Council of the European Union

Brussels, 20 March 2015
(OR. en)

7091/15

LIMITE

PHARM 11
SAN 65
MI 161
COMPET 118
CODEC 340

PUBLIC

Interinstitutional File:
2012/0266 (COD)

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
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 - *Chapter V and related annexes*

Delegations will find in the Annexes to this document the text of Chapter V of the proposal for a Regulation on medical devices as well as of related definitions from Article 2 and related annexes. The texts are based on the consolidated text of the draft Regulation set out in document 17152/14.

Changes introduced by the Latvian Presidency are highlighted in grey, as are changes in the annexes that were new in document 17152/14.

Annex A contains definitions from Article 2 that are subject to examination on 26 March 2015.

Annex B contains the text of Chapter V.

Annex C contains the text of Annex II (Technical documentation).

Annex D contains the text of Annex VII (Classification criteria).

Annex E contains the text of Annex VIII (Conformity assessment based on QMS).

Annex F contains the text of Annex IX (Conformity assessment based on type examination).
Annex G contains the text of Annex X (Conformity assessment based on product conformity verification).
Annex H contains the text of Annex XI (Procedure for custom-made devices).

ANNEX A

Definitions related to conformity assessment:

(18) 'putting into service' means the stage at which a device, ***[which has not been previously placed on the market]***[1] ~~other than an investigational device~~, ***[is]*** made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

(28) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

~~***(28a)***~~[2] ~~***'state of the art' means the highest level of knowledge and development achieved at a particular time. It is established using accessible and usable data such as standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases;***~~[3] [4]

---

1 **Pcy proposal** based on **DE** suggestion. Rationale: Clarification that "putting into service" does not mean the first use of medical devices which have been placed on the market in a legally allowed manner. Putting into service within this meaning should be up to national legislation as there already exist a lot of national provisions on the putting into service (safety checks, training, instruction of operators, etc.). It is crucial that these national provisions could be kept, especially as the proposed regulation does not foresee any provision on the use (or first use) of medical devices. Furthermore, the concept of "putting into service" of the current medical devices legislation should be retained. It only covers devices that are not placed on the market, but are constructed, built up or installed directly at the customer side (e.g. central medical gas supply systems). **Pcy** invites delegations to reflect upon whether a) they want this meaning of "putting into service" and b) how it works together with other provisions, *e.g.* Article 42?

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

3 **DK, DE, AT** do not agree with the definition proposed in document 12538/14.
DS 1439/14 BE "*'state of the art' 'the level of knowledge and development achieved in a technique or method. It is established using accessible and usable data such as standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases*.".

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

(29) ‘conformity assessment body’ means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

(30) ‘notified body’ means a conformity assessment body designated in accordance with this Regulation;

(31) ‘CE marking of conformity’ or ‘CE marking’ means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

Chapter V

Classification and conformity assessment

Section 1 – Classification

Article 41

Classification of medical devices

1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the~~ir intended~~ purpose ***intended by the manufacturer***[5] and inherent risks. Classification shall be carried out ~~***by the manufacturer***~~[6] ~~***under its responsibility***~~[7] in accordance with the classification criteria set out in Annex VII.

---

5 **DS 1483/13 DE** replace '*intended purpose*' by '*purpose intended by the manufacturer*'; **DK** delete "*intended by the manufacturer*".

6 **BE, CZ, DK, IE, ES, AT** delete "by the manufacturer"

7 **DK, ES, PT, ~~AT~~** delete "*by the manufacturer under its responsibility*". **DE, IT, LT, PL** it should be clarified that classification is an act of the responsibility of the manufacturer. AT suggests information about manufacturer's responsibility include in Article 8.

Pcy proposes to consider reverting back to the original Cion proposal, as the definition for intended purpose sufficiently describes the manufacturer's role in classification:
(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;
Pcy could also consider to amend Article 8.1:
"*When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been* ***~~classified~~****, designed and manufactured in accordance with the requirements of this regulation*"

2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority[8] of the Member State where the manufacturer has his registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business. ***[Where the notified body concerned is located in a different Member State to the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.]***[9]

~~At least 14 days prior to any decision,~~[10] the[11] competent authority ***[of the manufacturer]*** shall notify the MDCG and the Commission of its ~~envisaged~~ decision.[12]

---

8 **SK** who is the authority that decides? The current Directive states that it is the competent authority which appoints the notified body; this provision should be retained. **DK, SE** support.

9 **Pcy** for the purpose of compromise proposes to include a consultation/agreement with the NCA of the NB.

10 **UK** would prefer that the communication is done after the decision has been taken. **Cion** the communication should be done before the decision has been taken to allow any necessary intervention. **DE** a decision from a national authority cannot be reviewed by **Cion**, only by a national court. **Cion** the Cion can launch an infringement procedure.

11 ~~**Pcy** compromise proposal.~~

12 **DE, ES, IT** what is the purpose of the communication? What is the next step following the communication? **DE, ES** Suggested deleting this sentence. Each authority is totally competent and will not change its classification on the basis of the decisions of the other authorities. **PT, UK** the decision should be communicated in order to achieve harmonisation of the classification.

3. ~~The Commission may, *a*~~ *A*t[13] [14] [15] ~~the~~ ***a duly substantiated***[16] request of a Member State ***the Commission shall***[17]***,*** ~~or on its own initiative *and*~~ ***after consulting the MDCG, the Commission may***[18] ***decide***, by means of implementing acts, ~~decide~~ on the ***following:***

(a) application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification***;***

(b) ***that a device, or category or group of devices shall for [compelling[19]] reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activates [described in Article 61 to 75]***[20] ***~~should,~~ by way of derogation from the classification criteria set out in Annex VII, be reclassified ~~in a higher another class~~***[21]~~.~~

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).[22]

3a. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 3, points (a) and (b).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

---

13 **DS 1483/13 DE** replace '*Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, decide*' by '*MDCG shall, at the request of a Member State or of the Commission, give an opinion*'.

14 **DE** when there is a need to upgrade the classification, the MDCG can take the initiative? The Cion can take the initiative? Would it be done by means of delegated acts?

15 **Pcy** as this is a source of dispute and ambiguity and the **Cion** proposal did not foresee "duly substantiated" requests, the **Pcy** invites to delete this term.

16 **CZ, DE, AT** delete "*at duly substantiated*"

17 **DE, AT** there should be a deadline for **Cion** to act.

18 **IT Pcy** compromise proposal.

19 **Pcy** would like to know if there are delegations who are of the opinion that this term is absolutely needed. **AT** is noted to have concerns on it.

20 **Pcy** sentence moved from paragraph 4. If Delegations agree that the part in brackets is superfluous, it could be deleted.

21 **Pcy** proposes to replace "*classified in a higher class*" with "*reclassified*".

22 **DS 1483/13 DE** add the following sentence: '*The Commission shall take a final decision following the MDCG' s opinion by means of an implementing act, adopted in accordance with the examination procedure referred to in Article 88 (3).*'

4. In ***order to ensure the uniform application of the classification criteria set out in Annex VII*** ~~the light of technical ***and scientific***[23] progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 61 to 75,~~ the Commission ~~shall be empowered to~~ ***may*** adopt ~~delegated~~ ***implementing*** acts[24] in accordance with Article 89***(3)*** ~~as regards the following:~~

~~(a) deciding, that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class;~~

~~(b) amending or supplementing ***updating*** the classification criteria set out in Annex VII.~~[25]

~~***The Commission shall take into account any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 61 to 75.***~~[26]

---

[23] **DS 1257/13 AT** suggested adding "*and scientific*". **Cion** agreed.

[24] **DK, ES, CY, AT, PT** in relation to point (a), would prefer implementing acts (instead of delegated acts) to be adopted on the initiative of the national authorities.
UK opposed to the delegated acts, suggested deleting the paragraph.
DK delegated acts provision should be moved to paragraph 3.
IT doubts whether delegated acts are the more appropriate.

[25] **DS 1483/13 DE** replace '*shall be empowered to adopt delegated acts in accordance with Article 89 as regards the following: (a) deciding*' by '*after having received an opinion by the MDCG, shall by means of an implementing act, adopted in accordance with the examination procedure referred to in Article 88 (3) decide*'. Delete point (b).

[26] **Pcy** moved to previous paragraph.

Section 2 – Conformity assessment

Article 42

Conformity assessment procedures

1. Prior to placing a device on the market ***[or .for a device not intended to be placed on the market, prior to its putting into service]***[27], manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI. ***[By way of exception, where, due to the specific nature or characteristics of a device intended to be placed on the market, it is not possible to assess the conformity of that device until it is ready to be put into service, the manufacturer may undertake the assessment of conformity prior to the device being put into service.[***[28]

[27] **BE, ES, AT, PT, SK,SE, Cion** reinstate "*or its putting into service*"; **DK, DE** disagree. **Pcy** proposes to split the into two cases, the first one being devices not intended to be placed on the market.

[28] **Pcy** has added this sentence in order to cover the second case, namely a device that can for external objective reasons not be assessed at the time of its placing on the market.

~~*1a. Prior to putting into service devices that are not placed on the market, with the exception of in-house devices, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI*~~.[29]

2. Manufacturers of devices classified as class III, other than ~~*not implantable*~~[30] custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance and design dossier examination as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.

For implantable devices classified as class III, the notified body shall follow the procedure regarding clinical evaluation as specified in section 6.0 of Chapter II of annex VIII or Section 6 of Annex IX, as applicable.[31]

This procedure is not required where[32]

- ***the device has been designed by modifications of a device already marketed by the same manufacturer for the same intended purpose if the modifications have been demonstrated by the manufacturer and accepted by the notified body as not adversely affecting significantly the benefit/risk ratio.***
- ~~*or*~~ ***the principles of the clinical evaluation of the device category have been addressed in a common specification referred to in Article 7.***

In the case of devices referred to in the first subparagraph of Article 1(4), the notified body shall follow the consultation procedure as specified in Section 6.1 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.

---

29 **PT, Cion** redundant; **DK** disagrees; **SE, SK** text unclear.
30 **DK, LT** delete "*not implantable*".
31 This subparagraph is linked to the changes of Article 44 (doc. **15546/14**).
32 This subparagraph is linked to the changes of Article 44 (doc. **15546/14**). Compromise suggested in **DS 1512/15 FR**. **DE** delete the added text.

