information supplied by the manufacturer.".*

350 **DS 1698/13 NL** "*(xx) The patient leaflet must be updated where appropriate and updates should be available to the patient in non-paper format in accordance with part B, 21 of Annex V.*".

(g) Where appropriate, this information should take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CTS. In areas for which no standards or CTS exist, the symbols and colours shall be described in the documentation supplied with the device.

[351]

19.2. Information on the label[352]

The label shall **visibly**[353] bear the following particulars:[354]

(a) The name or trade name of the device.

(aa) The sentence: "this product is a medical device".[355]

(b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device.

(c) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established.

(d) For imported devices, the name, registered trade name or registered trade mark of the authorised representative established within the Union and the address of his registered place of business at which he can be contacted and his location be established.[356]

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[351] **DS1568/13 BE** add "*(h) Where applicable, taking into account the specifications under Annex I, point 7.4, the labelling will either mention that the medical device "includes a hazardous substance in quantity equal or above 0.1%" or, alternatively, will foresee an according internationally recognized pictogram. In addition, the list of the hazardous chemicals including their name and weight ratio will be mentioned, based on an internationally recognized nomenclature.*".

[352] **DS 1929/13 DE** replace "*information on the label*" with "*Labelling*"; **ES** support.

[353] **DS 1951/13 CZ** add "*visibly*".

[354] **DS 1929/13 DE** modify: "~~*The label shall bear the following particulars*~~ *The following particulars shall appear on the device or, where not practicable or appropriate on the*".

[355] **DS 1937/13 FR** adding "*(aa) The sentence: "this product is a medical device"*"; **AT, Cion** support.

[356] **ES**, **Cion** align the text to article 11; **Pcy** this section of regulation is about the information to be supplied by the manufacturer.

(e) Where applicable, an indication that the device contains or incorporates**,**[357]

- a medicinal substance, including a human blood or plasma derivative, or
- tissues or cells, or their derivatives, of human origin, or
- tissues or cells, or their derivatives, of animal origin as referred to in Commission Regulation (EU) No 722/2012.[358]

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[357] **DS 1937/13 FR**

"*(e) Where applicable, ~~an indication~~ a mention of the presence and the composition of ~~that~~ the device which contains or incorporates*

- *a medicinal substance, including a human blood or plasma derivative, non-viable or rendered non-viable or*
- *issues or cells, or their derivatives, of human origin, non-viable or rendered non-viable or*
- *tissues or cells, or their derivatives, of animal origin as referred to in Commission Regulation (EU) No 722/2012.*".

add:

"*(e bis) For devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered parenterally, rectally or vaginally and which are absorbed by or dispersed in the human body, the exact composition of the device.*"

PT support; **Pcy** consider joint **PT, UK** suggestion on this issue.

"*(e ter) where applicable, the mention of substances, other than those which are referred to in points (e) and (e bis), contained in the device and which come into direct contact with the human body.*"

AT, SE support (e ter).

[358] **DS 1929/13 DE** delete

"~~*(e) Where applicable, an indication that the device contains or incorporates*~~

- ~~*a medicinal substance, including a human blood or plasma derivative, or*~~
- ~~*tissues or cells, or their derivatives, of human origin, or*~~
- ~~*tissues or cells, or their derivatives, of animal origin as referred to in Commission Regulation (EU) No 722/2012*~~".

(f) Where applicable, an indication that the device incorporates or consists of nanomaterial 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.[359] [360] [361]

(fa) Where applicable, an indication that the device contains phthalates.[362]

(g) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate.

(h) Where applicable[363], the unique device identification (UDI).

(i) An unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month, where this is relevant.

(j) Where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable.

(k) An indication of any special storage and/or handling condition that applies.

(l) If the device is supplied sterile, an indication of its sterile state and the sterilisation method.

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[359] **DS 1930/13 NL** If formulated in this way, the labelling requirement for nanomaterials may be applicable to more devices than intended by the regulator: 1) many more devices than foreseen may incorporate nanomaterials and 2) "*cannot be released*" is impossible to prove, so not useful to reduce the number of devices to be labelled. Note: The NET WG has initiated the collection of data needed to analyse the situation.

[360] **DS 1929/13 DE** delete
"*(f) Where applicable, an indication that the device incorporates or consists of nanomaterial 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*".