In the case of devices that are covered by this Regulation in accordance with point (e) of Article 1(2), the notified body shall follow the consultation procedure as specified in Section 6.2 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.

3. Manufacturers of devices classified as class IIb, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of ~~the design documentation within~~[33] the technical documentation [on a representative basis ***/ of at least one representative device per generic device group***[34]]. ***By way of derogation, the design dossier examination as specified in Chapter II of Annex VIII shall be applicable for Class IIb implantable devices***[35]**.** Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.

4. Manufacturers of devices classified as class IIa, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of ~~the design documentation within~~ the technical documentation [on a representative basis ***/ of at least one representative device of the manufacturers portfolio***]. Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annex II coupled with a conformity assessment based on product conformity verification as specified in Section 7 of Part A or Section 8 of Part B of Annex X.

---

[33] **BE, DK, ES, IE, AT, PT, SE, UK** delete "*design documentation within*".

[34] **DE** is of the opinion that the term "*on representative basis*" is misleading, therefore, alternative is proposed.

[35] **DS 1365/13 BE** add '*However, the design dossier examination as specified in Chapter II of Annex VIII shall be applicable for all Class IIb implantable devices*'. **IE, ES, FR** support. **DE, UK** oppose the added words.
Pcy as there are diverging views, **Pcy** would like to know if there are other delegations that have strong views on this sentence.

5. Manufacturers of devices classified as class I, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annex II. If the devices are placed on the market in sterile condition or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII, except for its Chapter II, or in Part A of Annex X. However, the involvement of the notified body shall be limited:

(a) in the case of devices placed on the market in sterile condition, to the aspects of manufacture[36] concerned with ***establishing*** [37]securing and maintaining sterile conditions,

(b) in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements.[38]

~~6.~~ ***[***Manufacturers ***of devices ~~in~~ classifieds as class IIa and IIb***[39] may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question***]***.[40]

---

[36] **DE** delete "*of manufacture*" as the NB only assess the processes for establishing [...] sterility.

[37] **DE** add "*establishing*".

[38] **DE** delete '*of manufacture*'.

[39] **IT Pcy** compromise proposal.

[40] **PL** reservation on Art 42(6) – either delete it completely or put it elsewhere in the Proposal.
DE, ES, IT Delete Art 42(6).
Pcy would like to know if there are delegations who can not live ***without*** this paragraph in the regulation.

7. Manufacturers of custom-made devices***, other than class III implantable devices,*** shall follow the procedure set out in Annex XI and draw up the statement set out in that Annex before placing the device on the market.[41] ***Manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment procedure based on full quality assurance as specified in Annex VIII, except for its Chapter II, [with assessment of the ~~design documentation within the~~ technical documentation on a representative basis]***[42].[43]

~~***7a. Furthermore, for devices intended for use by lay users, the manufacturer shall comply with the requirements laid down in Section 2 of Annex IX.***~~[44]

8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language. Otherwise they shall be available in an official Union language acceptable to the notified body.[45] [46]

9. Investigational devices shall be subject to the requirements set out in Articles 50 to 60.

---

41 **DS 1364/13 FR** add subparagraph '*Manufacturers of custom-made implantable devices shall be subject to the conformity assessment procedure based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the design documentation within the technical documentation on a representative basis.*'
Cion suggests adopting a more gradual risk-based approach for implantable custom-made devices by submitting class III implantable custom-made devices not only to Chapter I of Annex VIII but also to its Chapter II on Design examination. For implantable custom-made devices in class IIb, **Cion** agrees with the approach proposed by **FR**.

42 **Pcy** compromise proposal.

43 **IE, FR, AT** support. **DK** concerns on the costs for the manufacturer; **DE** custom made devices are produced on basis of prescription and there will not be technical documentation in the sense of Annex.
Pcy proposes to delete the last part of sentence to avoid ambiguity.

44 **DS 1364/13 FR** add Article 42(7a): '*Furthermore, for devices intended for use by lay users, the manufacturer shall comply with the requirements laid down in Section 2 of Annex IX.*'

45 **DE** correspondence between notified body and manufacturer should be recorded.

46 **ES** should be drafted in the language of the competent authority of the manufacturer.

10. The Commission may, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:
    – the frequency and the sampling basis of the assessment of ~~the design documentation within~~ the technical documentation on a representative basis as set out in Sections 3.3(c) and 4.5 of Annex VIII in the case of devices of classes IIa and IIb, and in Section 7.2 of Part A of Annex X in the case of devices of class IIa;
    – the minimum frequency of unannounced factory inspections and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;
    – the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, design dossier examination and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII, Section 3 of Annex IX and Section 5 of Part B of Annex X.

    Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

~~11. In the light of technical ***and scientific*** progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 28 to 40, or of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts[47] in accordance with Article 89 amending or supplementing ***updating*** the conformity assessment procedures set out in Annexes VIII to XI.~~

[47] **DK, IT, NL** reservation on delegated acts. **UK** delete reference to delegated acts.

Article 43

Involvement of notified bodies

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities,[48] the conformity assessment procedures and the devices concerned. ~~***Without prejudice to Article 46,***~~[49] An application may not be lodged in parallel with ~~more than one~~ ***another*** notified body for the same conformity assessment activity.

2. The notified body concerned shall inform the other notified bodies ~~***notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned***~~[50] of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment, ***by means of the electronic system referred to in article 25***.[51]

2a.[52] ***Manufacturers shall ~~also~~ declare whether they have withdrawn an application with another notified body prior to the decision of that notified body or information about any previous application for the same type that has been refused by another notified body.***[53] [54]

3. The notified body may require any information or data from the manufacturer which is necessary in order to properly conduct the chosen conformity assessment procedure.

---

48 **DE** delete '*conformity assessment activities*'.

49 ~~Article on change of Notified Body.~~ **FR**, **Cion** delete "*Without prejudice to Article 46*".

50 **Pcy** it doesn't seem to be a practical solution.

51 **DE** add "*by means of the electronic system referred to in article 25*"; **CZ**, **AT** support.

52 **Pcy** invites delegations to consider whether 2a is redundant in the light of changes in paragraph 2.

53 **BE** is this internal or via the databank so national competent authorities can access it?

54 **UK** manufacturers should also have to declare whether they have withdrawn an application with another notified body prior to the decision. **ES, HU, PT** Support. **DE** the declaration should be done prior to the application to another Notified Body .

4.[55] Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical ***and scientific***[56] competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.[57]

[58]

Article 44

Mechanism for scrutiny of certain conformity assessments

[will be discussed in another meeting]

Article 45

Certificates

1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body[59]. The minimum content of the certificates is set out in Annex XII.

---

[55] **LT** move to chapter IV.

[56] **DS 1257/13 AT** add '*and scientific*'.

[57] **DE** delete this provision, already in Annex. **Cion** preferred to keep this is the body of text and not in the Annex.

[58] **DS 1520/13 FR** add the following paragraph: '*5. The notified body shall perform unannounced factory inspections of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, including sampling, as described in paragraph 4.4 of Annex VIII.*' **HU** Support. **Cion** Cannot put this in the text.

[59] **DE** replace "*notified body*" with " *Member State*".

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment[60] [61] in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

2a. Notified bodies may impose restrictions to ~~the use~~ the intended purpose[62] of a device to certain numbers or groups of patients or require manufacturers to undertake specific post-market clinical follow-up studies pursuant to Part B of Annex XIII. [63]

3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

4. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into this electronic system information regarding certificates issued, including amendments and supplements, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.

---

60 **~~DE~~** ~~concerns on the lack of clarity on the re-assessment procedures.~~

61 **DE** The meaning of re-assessment must be clarified. Periodic updating by NB is required even if the device has not been subject to substantial changes?

62 **Pcy** it is up to MS to restrict use of device.

63 This paragraph is linked to the changes of Article 44 (doc. **15546/14**).

5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum content of the certificates set out in Annex XII[64].

Article 46[65]

Voluntary change of notified body

1. In cases where a manufacturer terminates his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, ***where practicable*** the outgoing notified body[66] and the incoming notified body. This agreement shall address at least the following aspects:
   (a) the date of invalidity of certificates issued by the outgoing notified body;
   (b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;
   (c) the transfer of documents, including confidentiality aspects and property rights;
   (d) [67] the date as of which the incoming notified body assumes full responsibility for the conformity assessment tasks.
   (e) the date ~~of transfer~~ after which the full responsibility for the manufacturer's products including products assessed by the outgoing Notified Body is ~~are~~ is assigned to the incoming notified body; [68]
   ***(f) the last serial number or batch number for which the outgoing Notified Body is responsible*[69].**

---

64 **DE** delete paragraph 5.
65 **PT** include deadline for voluntary change. **Cion** could include '*date of transfer*' so products after that date would be assigned to the new notified body.
66 **DE** delete "*the outgoing notified body*" or add "*if possible*".
67 **Cion** paragraph (d) becomes superfluous in light of paragraph (e)
68 **DE** The meaning of re-assessment must be clarified.
69 **ES, PT** asked for including serial number, batch number and lot number.

2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.

Article 47

Derogation from the conformity assessment procedures

1. By way of derogation[70] from Article 42, any competent authority may authorise, on duly justified request[71], the placing on the market or putting into service[72] within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 42 have not been carried out and use of which is in the interest of public health or patient safety ***or*** [73] ***health*** ~~***if the effectiveness and safety and performance of that device can be presumed according to the current state of scientific knowledge***~~[74] [75].

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service[76] of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.[77]

---

70 **AT** derogation should be issued for a specific device. **SK** which competent authority can authorise a derogation?

71 **DE** delete "*on duly justified request*" as it might imply that only manufacturers can request.

72 **DE** delete '*or putting into service*'.

73 Reinstated word. **DE** does not agree.

74 **DS 1520/13 FR** replace '*patient safety*' by '*health of patients if the effectiveness and safety of that device are presumed according to the current state of scientific knowledge.*' **ES** supports the replacement of the word "*safety*" with "*health*".

75 **DK, DE, ES, NL, AT, PT, UK** delete the last sentence of paragraph 47(1) and the corresponding provision in paragraph 47(3)

76 **DE** delete '*or putting into service*'.

77 **SE** suggested setting out some criteria for when there is an obligation to inform **Cion**.

3[78][79]. ~~Upon request by a Member State and where this is in the interest of~~ ***Following an notification pursuant to*** ~~***information as referred to in***~~ ***paragraph 2, the Commission, in exceptional cases relating to a*** public health ***[threat]*** or patient~~s~~ safety ***[or health] [in several Member States],*** ~~***if the effectiveness and safety and performance of that device can be presumed according to the current state of scientific knowledge***~~ ~~in more than one Member State, the Commission~~[80] [81] may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).[82] [83]

---

78 **Pcy** proposes to delete "*threat*" as it narrows the scope of cases and balance this with narrowing the scope in case of individual patient safety. If the majority is willing to have "patient health" and "in several Member States" Pcy will leave it in the text.

79 **CZ, DK, EL** delete paragraph 47(3).

80 **DS 1229/14 FR** replace "*Upon request by a Member State and where this is in the interest of public health or patient safety in more than one Member State, the Commission*" with "*Following an information as referred to in point 2, the Commission, in exceptional cases relating to public health threat or patients safety in several Member States, if the effectiveness and safety of that device can be presumed according to the current state of scientific knowledge* "

81 **NL** replace '*Upon request by a Member State and where this is in the interest of public health or patient safety*' with '*Upon request by a Member State or where this is in the interest of public health and patient safety*'. ~~**LV,**~~ **PL** support.

82 **NL** more detail required – not clear how **Cion** will deal with this procedure. **PL** support.

83 **DE** delete Art 47(3). **ES, PL, SK** support.

Article 48[84]

Certificate of free sale[85]

1. For the purpose of export and upon request by a manufacturer ***or an authorised representative***, the ~~***competent authority***~~[86] ~~***of the***~~ Member State[87] in which the manufacturer ***or the authorised representative***[88] has its registered place of business shall issue a certificate of free sale declaring that the manufacturer ***or the authorised representative, as applicable,*** is ~~***properly***~~[89] established ~~***registered in the Member State in question***~~ and that the device in question bearing the CE-marking in accordance with this Regulation may be ~~legally~~[90] marketed in the Union. The certificate of free sale shall ~~be valid for the period indicated on it which shall not exceed five years and shall not exceed the validity of the~~ ***set out the identification of the device in the electronic system set up under Article 25.***[91] ***Where a notified body has issued a*** certificate referred to in Article 45***, the certificate of free sale shall set out the number of the certificate*** ~~issued for the device in question~~.[92] [93][94]

---

84 Text based on document MDEV-51 (10 April 2014). Also new associated recital; **DK** delete, should be national responsibility.

85 This Article should be associated with a new recital:
"*(X) It is appropriate that certificates of free sale contain information that makes it possible to use the European databank on medical devices (Eudamed) in order to obtain information on the device and in particular whether it is on the market, no longer manufactured, withdrawn from the market or recalled and on any certificate on its conformity.*" **PT** agree

86 **HU** reinstate "competent authority"

87 **DE** should specify that the competent authority must issue the certificate. **SK** Support.

88 **ES** extend the possibility to require a free sale certificate to all economic operators; PT not agree

89 **DE** deleting since there are no criteria to make this evaluation

90 **DS 1520/13 FR** delete '*legally*'.

91 **DE** add number of registration of the manufacturer and basic UDI

92 **DS 1520/13 FR** replace '*which shall not exceed five years and shall not exceed the validity of the certificate referred to in Article 45 issued for the device in question*' with '*That period shall not exceed the validity of the certificate.*'

93 **BE** remove validity period. ~~**DE,**~~ **ES, IT, PL, PT** Support.

94 **DE** delete last sentence as it is unnecessary burden.
Cion explains that this additional number is needed as UDI system will be introduced gradually and particularly for low risk devices.

2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).[95]

---

[95] **DE** Art 48(2) is unnecessary.

ANNEX II[96]

TECHNICAL DOCUMENTATION[97]

The technical documentation[98] and, if applicable, the summary technical documentation (STED)[99] to be drawn up by the manufacturer ***shall be presented in a clear, organized, readily searchable and unequivocal way and***[100] shall include in particular the ~~following~~ elements~~:~~ ***described in this Annex. The STED shall*** ~~***contain,***~~ ***summarize*** ~~***or reference***~~[101] ***the elements of the technical documentation.*** [102] [103] [104]

---

[96] The text in this annex is based on that presented in document 12772/14. The Italian Presidency has added footnotes and included further changes to the legislative text based on the discussion in the Working Party.

[97] **DS 1104/14 NL** The wording of the summary technical documentation (STED) is used both in Article 8 and Annex 2. The term STED comes from the GHTF, where the STED was used to describe a relatively limited set of documentation, which should allow third parties like regulators a 'quick' understanding of the device. What is described in Annex II resembles the STED. It is not clear how this information can be summarized, what can be left out? It should be noted, that in Annex VIII, 3.3 c it is stated that 'the design documentation within the technical documentation as referred to in annex II' has to be assessed by the notified body. It is unclear which subsection of the technical documentation is meant. It is most likely that the manufacturer has much more information, e.g. design calculations, the raw data of all tests performed etc. It is unclear what this full set of data is called, most likely design dossier? However, the content of the design dossier need to be specified, as it is mentioned several times in the text of the regulation. Therefore, the levels of detail in the different types of documentation sets need to be more clearly stated. **DS 1435/14 SE** support.

[98] **LT** need clarify if the manufacturer must provide the documentation on request.

[99] **CZ, DE, NL, AT, PT, UK, Cion** ask for clarification of the content of STED; **Pcy**

[100] **DS 1105/14 FR** add "*shall be presented in a clear, organized, readily searchable and unequivocal way and*". **DS 1435/14 SE** support.

[101] **NL** "reference" not clear.

[102] **DS 1125/14 IT** add "*described in this Annex. The STED shall contain, summarize or reference the elements of the technical documentation.*".

[103] **DS 1421/14 DE** "*The technical documentation* ~~*and, if applicable, the summary technical documentation (STED)*~~ *to be drawn up by the manufacturer* *shall be presented in a clear, organized, readily searchable and unequivocal way and* *shall include in particular the* ~~*following*~~ *elements:* *described in this Annex. The STED shall* ~~*contain,*~~ *summarize* ~~*or reference*~~ *the elements of the technical documentation*".

[104] **DS 1416/14 HU** add "*The STED shall* ~~*contain,*~~ *summarize* ~~*or*~~ *and reference the elements of the technical documentation.*" or "*The STED shall* ~~*contain,*~~ *summarize the technical documentation* ~~*or*~~ *with a clear reference to the elements of the technical documentation.*"

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification[105]

(a) product or trade name and a general description of the device including its intended purpose~~, *intended use*~~[106] ***and intended user***[107]***;***

(b) [108]**[**the UDI device identifier ***[and the Basic UDI devices identifier]*** as referred to in item (i) of point (a) of Article 24(1) attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;]

(c) the intended patient population and medical condition***s*** to be diagnosed ~~**and/or**~~ treated ***and/or monitored***[109] and other considerations such as patient selection criteria***,*** ***indications,***[110] ***contraindications***[111]***,*** ***warnings***[112];

---

105 **DS 1421/14 DE** suggestion
"*1.1. Device description and specification*
a) including its intended purpose, ~~intended use~~ and intended user;
b) […]
c) as patient selection criteria, ~~indications,~~ contraindications;
d) principles of operation of the device and its mode of action, and where necessary a scientific justification that the principle mode of action is not pharmacological, immunological or metabolic ~~scientifically demonstrated~~;
e) risk class and the justification of the applicable classification rule according to Annex VII;
f) […];
g) to be used in combination with it; including a description of the interface;
h) […];
i) its formulation, its qualitative and quantitative composition where appropriate;
j) …;
k) any variants/configurations and accessories that would […];"

106 **DS 1103/14 AT** add "*(ba) intended purpose(s) and use*"; **CZ, DK, ES, Cion** prefer "*intended purpose*"; **IE** intended use and use setting.

107 **DS 1105/14 FR** add "*and the intended user*"; **ES** support.

108 The paragraph is subject to revision after discussion on Chapter III

109 **Cion** asked for adding "*monitored*".

110 **ES** concept already expressed; add contraindications.

111 **DS 1103/14 AT** add "*indications, contraindications*"; **DS 1435/14 SE** support; **NL** not in favour for contraindications.

112 **DK** add "*warnings*".

(d)[113] principles of operation of the device ***and its mode of action scientifically demonstrated, if necessary***;[114]

(e) risk class and ***the justification of***[115] the applicable classification rule according to Annex VII;

(f) an explanation of any novel features[116];

(g) a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it;

(h) a description or complete list of the various configurations/variants of the device that will be made available;

(i) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its ~~***qualitative and quantitative***~~[117] [118] composition, its functionality ***and, where relevant, its qualitative and quantitative composition***[119]. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

(j) a description of the (raw) materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;

(k) technical specifications (features, dimensions and performance attributes) of the medical device and any variants***/configurations***[120] and accessories that would typically appear in the product specification made available to the user, e.g. in brochures, catalogues and the like.

---

113 **AT** join d) and e).

114 **DS 1105/14 FR** add "*and its mode of action scientifically demonstrated*", **DE** add "*if necessary*"; **DK, ES, NL** not always necessary.

115 **DS 1105/14 FR** add "*the justification of*"; **DS 1435/14 SE** support.

116 **DE** not clear.

117 **DS 1232/13 PT** add "*qualitative and quantita*tive".

118 **Cion** not valid for certain products.

119 **DS 1518/14 PT, UK** joint suggestion.

120 **DS 1103/14 AT** add "*configurations*"; **ES** support. **NL** not in favour.

1.2. Reference to previous and similar generations of the device

(a) an overview of the manufacturer's previous generation(s) of the device, if such exist;

(b) an overview of ~~the manufacturer's~~[121] ***identified*** similar devices available on the EU or international markets, if such exist.

2. INFORMATION SUPPLIED BY THE MANUFACTURER

(a) a complete set of

- the label(s) on the device and on its packaging ***(single unit packaging, sales packaging, transport packaging in case of specific management conditions***),[122] ***in the languages accepted in the ~~UE countries~~ Member States where the device is sold***[123];
- the instructions for use ***in the languages accepted in the ~~UE countries~~ Member States where the device is envisaged to be sold***;[124] [125];

~~(b) a list of the language variants for the Member States where the device is envisaged to be marketed.~~[126]

---

[121] **DS 1104/14 NL** delete "*the manufacturer's*", as similar devices should also include devices from other manufacturers, to allow a better insight into the other options for that specific device. **IE, FR** support; **DE** not in favour**; DK, ES** add "*identified*".