[361] **DS 1937/13 FR** modify
"*(f) Where applicable, an indication that the device incorporates or consists of nanomaterial coming into direct contact with the human body ~~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;~~*".

[362] **DS 1937/13 FR** add
"*(ff) where applicable, an indication that the device contains phthalates*".

[363] **DS 1929/13 DE**
"*(h) ~~Where applicable, the~~ The unique device identification (UDI).*" **AT, Cion** against.

(m) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device as relevant, and to any other person where appropriate[364]. This information may be kept to a minimum in which case more detailed information should appear in the instructions for use.

(n) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union.

(o) [365]If the device is a single use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles.

(p) If the device is custom made, an indication of that fact.

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

[366]

(r) In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent(s) responsible for achieving the principal intended action.[367]

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[364] **DS 1937/13 FR** modify
"*(m) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device as relevant, and to any other person where appropriate <u>especially for substances which come into direct contact with the human body and may generate a remaining risk.</u> This information may be kept to a minimum in which case more detailed information should appear in the instructions for use.*".

[365] **DS 1929/13 DE** and **DS 1937/13 FR** delete
"*(o) If the device is a single use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles.*"
Cion against.

[366] **DS 1232/13 PT** add
"*(r) in the case of ingested devices, overall qualitative composition and also quantitative information on the main constituent responsible for achieving the principal intended action.*"

[367] **DS 1518/14 PT, UK** joint suggestion on substances to be introduced into the human body.

19.3. Information in the instructions for use

The instructions for use shall contain the following particulars[368]:

(a) The particulars referred to in points 19.2. (a), **(aa),** (c), (e), (f), **(fa),** (k), (l)**,** ~~and~~ (n) **and r)**.[369] [370]

(b) The device's intended purpose[371] including the intended user (e.g. professional or lay person), as appropriate.

(c) The performance of the device intended by the manufacturer.[372] [373]

(d) Any residual risks, contraindications and any expected and foreseeable undesirable side-effects, including information to be conveyed to the patient in this regard.[374]

(e) Specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it.

(f) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilisation, final assembly, calibration, etc.).[375]

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368 **DS 1937/13 FR** modify
"*The instructions for use shall contain the following particulars:*
(a) The particulars referred to in points 19.2. a), a bis), c), e), e bis), e ter), f), k), l) and n).
(b) The device's intended purpose ~~including the intended user (e.g. professional or lay person), as appropriate~~
(bb) the intended user of the device (e.g. professional or lay person)
(bbb) Where applicable, therapeutic indications for which the risk/benefit balance has been demonstrated by the clinical evaluation".
IE, ES, PT, Cion support.

369 **DS 1929/13 DE**
"*(a) The particulars referred to in points 19.2. a), c), ~~e), f),~~ k), l) and n).*"

370 Following **DS 1518/14**.

371 **DS 1910/13 AT**
"*(b) The device's intended purpose with clear specification of target group(s), indications, contraindications, including the intended user (e.g. professional or lay person), as appropriate;*".
IE, ES, PT, Cion support.

372 **DS 1929/13 DE**: What is this? What is the difference to b? **ES** considers c) to be unnecessary.

373 **DS 1910/13 AT** add "*including specification of clinical benefits to be expected and corresponding measures of efficacy and effectiveness, where applicable, together with links to relevant further scientific information*" **DK, Cion** not support; **IE, PT** support; **LT** not support.

374 **DS 1910/13 AT** add "*as well as information on the benefit/risk ratio according to the state of the art in medicine.*" **DK, Cion** not support; **IE, PT** support; **LT** not support.

375 **DS 1930/13 NL** add "*for the device to be used as intended by the manufacturer*".

(g) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons.

(h) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

- details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;
- identification of any consumable components and how to replace them;
- information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime**;**
- methods of eliminating[376] the risks encountered by persons involved in installing, calibrating or servicing devices.

(i) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged before use.

(j) If the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate[377] instructions for sterilisation.

(k) If the device is reusable, information on the appropriate[378] processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilisation[379]. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.

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376 **DS 1930/13 NL** "*methods of ~~eliminating~~ reducing, to a level as low as reasonably practicable the risks encountered by persons involved in installing, calibrating or servicing devices.*" **Cion** not support.