[122] **DS 1435/14 SE** does not support the addition "*single unit packaging, sales packaging, transport packaging in case of specific management conditions*"

[123] **DS 1125/14 IT** add "*single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the UE countries where the device is sold*".

[124] **DK, DE, ES, LT** for point a) back to Cion proposal.

[125] **DS 1435/14 SE** "*in all the languages accepted by the Member States where the device is intended to be made available*"; **DS 1421/14 DE** "*the instructions for use in the languages accepted in the EU countries where the device is envisaged to be sold*".

[126] **DS 1125/14 IT** delete "*– the instructions for use*" and "*(b) a list of the language variants for the Member States where the device is envisaged to be marketed.*"; add "*the instructions for use in the languages accepted in the UE countries where the device is sold*". It is preferable that the manufacturer itself manages, supervises and approves the translation of the instructions for use in other languages when required, to avoid mistakes in the information provided to the user. The provision of this section should be in line with the final version of Chapter II.
LT delete "*where the device is envisaged to be marketed*";

3. DESIGN AND MANUFACTURING INFORMATION

(a) Information to allow ***the*** ~~a general~~ understanding of the design stages applied to the device ~~and the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures~~; [127] [128]

(aa) Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation; [129] [130]

(b) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

---

[127] **DS 1421/14 DE** suggestion

"*(a) Information to allow the ~~a general~~ understanding of the design stages applied to the device, for software in particular the life cycle validation process and the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures;*

~~(aa) Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;~~."

[128] **ES, NL, AT** prefer Cion proposal.

[129] **DS 1105/14 FR** add

"*(b) Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation.*".

[130] **LT** only synthetic information into the technical documentation . More detailed information into the quality documentation.

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENT

[131]The documentation shall contain ***demonstration of conformity with*** ~~information regarding the solutions adopted to meet~~ the general safety and performance requirements laid down in Annex I***, applicable to the device and its intended*** ~~***use***~~ ***purpose***[132]***, including the justification, validation and verification of the solutions adopted to meet those requirements***. This ~~information may take the form of a checklist identifying~~ ***demonstration shall include:***[133]

(a) the general safety and performance requirements that apply to the device and why others do not apply;

(b) the method(s) used to demonstrate conformity with each applicable general safety and performance requirement;

(c) the harmonised standards or ~~CTS~~ ***CS*** applied ***and to which extent*** or other method(s) employed ***and to which extent***[134];

---

131 **DS 1421/14 DE** suggestion
"*The documentation shall contain demonstration of conformity with ~~information regarding the solutions adopted to meet~~ the general safety and performance requirements laid down in Annex I, applicable to the device and its intended use~~, including the justification, validation and verification of the solutions adopted to meet those requirements~~. This information may take the form of a checklist identifying ~~demonstration shall include~~:*
(a) the general safety and performance requirements that apply to the device and why others do not apply;
(b) the method(s) used to demonstrate conformity with each applicable general safety and performance requirement;
(c) the harmonised standards or ~~CTS~~CS applied and to which extent or other method(s) employed, including the justification, verification and validation that these methods meet the general safety and performance requirements ~~and to which extent~~;
(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, ~~CTS~~CS or other method employed to demonstrate conformity with the general safety and performance requirements. ~~This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.~~"

132 **DK, Cion** replace "*intended use*" with "*intended purpose*".

133 **DS 1103/14 AT** replace with "*The documentation shall contain demonstration of conformity with ~~information regarding the solutions adopted to meet~~ the general safety and performance requirements laid down in Annex I, applicable to the device and its intended use, including the justification, validation and verification of the solutions adopted to meet those requirements. This ~~information may take the form of a checklist identifying~~ demonstration shall include*". **SE** support.

134 **DS 1104/14 NL** add "*and to which extent*".

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, ~~CTS~~ ***CS*** or other method employed to demonstrate conformity with the general safety and performance requirements. This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT[135]

The documentation shall contain ~~a summary of~~[136]

(a) the risk/benefit analysis referred to in Sections 1 and 5 of Annex I, and

(b) the solutions adopted and the results of the risk management referred to in Section 2 of Annex I.

6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results [137] of ***all the*** verification and validation testing and/or studies undertaken ***and their critical analysis***[138] to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

---

135 **LT** need clarify if AC must control and where the documentation should be kept in. Change the title to "*risk management*" delete "*risk-benefit analysis*", already part of the risk management. **RO** agree deletion "*summary of*".

136 **DS 1125/14 IT** delete "a summary of". The technical documentation should include the complete risk/benefit analysis referred to in Sections 1 and 5 of Annex I and the solutions adopted and the results of the risk management referred to in Section 2 of Annex I. As described above, the STED, if applicable, will contain the summary of such documentation.

137 **DS 1421/14 DE** add "*including the reports*"

138 **DS 1105/14 FR** add "*and their critical analysis*".

6.1. Pre-clinical and clinical data[139]

(a) results [140] of (engineering, laboratory, simulated use, animal) tests[141] and evaluation of published literature applicable to the device ***and taking into account its intended*** ~~***use***~~ ***purpose***[142] [143] or substantially similar devices regarding the pre-clinical safety of the device and its conformity with the specifications;

(b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding ***in particular:***

- biocompatibility ***of the device including the identification of***[144] ~~(identifying~~ all materials in direct or indirect contact with the patient or user~~)~~[145] [146] [147];
- physical, chemical and microbiological characterisation;
- electrical safety and electromagnetic compatibility;
- software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);

---

139 **DS 1416/14 AT** delete "*data*" and add "*evaluation*".

140 **DS 1421/14 DE** add "*including reports*".

141 **DS 1416/14 AT** add ", *including the test reports*"

142 **DS 1103/14 AT** add "*and its intended use*".

143 **DS 1416/14 AT** change "*use*" to "*purpose*". **DE** support.

144 **DS 1105/14 FR** add "*of the device including the identification of*".

145 **DS 1103/14 AT** add "*and its potential biological impact*".

146 **DS 1416/14 AT** change this point to "*biocompatibility of the device including the identification and quantification of~~(identifying~~ all materials, particles, substances, degradation products, including wear debris, and leachables in direct or indirect contact with the patient or user~~)~~*"; (in line with UK suggestion for Annex I.II.7.4).

147 **DS 1416/14 HU** change this indent to "*biocompatibility of the device including the identification of all materials in direct ~~or indirect~~ contact with the patient or user or any body parts (cells, tissues, organs, body fluids) that are implanted or returned to the patient*".

- stability/shelf life***;***
- ***[~~efficacy~~/performance] and safety***[148] [149].

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances[150] shall be demonstrated.

Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision, e.g. biocompatibility[151] testing on the identical materials was conducted when these were incorporated in a previous version of the device that has been legally placed on the market or put into service; [152]

(c) [153] the report on the clinical evaluation ***plan*** in accordance with Article 49(5) and Part A of Annex XIII ***and its updates*** [154];

(d) the PMCF plan and PMCF evaluation report in accordance with Part B of Annex XIII or any justification why a PMCF is not ~~deemed necessary or appropriate~~ ***applicable***[155].[156]

---

148 **DS 1104/14 NL** add "*efficacy and safety*".

149 **DK, DE** "*performance*" not "*efficacy*"; **DE, ES, AT, UK, Cion** support; **SE** efficacy and safety not sufficiently specific. **DE DS 1421/14** delete "*efficacy and safety*".

150 OJ L 50, 20.2.2004, p. 44.

151 **AT** harmonize with Section 7.4 Annex 1; **NL, PT** support.

152 **DS 1105/14 FR** delete "*Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision, e.g. biocompatibility testing on the identical materials was conducted when these were incorporated in a previous version of the device that has been legally placed on the market or put into service*". **DE** support.

153 **DS 1416/14 AT** add "*the clinical evaluation plan and*"; **DE DS 1421/14** support.

154 **DS 1416/14 AT** add "*, and it's updates*".

155 **DS 1416/14 AT** replace "*deemed necessary or appropriate*" by "*applicable*" ; **PT** support.

156 **DS 1351/14 NL** delete "*the PMCF plan and PMCF evaluation report in accordance with Part B of Annex XIII or any justification why a PMCF is not deemed*".

6.2. Additional information in specific cases

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, referred to in the first subparagraph of Article 1(4), a statement indicating this fact [157]. In this case, the documentation shall [158] identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.[159] [160]

(b) Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are covered by this Regulation in accordance with point (e) of Article 1(2), a statement indicating this fact [161]. In this case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 10.1. or 10.2., respectively, of Annex I.[162]

[163]

---

157 **DS 1416/14 AT** add "*and a scientific justification of it is added value*".

158 **DS 1421/14 DE** add "*describe the ancillary function of that substance*".

159 **DS 1103/14 AT** add "*Reports or certificates by relevant competent authorities, reference labs acc. to Art. /Annexes XY have to be attached*". **ES, UK** support.

160 **DS 1104/14 NL** add "*including the scientific opinion of the consulted medical evaluation board*". The scientific opinion of the MEB consulted about the medicinal product used in the device shall also be part of the technical documentation. **ES, UK** support.

161 **DS 1416/14 AT** add "*and a scientific justification of it is added value*".

162 **DS 1103/14 AT** add "*Reports or certificates by relevant competent authorities, reference labs acc. to Art. /Annexes XY have to be attached.*". **ES, UK** support.

163 **DS 1232/13 PT** add:
"*Where a device is intended to be ingested, detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding:*
- *dynamic and kinetic activities;*
- *possible interactions, or of their products of biotransformation, with other devices, medicinal products or other substances, considering the target population, and their associated medical conditions;*
- *local tolerance;*
- *toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable according to total exposure to the device*".

Pcy proposed a question related to the issue in the questionnaire concerning Chapter I.

(ba)[164] 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, [injected for local effect][165] applied on skin or mucous membrane and that are absorbed by or locally dispersed in the human body, detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions, or otherwise justification for the absence of such studies, regarding:

- ***absorption, distribution, metabolism and excretion;***
- ***possible interactions, or of their products of metabolism, with other devices, medicinal products or other substances, considering the target population, and their associated medical conditions;***
- ***local tolerance;***
- ***toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable according to total exposure to the device.***

(c) In the case of devices placed on the market in a sterile or defined microbiological condition a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

(d) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

---

164 **DS 1518/14 PT, UK** joint suggestion.

165 Following the discussion at Coreper on 18 March and the support for the text in **DS 1170/15 IT** the **Pcy** is compelled to reopen this discussion. **BE, BG, DE, EL, AT** are noted at Corper level to agree with **DS 1170/15 IT** to delete "*injected for local effect*"**. FR** is noted to disagree with the deletion. **Pcy would like to know if there are other delegations that cannot live with the deletion of "*injected for local effect*" and if so, Pcy accordingly invites that delegation(s) to engage in finding a new and better compromise.**

(e) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination***/configuration*** including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

166

167

---

166 **DS 1421/14 DE** add a new point (refer to **DS 1232/13 PT**)

"*(f) Where a device is intended to be ingested, inhaled, be administered rectally or vaginally and that is absorbed by or dispersed in the human body detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding:*

- *dynamic and kinetic activities;*
- *possible interactions, or of their products of biotransformation, with other devices, medicinal products or other substances, considering the target population, and their associated medical conditions;*
- *local tolerance;*
- *toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable according to total exposure to the device*".

167 Editorial comment - former Section 7 is set out in Annex IIa on Post Market Surveillance.

ANNEX VII[168]

CLASSIFICATION CRITERIA

I. SPECIFIC DEFINITIONS FOR THE CLASSIFICATION RULES

1. DURATION OF USE[169]

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

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

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

2. INVASIVE AND ACTIVE DEVICES

2.1 'Body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma ~~or permanent tracheotomy~~.[170]

---

[168] The text of this Annex is based on document 13826/14 but with further footnotes and changes proposed by **IT Pcy**.

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

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

2.2 'Surgically invasive device' means

(a) an invasive device which penetrates inside the body through the surface of the body, ***including through mucus membranes of body orifices*** with the aid or in the context of a surgical operation ***or other interventional procedure***[171];

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

2.3 'Reusable surgical instrument'[172] means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures ***such as*** ~~for~~ cleaning, ***disinfection***[173] and/~~or~~r sterili~~z~~***s***ation have been carried out.

2.4 'Active therapeutic device' means any active ~~medical~~ device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.

2.5 'Active device intended for diagnosis ***and monitoring***[174]**,** means any active ~~medical~~ device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating[175] physiological conditions, states of health, illnesses or congenital deformities.

---

171 **SE** insert "*or other interventional procedure"*(Ref DS 1366/13) to capture invasive devices used in other non-surgical procedures, however some experts expressed concern that it may risk up-classifying some devices unjustly. **IE**, **ES**, **AT**, **PT, Cion** support.

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

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

174 **IE Pcy** Experts suggested this additional wording to make consistent with the text further on.

175 **IE, AT** delete "*treating*"; **ES**, **Cion** not agree.

2.6 'Central circulatory system'[176] means the following blood vessels: arteriae pulmonales, aorta ascendens, arcus aorta*e*, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.

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

2.8 'Injured skin or mucus membrane' means an area of skin or a mucus membrane presenting a pathological change or change following disease or a wound.

II. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES

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

2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

[176] **IE Pcy** Experts suggested that this definition should include the heart. **IT Pcy** this is covered by explicit mention under Rules 6, 7 and 8. **Cion** support **IE** position.

3.[177] ~~Stand alone software,~~ ***Software,*** which ***[has a medical purpose and]***[178] drives a device or influences the use of a device, falls automatically in the same class as the device.

~~***Standalone software, which has a medical purpose as defined in article 2, point 1(1), is classified in its own right.***~~[179] [180]

If ~~stand alone~~ ***the*** software is independent of any other device, it is classified in its own right. [181]

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

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

---

[177] Reinstated numbering from the Cion proposal.

[178] **Pcy** can be considered redundant as software that drives or influences the device does not necessarily need to have a medical purpose.

[179] Based on **DE** suggestion.
Pcy should the delegations want to align with IMDRF it would be worded as:
"If the software ***achieves its medical purpose without being part of a hardware medical device, it is clarified in its own right*** *is independent of any other device, it is classified in its own right."*

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

[181] Reinstated text from the Cion proposal with change proposed by **IT Pcy**.

6. In calculating the duration referred to in ~~Chapter I,~~[182] Section 1 continuous use means:

(a) The entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior and after the period when the use is interrupted or the device removed.

(b) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.[183] [184]

~~***an uninterrupted actual use of the device for its intended purpose. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device.***~~ [185] [186] [187]

7. A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition by itself or when it provides decisive information for the diagnosis.[188]

---

[182] Editorial remark, this deletion seems to be a mistake.

[183] **IE Pcy** Some experts considered that the accumulated use of a device needs to be incorporated within the definition of 'duration of use' and suggested deleting implementing rule 6.

[184] The highlighted text in (a) and (b) is reinstated from the Cion proposal.

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

[186] **DS 1343/13 DE** Directive 93/42/EEC wording seems to be more appropriate

[187] **Pcy** suggests to revert to the wording provided in directive 93/42/EEC; risk associated with the total exposure to a device may be better addressed within the Essential Requirements. At the WP on 7-8 October 2014 **FR**, **PT**, **Cion** suggested reverting to the Cion proposal.

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

III. CLASSIFICATION RULES

3. NON-INVASIVE DEVICES

3.1 Rule 1

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

3.2 Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids***, cells*** or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in class IIa:

- if they may be connected to an active medical device in class IIa or a higher class,
- if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body ***cells and*** tissues***, except for blood bags, which are in class IIb***[189].

In all other cases they are in class I~~***, except for blood bags, which are in class IIb***~~[190].

[189] **ES** derogation for blood bags shall be inserted at the end of the second indent.
[190] **DS 1295/13 UK** insert '*except for blood bags, which are in class IIb'*.

3.3 Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or ***administration*** ~~infusion~~ into the body are in class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in class IIa.

All non-invasive devices ***consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken off from the human body or with human embryos before their implantation or administration into the body are in class III*** ~~intended to be used for in vitro fertilisation (IVF) or assisted reproduction technologies (ART) which are liable to act with close contact on the inner or outer cells during the IVF/ART, such as washing, separating, sperm immobilising, cryoprotecting solutions, are in class IIb~~.[191]

3.4 Rule 4

All non-invasive devices which come into contact with injured skin ***or mucous membrane*****:**

- are in class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,
- are in class IIb if they are intended to be used principally ***for injuries to skin or mucous membrane*** ~~with wounds~~ which have breached the dermis and can only heal by secondary intent,
- are in class IIa in all other cases, including devices principally intended to manage the micro-environment ~~of a wound~~ ***injured skin or mucous membrane.***

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

4. INVASIVE DEVICES

4.1 Rule 5[192]

All invasive devices with respect to body orifices, other than surgically invasive devices ~~and~~ which are not intended for connection to an active medical device or which are intended for connection to ***a Class I*** ~~an~~ active medical device ~~classified as class I~~:

- are in class I if they are intended for transient use,
- are in class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in *the* ~~a~~ nasal cavity, in which case they are in class I,
- are in class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in ~~a~~ *the* nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in class IIa or a higher class, are in class IIa.

4.2 Rule 6

All surgically invasive devices intended for transient use are in class IIa unless they:

- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,[193]
- ~~are reusable surgical instruments, in which case they are in class I,~~[194]

---

192 **ES** reference to the products with biological effect should be added

193 **Pcy** It seems to be superfluous following the addition to third indent; **SE** support

194 **IE Pcy** Experts discussed that risk associated with reusable instrument should be based on its intended use rather than being the lowest risk class based on the fact that it is reusable. (**ES, NL, PT, SE, UK, Cion** – in favour of deletion). **DE, PL** – against deletion stating that there have been no identified safety issues with having reusable surgical devices as class I.
WP 7-8 October 2014 **CZ, IE, ES, FR, AT, PL, PT, UK, Cion** delete second indent. **DE** does not agree.

- are intended specifically for use in direct contact with the ***heart or central circulatory system or the***[195] central nervous system, in which case they are in class III,
- are intended to supply energy in the form of ionising radiation in which case they are in class IIb,
- ~~***are intended to***~~[196] have a biological effect or are wholly or mainly absorbed in which case they are in class IIb,[197]
- are intended to administer ~~medicines~~ ***medicinal products*** by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in class IIb.

4.3 Rule 7

All surgically invasive devices intended for short-term use are in class IIa unless they:

- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,[198]
- are intended specifically for use in direct contact with the ***heart or central circulatory system or the***[199] central nervous system, in which case they are in class III,
- are intended to supply energy in the form of ionizing radiation in which case they are in class IIb,
- ~~***are intended to***~~[200] have a biological effect or are wholly or mainly absorbed in which case they are in class III,
- are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in class IIb.

---

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

196 **CZ, IE, AT, PL, UK, Cion** delete "*are intended to*" to avoid abuse; **DK, DE** not agree.

197 **IE Pcy** Experts suggested adding '*are intended to*' for consistency. Post-meeting comments suggested retaining original text.

198 **Pcy** It seems to be superfluous following the addition to second indent. **SE** support

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

200 **CZ, IE, AT, PL, UK, Cion** delete "*are intended to*" to avoid abuse; **DK, DE** not agree.

4.4 Rule 8[201]

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

- are intended to be placed in the teeth, in which case they are in class IIa,
- are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III,
- have a biological effect or are wholly or mainly absorbed, in which case they are in class III,
- are intended to undergo chemical change in the body, except[202] if the devices are placed in the teeth, or to administer medicines, in which case they are in class III,
- are active implantable medical devices ***and their accessories*** ~~or implantable accessories to active implantable medical devices~~[203], in which case they are in class III,
- are breast implants, in which case they are in class III;
- are ~~hip, knee~~***, hand, wrist, ankle, elbow***[204] ~~or shoulder~~[205] total and partial joint replacements, in which case they are in class III, with the exception of ancillary components such as screws, wedges, plates and instruments,
- are spinal disc replacement implants and implantable devices that come into contact with the spinal column[206], in which case they are in class III ***with the exception of*** ~~***ancillary***~~ ***components such as screws, wedges, plates***[207] ***and instruments***[208]***.***

---

[201] **SE** all implantable devices should be class III. **FR, AT, PT, SE** in favour. Further analysis and caution suggested by **ES, NL, UK**. **Cion** suggested that it may be logical but that further impact analysis would be required. (Ref DS 1366/13).

[202] **ES, NL** disagree with the exception.

[203] **PL** programmes for active implantable devices were already covered under rule 9.