377 **DS 1930/13 NL** add "*and validated*". **ES, PT, Cion** not support; **FR** methods shall be validated by the manufacturer; the term "*validated*" is not unambiguous.

378 **DS 1930/13 NL** add "*and validated*" ; **DE** support.

379 **DS 1928/13 UK** add "*appropriate to the Member State(s) where the device is placed on the market*". **Cion** not support; **ES, FR, AT, PT** support.

(l) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with point c) of Section 19.1 no instructions for use are needed,[380] the information shall be made available to the user upon request.[381]

(m) For devices intended for use together with other devices and/or general purpose equipment:

- information to identify such devices or equipment, in order to obtain a safe combination, and/or
- information on any known restrictions to combinations of devices and equipment.

(n) If the device emits hazardous, or potentially hazardous levels of radiation for medical purposes:

- detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation;
- the means of protecting the patient, user, or other person from unintended radiation during use of the device.

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

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[380] **DS 1929/13 DE** modify
"*(l) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with point c) of Section 19.1 no instructions for use are needed, nevertheless the device shall be accompanied by this ~~the~~ information ~~shall be made available to the user upon request~~*";
EL, PT, FI support.

[381] **ES** not agree with the last sentence since consider that IFU shall be supplied in any case.

- warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;[382]
- warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
- warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);
- if the device is intended to administer medicinal products, tissues or cells, or their derivatives, of human or animal origin or biological substances, any limitations or incompatibility in the choice of substances to be delivered;
- warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device;
- precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user;

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[382] **DS 1232/13 PT** add
"- *For ingested products:*
  - *general profile of interaction, namely with medicinal products, other medical devices, and other substances, as well as contraindications, undesirable effects and precautions regarding overdosage;*
  - *products of biotransformation, namely in the case of contraindications for special populations (for instance, aluminium-based products in renal-impaired patients).*"
ES, AT, Cion support; **Pcy** outdated since **DS 1518/14** has been issued by **PT, UK**.

- **in the case of devices that are composed of substances or combination of substances that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side effects and risks relating to overdose.**

(p) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:

- infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);
- physical hazards (e.g. from sharps).

(q) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.

(r) For devices listed in Annex XV[383] for which the manufacturer does not claim a medical purpose, information regarding the absence of a clinical benefit and the risks related to the use of the device.

(s) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision[384] of the instructions for use.

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[383] **DS 1929/13 DE**
"~~*(r) For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, information regarding the absence of a clinical benefit and the risks related to the use of the device.*~~"

[384] **DS 1930/13 NL** Is the revision number also acceptable?

(t) A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established.[385]

[386]

[387]

[385] **DS 1929/13 DE** delete
"*(t) A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established*".

[386] **DS 1698/13 NL** add
"*(u) For implantable devices and devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally on skin or mucous membrane a list of ingredients of the medical device without prejudice to the protection of intellectual property rights unless the ingredient cannot be released into the patient's or user's body when the device is used within its intended purpose.*".
PT support except last sentence.

[387] **DS 1930/13 NL** add
"*(x) where relevant, information regarding batch to batch variation provided with relevant figures and units of measure.*".

388

388 **DS 1568/13 BE**

"***19.4. Information in the leaflet***

The leaflet shall contain the following particulars:

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

(b) The device's intended purpose including the intended user (e.g. professional or lay person), as appropriate.

(c) The performance of the device intended by the manufacturer.

(d) Any residual risks, contraindications and any expected and foreseeable undesirable side-effects, including information to be conveyed to the patient in this regard.

(e) If the device is reusable, information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.

(f) For devices intended for use together with other devices and/or general purpose equipment:
- *information to identify such devices or equipment, in order to obtain a safe combination, and/or*
- *information on any known restrictions to combinations of devices and equipment.*

(g) Information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information should cover, where appropriate:
- *warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;*
- *warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;*
- *warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);*
- *if the device is intended to administer medicinal products, tissues or cells, or their derivatives, of human or animal origin or biological substances, any limitations or incompatibility in the choice of substances to be delivered;*
- *warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device;*
- *precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user.*

(h) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.

(i) any information about the expected lifetime of the device and any necessary follow-up.

(j) For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, information regarding the absence of a clinical benefit and the risks related to the use of the device.

(k) Date of issue the leaflet or, if they have been revised, date of issue and identifier of the latest revision of the leaflet.

(l) A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established.

(m) Information that allows the user and/or patient to be informed of the presence of latex or DEHP".

It is noted that **LT** does not support point e).

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389 **DS 1698/13 NL**

"***19.4. Information in the patient leaflet***

The leaflet shall contain the following particulars:

(a) The particulars referred to in points 19.2. except d), g), o), p) and q).

(b) The particulars referred to in points 19.3 b), c), d), m), n), o), p), r), t) and u).

(c) Date of issue of the leaflet or, if it has been revised, date of issue and identifier of the latest revision of the leaflet.".

ANNEX III[390]

EU DECLARATION OF CONFORMITY

1. [391]Name, registered trade name or registered trade mark of the manufacturer and, if applicable, his authorised representative, and the address of their registered place of business ~~**if applicable the address of other branches**~~[392] where they can be contacted and their location be established[393];[394]

2. A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;

3. The UDI device identifier as referred to in item (i) of point (a) of Article 24(1) as soon as identification of the device that is covered by the declaration shall be based on a UDI system;

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390 This text is based on that in document 12772/14 but takes into account the discussion in the Working Party based on that document.

391 **WP Sept 16 CZ, DK, DE, ES, LT, AT, PT, SE** adding unnecessary; could lead to lack of clarity; **Cion** support. Reinstate deleted sentence.

392 **DS 1125/14 IT** add "*if applicable the address of other branches*". If the manufacturer cannot be contacted in its registered place of business, additional contact details should be also provided.

393 Reinstated text from the Cion proposal.

394 **DS 1421/14 DE**

"*1. Name, or registered trade name ~~or registered trade mark~~ of the manufacturer and, if applicable,……*
their registered place of business ~~and if applicable the address of other branches~~ ~~where they can be contacted and their location be established;~~".

4. Product ~~or~~ **and**[395] trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered by the declaration (it may include a photograph, where appropriate)**, including its intended purpose**[396]. Except for the product or trade name, the information allowing identification and traceability may be provided by the device identifier referred to in point 3;[397]

5. Risk class of the device in accordance with Annex VII;

6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;

7. References to the relevant harmonised standards or ~~CTS~~ ***CS*** used in relation to which conformity is declared; [398]

8. Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued; [399]

9. Where applicable, additional information[400];[401]

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395 **DE, ES, PT** replace "*or*" with "*and*".

396 **DS 1105/14 FR** add "*including its intended purpose*".

397 **DS 1421/14 DE**
"*4. Product ~~or~~ and if applicable trade name, ……(it may include a photograph, where appropriate), including its intended purpose. Except for the product ~~or~~ and trade name, the information ..*".

398 **DS 1421/14 DE**
"*7. ~~References to the relevant harmonised standards or CTS **CS** used in relation to which conformity is declared;~~*".

399 **DS 1421/14 DE**
"*8. ……procedure performed ~~and identification of the certificate(s) issued;~~* "

400 **DE** delete "*additional information*"; **CZ, SE** support.

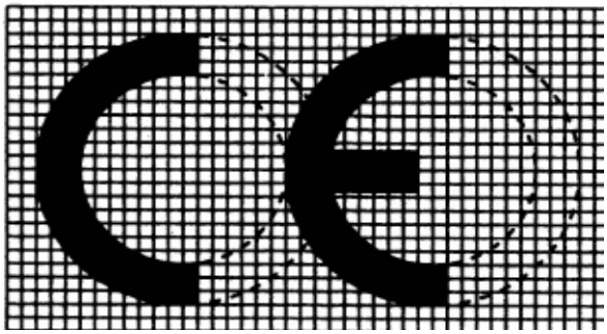
401 **DS 1421/14 DE** "*9. ~~Where applicable, additional information;~~*".

10. Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.

ANNEX IV[402]

CE MARKING OF CONFORMITY[403]

1. The CE marking shall consist of the initials 'CE' taking the following form:



2. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing shall be respected.

3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

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[402] This text is based on that in document 12772/14.

[403] **WP Sept 16**
DE add the identification of the authority; regulate the size of the information.
Cion this Annex must focus on marking and not other information provided elsewhere.
Council Legal Service Art. 30 of Regulation (EC) No 765/2008 Annex II states the format and content of the CE mark.