[204] **IE Pcy** Experts suggested adding '*hand, wrist, ankle*'. **FR** should '*elbow*' joints be included? **AT** small joint implants should be included as class III. **NL** supported more general wording.

[205] **CZ, FR, AT, PT, RO, SE** agree on adding all joint replacements in class III.

[206] **DK, AT, PT, ES, Cion** reinstate "a*nd implantable devices that come into contact with the spinal column*".

[207] **ES** not consider "*plates*" a right exception.

[208] **DK** not in favour of the adding.

5. ACTIVE DEVICES

5.1 Rule 9[209]

All active therapeutic devices intended to administer or exchange energy are in class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in class IIb.

All active devices intended to control or monitor the performance of active therapeutic devices in class IIb, or intended directly to influence the performance of such devices are in class IIb.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are in class IIb.[210]

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable medical devices are in class III.

---

[209] **FR** add *'All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are in class III.*' **DE, UK** delegates opposed and questioned evidence basis for up-classification proposed. **UK** suggests that recent incidents have been a result of user issues.

[210] **FR** consider class III for devices intended to emit ionizing radiation for therapeutic purposes.

5.2 Rule 10

Active devices intended for diagnosis are in class IIa:

- if they are intended to supply energy which will be absorbed by the human body, except for devices ~~used~~ ***intended*** to illuminate the patient's body[211], in the visible spectrum,
- if they are intended to image *in vivo* distribution of radiopharmaceuticals,
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system ***or diagnosis in clinical situations where the patient is in immediate danger,*** in which case they are in class IIb[212].

Active devices intended to emit ionizing radiation and intended for ~~diagnostic or therapeutic~~[213] interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in class IIb.

5.3 Rule 11

All active devices intended to administer and/or remove ~~medicines~~ ***medicinal products*****,** body liquids or other substances to or from the body are in class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in class IIb.

214

---

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

212 **UK** insert wording as per GHTF Rule 10 (i)(a) and (b). **FR** support.

213 **FR** support the deletion

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

5.4 Rule 12

All other active devices are in class I.[215]

6. SPECIAL RULES

6.1 Rule 13

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, with action ancillary[216] to that of the devices, are in class III.

6.2 Rule 14

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

6.3 Rule 15[217]

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in class IIb.

All devices intended specifically to be used for disinfecting or sterilising medical devices are in class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are in class IIb.

This rule does not apply to devices that are intended to clean medical devices other than contact lenses by means of physical action only.

---

215 **FR** add exception for software.

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

217 **IE Pcy** notes that **DS 1285/13 FR**, **DS 1295/13 UK**, **DS 1299/13 AT**, **DS 1343/13 DE**, **DS 1357/13 DK**, **DS 1366/13 SE**, **DS 1395/13 PL** all have differing suggestions for amending this rule.

6.4 Rule 16

Devices specifically intended for recording of diagnostic images generated by X-ray, ~~MRI, ultra-sound or other diagnostic devices~~[218] are in class IIa.

6.5 Rule 17

All devices manufactured ~~utilising~~ ***incorporating or consisting of***[219] [220] tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable are in class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable that are intended to come into contact with intact skin[221] only.

~~**6.6 Rule 18**~~[222]

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

---

[218] **AT, SE** reinstate deletion; **DE** agree with the deletion since devices specifically intended for recording of diagnostic images generated by MRI and ultra-sound are classified with the apparatus.

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

[220] **UK** replace "*utilising*" with "*incorporating*"; **AT** not support; **Cion** replace with "*consisting of or incorporating*".

[221] **AT** suggests that this is incomplete

[222] **IE Pcy** delete Rule 18 due to amendment of rule 2.

6.7 Rule 19[223] ~~18~~[224]

All devices incorporating or consisting of nanomaterial are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.

~~6.8 Rule 20~~[225]

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

6.9 Rule 21[226] ~~20~~ ~~*19*~~[227]

Devices that are composed of substances or combination of substances ~~***presented as one of the pharmaceutical dosage forms of the European Pharmacopoeia,***~~ ***that are*** intended to be ~~ingested, inhaled or administered rectally or vaginally~~ ***introduced into the human body via a body orifice, [injected for local effect] or applied on skin or mucous membrane*** and that are absorbed by or ***locally*** dispersed in the human body are***:***

- in class III ***if they, or their products of metabolism, are systemically absorbed by the human body [in order to achieve the intended purpose[228]],***

---

223 Editorial remark - no change of numbering now - could be done at legal-linguistic finalisation.

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

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

226 Editorial remark - no change of numbering now - could be done at legal-linguistic finalisation.

227 **IE Pcy: ES, PL, SE, UK** delete the rule as these products are considered to be medicinal products. **DK, DE, FR, AT, PT** support **Cion** text.

228 Following Coreper discussions **BE, BG, CZ, DE, EL, NL, AT, FI** are noted to strongly request rule 21 as presented in **DS 1170/15 IT. FR, PT, UK** are noted to disagree. Delegations that strongly disagreeing with Rule 21 as presented in **DS 1170/15 IT** are invited to engage in seeking alternative compromise.

- ***in class IIb in all other cases [if they, or their products of metabolism, are locally dispersed but not absorbed by the human body,] except if they are administered on skin or mucous membrane via a body orifice, in which case they are in class IIa.***[229]

6.10 ~~New~~ Rule 22[230] ***~~X 20~~***[231] [232]

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

6.11 Rule 23[233] ***~~21~~***[234] [235]

Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determinates the patient management by the device are in class III, such as closed loop systems or automated external defibrillators.

---

229 Text from compromise suggestion in **DS 1518/14 PT, UK**.

230 Editorial remark - consequence of keeping numbering for other rules.

231 **DE** New rule capturing devices which may impact on the efficacy and safety of drugs administered to treat severe diseases such as asthma/COPD. (Ref DS 1343/13). **DE, AT, UK, Cion** agree on adding a new rule; **AT, Cion** not only for pulmonary route.

232 **IE Pcy** General agreement for its inclusion amongst experts, however, an impact assessment may be required to realise what products would be affected by the inclusion of this rule.

233 Editorial remark - consequence of keeping numbering for other rules.

234 **IE Pcy** A number of experts agreed in principle with the introduction of a new rule to capture AED given their criticality, public use and incidents of recalls. However, several experts suggested that the issues with these devices are primarily user related and not device related and therefore would not support the increase in classification which this rule would result in. **DE** revised the text for this new rule after the Expert Meeting *'Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determinates the patient management by the device are in class III, such as closed loop systems or automated external defibrillators'*. **DK, DE, FR, AT, UK, Cion** agree on adding a new rule to capture AED.

235 **Pcy** considers that the increase in classification would not correctly address the safety of automatic external defibrillators

ANNEX VIII[236]

CONFORMITY ASSESSMENT BASED ON ~~FULL~~ QUALITY ~~ASSURANCE~~ *MANAGEMENT SYSTEM* AND DESIGN EXAMINATION

Chapter I: ~~Full~~ Quality *Management* ~~Assurance~~ System

1. The manufacturer shall ***establish, document, implement a*** ~~ensure application of the~~ quality management system ***as described in Article 8(5) of this Regulation and maintain its effectiveness through the life cycle***[237] ~~approved for the design, manufacture and final inspection~~ of the ~~products~~ ***devices*** concerned~~.~~***. The manufacturer shall ensure the application of the quality management system*** as specified in Section 3 and is subject to audit as laid down in Sections 3.3 and 3.4 and to the surveillance as specified in Section 4.

~~2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 17 and Annex III for the device model covered by the conformity assessment procedure. By issuing a declaration of conformity the manufacturer ensures and declares that the devices concerned meet the provisions of this Regulation which apply to them.~~[238]

---

[236] The text of this annex is based on that in DS 2086/13 with addition of changes and footnotes prepared by **IT Pcy**.

[237] Article 8.5 should be amended with regard continuous life cycle processes as e.g. risk management, clinical evaluation, post market surveillance.

[238] Such general provision should be part of Article 8, as manufacturer is allowed to draw up declaration of conformity only after the conformity is assessed and approved. A draft of an EU declaration should be send to the NB according to clause 3.1 of this Annex.

3. Quality management system *assessment*

3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:

- the name and address ***of the registered place of business*** of the manufacturer and any additional manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative[239], his name and ***the*** address ***of his registered place of business*** as well,[240]
- all the relevant information on the device or [~~device category~~/***group of devices***][241] covered by the ***quality management system*** ~~procedure~~,
- a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system ~~that has been refused by another notified body~~,
- ***a draft of an EU declaration of conformity in accordance with Article 17 and Annex III for the device model[242] covered by the conformity assessment procedure*,**
- the documentation on the quality management system[243],
- a ***documented*** description ~~***documented***~~ [244]of the procedures in place to fulfil the obligations imposed by the quality management system ~~approved~~ ***and required by this Regulation*** and the undertaking by the manufacturer to apply these procedures,
- a description of the procedures in place to keep the ~~approved~~[245] quality management system adequate and efficacious and the undertaking by the manufacturer to apply these procedures,

---

239 **DE** has doubts if an authorised representative can lodge an application in the light of Article 9.5 and 8.5 and suggests deleting this part of sentence.

240 **PT, IE** reference to subsidiaries should be included.

241 A definition of "*device category*" is required.
DE device category would be too broad and not sufficient because for e.g. the assessment of technical documentations on a sampling basis the notified body needs a complete list of devices and their classes.

242 A definition of "*device model*" is required.

243 The meaning of quality management system must be clarified, i.e. what elements it should include and what to cover. These questions should be discussed an decided in the CWP.

244 **Cion** a description of procedures, not documented procedures should be submitted**.**

245 **PT** not sure about this deletion.

- the documentation on the post-market surveillance plan, including, when applicable, a plan for the post-market clinical follow-up, and the procedures put in place to ensure compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66,
- a description of the procedures in place to keep up to date the post-market surveillance plan, including, when applicable, a plan for the post-market clinical follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66 as well as the undertaking by the manufacturer to apply these procedures.

3.2. ***Implementation*** ~~Application~~ of the quality management system shall ensure ~~that~~ the ***compliance*** ~~devices conform to~~ ***with*** the provisions of this Regulation ~~which apply to them at every stage, from design to final inspection~~. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of ***[a quality manual and[246]]*** written policies and procedures such as quality programmes, quality plans, ~~quality manuals~~ and quality records.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) the manufacturer's quality objectives;

(b) the organisation of the business and in particular:
- the organisational structures ***with clear assignment to [critical[247]] procedures***, the responsibilities of the managerial staff and their organisational authority ~~where quality of design and manufacture of the products is concerned~~,
- the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and of ~~product~~ ***device***, including control of ~~products~~ ***devices*** which fail to conform,

---

246 **DE** current state of the art is that the QMS is documented in a quality manual.

247 **Cion** concerned that only critical procedures are addressed.

- where the design, manufacture and/or final ~~inspection~~ ***verification*** and testing of the ~~products~~ ***devices***, or elements ***of any of these*** ~~thereof~~, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,
- where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;[248]

(c) the procedures and techniques for monitoring, verifying, validating and controlling the design ***(including procedures for preclinical and clinical evaluation)*** of the devices ***and***~~, including~~ the corresponding documentation as well as the data and records arising from those procedures and techniques; ***where these procedures and techniques shall specifically address:***

- ***the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence[249], choice of and compliance with conformity assessment procedures,***
- ***identification of applicable general safety and performance requirements and solutions to address these, under consideration of applicable CTS and harmonized standards or equivalent solutions,***
- ***the risk management according to section I.2 of Annex I,***
- ***the clinical evaluation, according to Art. 49 and Annex XIII, including post market clinical follow-up planning,***
- ***the solutions to address the applicable specific requirements regarding design and construction, including appropriate preclinical evaluation, addressing specifically section II of Annex I,***

---

[248] **IE, PT** specific reference to subsidiaries outside EU.

[249] A definition of "*equivalence*" is required.

- ***the solutions to address the applicable specific requirements regarding the information to be supplied with the device, addressing specifically section III of Annex I,***
- ***the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture,***
- ***management of design or quality management system changes***;

(d) the ~~inspection~~ ***verification*** and quality assurance techniques at the manufacturing stage and in particular:

- the processes and procedures which will be used, particularly as regards sterilisation~~, purchasing~~[250] and the relevant documents,
- ~~the product ***device*** identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;~~[251]

(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annex II.

[250] **PT** reinstate "*purchasing*".
[251] Superfluous as already mentioned in paragraph (c).

3.3. Audit

(a) The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 3.2. ***Where the manufacturer uses a harmonised standard or a C~~T~~S[252], it shall assess conformity with those standards or CS.*** Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or C~~T~~S conform to the requirements covered by the standards or C~~T~~S[253].

(b) The ~~assessment~~ ***audit*** team shall include at least one member with past experience of assessments of the technology concerned ***in accordance with section 4.4 of Annex VI[254]. In circumstances where this experience is not immediately obvious or applicable the notified body must provide a documented rationale for the allocation of this auditor[255]***. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to ~~inspect~~ **verify[256]** the manufacturing and other relevant processes.[257]

---

252 The scope of CTS should be clarified. According to Article 7.1, CTS can be adopted for 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.

253 **DE** delete "*Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonized standards or CS conform to the requirements covered by the standards or CS*" as it is the wrong place to formulate presumption of conformity

254 **DE** no added value for the reference to Annex VI.

255 **DE** Disagrees with the added text in bold.

256 **DE** Term "*inspection*" should be limited for national competent authorities.

257 **PT** need reference to audit to subsidiaries; **IE** support.

(c) [258]Moreover, in the case of devices falling into class IIa or IIb the ***quality management system assessment shall be accompanied by the design dossier[259] examination in accordance with the ~~relevant~~ provisions 5.3a to 5.3e[260] of Chapter II of this Annex, [on a representative basis / for selected devices]*** [261] ~~audit procedure shall include an assessment, on a representative basis, of the design documentation within the technical documentation as referred to in Annex II of the device(s) concerned~~. In choosing representative [sample(s**) / devices(s)]** the notified body shall [***follow the guidance developed and published by the MDCG according to Article 80 and in particular[262]]*** take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical, ~~or~~ biological ***or clinical*** properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample(s) taken.

(d) If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU ~~full~~ quality ~~assurance~~ ***management system*** certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the audit and a reasoned ~~assessment~~ ***report***.

---

258 **DE** lack of clarity what consequences are resulting in the case of a negative outcome of the design dossier examination while the overall quality management system assessment shows no deficiencies.

259 The term "*design dossier*" should be specified. It is suggested to amend Annex II accordingly.

260 **DE** add "*5.3a to 5.3e*" to specify the provision.

261 Article 42 should be amended accordingly.

262 **DE** *suggests adding highlighted text to achieve a largely harmonised approach to the choosing representative samples it is important to have detailed rules as soon as possible, therefore and to be in line with Annex VI, section 4.6.2 (a) it is proposed that the MDCG should develop the guidance on sample choosing.*

3.4. The manufacturer shall inform the notified body which approved the quality management system of any plan for substantial[263] changes to the quality management system, ***the devices*** or the ~~product~~ ***device***-range covered. The notified body shall assess the changes proposed***, determine the need for additional audits*** and verify whether after these changes the quality management system still meets the requirements referred to in Section 3.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the ***assessment, and where applicable, conclusions of additional*** audit***s*** ~~and a reasoned~~ ~~assessment~~. The approval of any substantial change to the quality management system or the ~~product~~ ***device***-range covered shall take the form of a supplement to the EU full quality assurance certificate.

4. Surveillance assessment

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.

4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including ~~inspections~~ ***site audits***, and supply it with all relevant information, in particular:

- the documentation on the quality management system,
- the documentation on ***any findings and conclusions resulting from the application of*** the post-market surveillance plan, including ~~a~~ ***the*** post-market clinical follow-up ***plan [for a selection of devices]***[264], ~~as well as, if applicable, any findings resulting from the application of the post-market surveillance plan, including the post-market clinical follow-up,~~ and of the provisions on vigilance set out in Articles 61 to 66,
- the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests, the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I , pre-clinical and clinical evaluation,
- the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

---

263 It is suggested to have guidance document with clarification of "*substantial changes*".

264 DE "*for selection of devices*" is unclear.

4.3. The notified body shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan, ~~*[and shall supply the manufacturer with an assessment report*~~[265]~~*]*~~. This shall include ~~inspections~~ ***audits*** on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such ~~inspections~~ ***on-site audits***, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a~~n inspection *site*~~ ***surveillance***[266] ***audit*** report and, if a test has been carried out, with a test report.

4.4. The notified body shall randomly perform unannounced factory ~~inspections~~ ***site audits*** to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3.[267] or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced ~~inspections~~ ***on-site audits*** which must not be disclosed to the manufacturer.

Within the context of such unannounced ~~inspections~~ ***on-site audits***, the notified body shall ~~check~~ ***test*** an adequate sample from the production or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation ~~and/or design dossier~~. Prior to the unannounced ~~inspection~~ ***on-site audits***, the notified body shall specify the relevant sampling criteria and testing procedure.

---

[265] **DE** There should be only one report concerning the annual surveillance which should include all aspects of the audit and the assessment and where applicable the tests that had been carried out.

[266] **DE** replace "*site*" with "*surveillance*".

[267] **DE** is of the opinion that combination of regularly performed surveillance audits, which are announced, with unannounced audits doesn't make sense.

Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market[268] to verify that the manufactured device is in conformity with the technical documentation ~~and/or design dossier~~. Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer with an ~~inspection~~ ***on-site audit*** report which shall include, if applicable, the result of the sample ~~check~~ ***test***.

4.5. In the case of devices classified as class IIa or class IIb, the surveillance assessment shall also include ***a design dossier examination in accordance with the provisions 5.3a to 5.3e of Chapter II of this Annex*** ~~the assessment of~~ ~~the design documentation within~~[269][270] ~~the technical documentation~~ of the device(s) concerned on the basis of further representative sample(s) chosen in accordance with the rationale documented by the notified body in accordance with point (c) of Section 3.3.

In the case of devices classified as class III[271] [272], the surveillance assessment shall also include a ~~check~~ ***test*** of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, the coherence between the quantities of produced or purchased parts and/or materials and the quantities of finished ~~products~~ ***devices***.

---

[268] **DE** this obligation collides with market surveillance authority tasks. Furthermore NBs are not empowered to take samples from the market but have to buy them. Therefore provisions on how they are reimbursed by the manufacturer should be in place.

[269] **DE** replace "*the assessment of the technical documentation*" with "*a design dossier examination in accordance with the provisions 5.3a to 5.3e of Chapter II of this Annex*" to align with 3.3.(c).

[270] The design documentation within technical documentation is not sufficiently covered in the technical documentation.

[271] These provisions should be applicable for class IIB implantable medical devices too. It should be amended in case if implantable medical devices will not be reclassified to class III.

[272] **DE** Clarification is required as to whether these tests have to be carried out for each class III device covered by the approved quality management system (which could be quite burdensome).

4.6. The notified body shall ensure that the composition of the assessment team assures experience with the ***evaluation of the devices, systems and processes*** ~~technology~~ concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall not lead [and attend[273]] an audit for more than three consecutive years in respect to the same manufacturer.

4.7. If the notified body establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate[274] or impose restrictions on it.

Chapter II: Design dossier[275] examination

5. Examination of the design of the device, applicable to devices classified as class III[276]

5.1. In addition to the obligations imposed by Section 3, the manufacturer shall lodge with the notified body referred to in Section 3.1 an application for examination of the design dossier[277] relating to the device which he plans to ~~manufacture~~ ***place on the market or put into service*** and ~~which falls into the device category~~ ***is*** covered by the quality management system referred to in Section 3.

---

[273] **DE** suggests to leave the option of attending the audit in order to facilitate knowledge of manufacturers internal organisation,

[274] **DE** suggests to apply these measures also in case of design dossier deficiencies carried out according to 4.5.

[275] The term "*design dossier*" is not defined. It is suggested to amend Annex II accordingly.

[276] These provisions should be applicable for class IIB implantable medical devices too. It should be amended in case if implantable medical devices will not be reclassified to class III.

[277] The term "*design dossier*" is not defined. It is suggested to amend Annex II accordingly.

5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II[278]; ~~where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request~~[279].

5.3. The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned ***and its clinical application***. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with ~~***all***~~ the ***relevant***[280] requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

~~The notified body shall provide the manufacturer with an EU design examination report.~~[281]

5.3a. The notified body shall review the clinical evidence presented by the manufacturer and the related clinical evaluation conducted. The notified body shall employ device reviewers with sufficient clinical expertise, including the use of external clinical expertise with direct and current experience of the device in question or the clinical condition in which it is utilised, for the purposes of this review.

---

[278] It should be clarified whether design dossier is a part of technical documentation. If not the term "*design dossier*" should be specified. It is suggested to amend Annex II accordingly.

[279] It is suggested that STED is not sufficient for the assessment of III class medical devices.

[280] **DE** replace "*all*" with "*relevant*".

[281] It was suggested to move this provision to Section 5.4.

5.3b. The notified shall, in circumstances when the clinical evidence is based on data, in total or in part, from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of this route, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalency, the relevance and adequacy of the data to demonstrate conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess that specific claims are supported by specific preclinical and clinical data in the risk analysis.

5.3c. The notified body shall ensure the adequacy of the clinical evidence and the clinical evaluation and verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. This review should include consideration of the adequacy of the benefit-risk assessment and management, instructions for use, user training, manufacturer's post-market surveillance plan, and include the need for, and adequacy of the post-market clinical follow up proposed, where applicable.

5.3d. Based on its assessment of the clinical evidence, the clinical evaluation, and the benefit-risk assessment the notified body shall consider if specific milestones are required to be defined to allow for review by the notified body on updates to the clinical evidence based on post market surveillance and post-market clinical follow up data.

5.3e. The notified body shall clearly document the outcome of its assessment in the clinical evaluation assessment report ~~as defined in Annex XIII~~[282].

[282] **DE** not defined in Annex XIII.

5.4. The notified body shall provide the manufacturer with an EU design-examination report, ***including a clinical evaluation assessment report***[283]***.***

If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU design-examination certificate. The certificate shall [contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the device ***/ be drawn up in accordance with Annex XII***][284].

5.5. Changes to the approved design shall receive further approval from the notified body which issued the EU design-examination certificate wherever the changes could affect ~~conformity with~~ the ~~general~~ safety and performance ~~requirements~~ of the ***device*** ~~Regulation~~ or ~~with~~ the conditions prescribed for use of the device. ~~The~~ ***Where the*** applicant ***plans to introduce any of the above mentioned changes he*** shall inform the notified body which issued the EU design-examination certificate ***thereof*** ~~of any planned changes to the approved design~~. The notified body shall examine the planned changes ***and decide whether the planned changes require a new conformity assessment in accordance with Article 42***[285] ***or whether they could be addressed by means of a supplement to the EU design-examination certificate. In the latter case, the notified body shall assess the changes***, notify the manufacturer of its decision and***, where the changes are approved,*** provide him with a supplement to the EU design-examination ***certificate*** ~~report~~. ~~The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate~~.

---

283 CWP should decide whether notified body should provide these reports to the manufacturer.

284 **DE** replace "*contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the device"* with "*be drawn up in accordance with Annex XII*".

285 Article 42 should be amended accordingly.

6. Specific procedures

6.0.[286] ***Procedure in the case of implantable devices classified as class III :***

(a) For implantable devices classified as class III, the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in article 49.5, prepare a clinical evaluation assessment report which concludes on the clinical evidence provided by the manufacturer, in particular concerning the benefit/risk ~~ratio~~ determination, the consistency with the intended purpose and the PMCF plan referred to in article 8.6 and part B of annex XIII.

The notified body shall transmit its clinical evaluation assessment report, along with the clinical evaluation documentation of the manufacturer referred to in points 6.1(c) and (d) of Annex II, to the Commission, at least 30 days prior to the examination of the matter by the relevant expert panel. The Commission shall immediately transmit these documents to the relevant expert panel referred to in article 81a.

(b) The notified body may be request to present its conclusion to the expert panel concerned.

(c) The expert panel shall provide, within a period of 30 days, a scientific opinion on the clinical evidence provided by the manufacturer, in particular concerning the benefit/risk determination, the consistency with the medical indication(s) and the PMCF plan.

[286] Text from **DS 1512/14 FR**.

(d) The notified body shall give due consideration to the views expressed in the scientific opinion of the expert panel. In particular, the notified body may, if necessary, require the manufacturer to restrict the use of the device to certain numbers or groups of patients, to limit the duration of validity of the certificate, to undertake specific PMCF studies, to adapt the instructions for use, or the summary of safety and clinical performance, or impose other restrictions.

In case the expert panel has found that the level of clinical evidence is not sufficient or otherwise gives rise to serious concerns about the benefit/risk determination, the consistency with the intended purpose and the PMCF plan, the notified body shall explicitly address these concerns before issuing the certificate and document it in its conformity assessment report.

6.1. Procedure in the case of devices incorporating a medicinal substance

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, with action ancillary to that of the device, the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

(b) Before issuing an EU design-examination certificate, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA'), acting particularly through its Committee on Human Medicinal Products in accordance with Regulation (EC) No 726/2004, on the quality and safety of the substance including the benefit/risk of the incorporation of the substance into the device. Where the device incorporates a human blood or plasma derivative or a substance that, if used separately may be considered to be a medicinal product falling exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA.

(c) When issuing its opinion, the medicinal products competent authority or the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

(d) The ~~opinion of the~~ medicinal products competent authority or the EMA shall ~~be drawn up~~ ***provide to the notified body its opinion***

- ~~within 150 days after receipt of valid documentation if the substance subject to the consultation is authorised in accordance with Directive 2001/83/EC; or~~
- within 210 days after receipt of valid documentation ~~in other cases~~.

(e) The scientific opinion of the medicinal products competent authority or the EMA, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.

(f) Before ***any*** change~~s~~ ***is*** ~~are~~ made with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the manufacturer shall inform the notified body of the changes which shall consult the ~~medicinal products competent~~ authority that was involved in the initial consultation, in order to confirm that the quality and safety of the ancillary substance are maintained. The ~~medicinal products competent~~ authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk of the addition of the substance in the device. It shall provide its opinion within ***60*** ~~30~~ days after receipt of the valid documentation regarding the changes. ***The notified body shall not deliver the supplement to the EU design examination certificate if the scientific opinion is unfavourable. It shall convey its final decision to the authority concerned.***

(g) When the ~~medicinal products competent~~ authority that was involved in the initial consultation has obtained information on the ancillary substance, which could have an impact on the established benefit/risk of the addition of the substance in the device, it shall provide the notified body with advice whether this information has an impact on the established benefit/risk of the addition of the substance in the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

6.2. Procedure in the case of devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable

(a) For devices manufactured utilising tissues or cells of human origin, or their derivatives, that are covered by this Regulation in accordance with point (e) of Article 1(2), the notified body shall, prior to issuing an EU design-examination certificate, ***seek a scientific opinion from one of*** ~~submit to~~ the competent authorit~~y~~***ies*** designated by the Member State***s*** in accordance with Directive 2004/23/EC (hereinafter referred to as 'human tissues and cells competent authority') ~~in which it is established~~ ***on the aspects related to the donation, procurement and testing and/or the benefit/risk of the incorporation of the human tissues or cells into the device. The notified body shall submit*** a summary of the preliminary conformity assessment which shall, among others, provide information about the non-viability of the human tissues or cells, their donation, procurement and testing and the benefit/risk of the incorporation of the human tissues or cells into the device.

(b) Within ~~90~~ ***120*** days after receipt of valid documentation, the human tissues and cells competent authority ~~may~~ ***shall*** ~~submit~~ ***provide to the notified body*** ~~comments~~ ***its opinion*** ~~on aspects related to the donation, procurement and testing and/or the benefit/risk of the incorporation of the human tissues or cells into the device~~.

(c) ***The scientific opinion of the human tissues and cells competent authority, and any possible update, shall be included in the documentation of the notified body concerning the device.*** The notified body shall give due consideration to ***the views expressed in the scientific opinion when making its decision*** ~~any comments received in accordance with point (b)~~. ***The notified body shall not deliver the certificate if the scientific opinion is unfavourable.*** It shall convey ***its final decision to the medicinal products competent authority concerned.*** ~~to the human tissues and cells competent authority an explanation as regards this consideration, including any due justification not to follow the comment received, and its final decision regarding the conformity assessment in question. The comments of the human tissues and cells competent authority shall be included in the documentation of the notified body concerning the device~~.

(d) Before any change is made with respect to an non-viable human tissue or cell incorporated in a device, in particular related to its donation, procurement, the manufacturer shall inform the notified body of the changes which shall consult the authority that was involved in the initial consultation, in order to confirm that the quality and safety of the ancillary substance are maintained. The authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk of the addition of the substance in the device. It shall provide its opinion within 60 days after receipt of the valid documentation regarding the changes. The notified body shall not deliver a supplement to the EU design examination certificate if the scientific opinion is unfavourable. It shall convey its final decision to authority concerned.

(e) In the case of devices manufactured utilising tissue which is rendered non-viable or non-viable products derived from animal tissue, 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, the notified body shall apply particular requirements laid down in that Regulation.[287]

[287] This section also concerns devices manufactured utilising tissues or cells of animal origin.

6.3. Procedure in the case of devices that are composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body[288]

(a) For devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, [injected for local effect] or applied-on skin or mucous membrane and that are absorbed by or locally dispersed in the human body, the quality and safety of the device shall be verified where applicable and limited to the requirements not covered by this Regulation, in accordance with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions.

(b) For devices in class IIb, the notified body shall assess the clinical evaluation report for every device covered by the EU design-examination certificate before issuing a certificate.

(c)[289] ***In addition, for devices, or their products of metabolism, that are*** [290] ***absorbed by the human body in order to achieve their intended purpose***[291]***, the notified body shall seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA'), acting particularly through its Committee on Human Medicinal Products in accordance with Regulation (EC) No 726/2004, on the compliance of the device with the relevant requirements laid down in Annex I to Directive 2001/83/EC.***

---

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

289 **DK, IT** is noted to have reservations on this additional procedure. The **Pcy** strongly advises not to reopen this debate at this stage.

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

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

(d) The opinion of the medicinal products competent authority or the EMA shall be drawn up within 150 days.

(e) The scientific opinion of the medicinal products competent authority or the EMA, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.

7. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)

Upon completing the manufacture of each batch of devices that incorporate a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(4), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

Chapter III: Administrative provisions

1. The manufacturer or ~~***and***~~ ***where the manufacturer does not have a registered place of business in a Member State*** his authorised representative[292] shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:
   - the declaration of conformity,
   - the documentation referred to in the ~~fourth~~ ***fifth*** indent of Section 3.1 and in particular the data and records arising from the procedures referred to in point (c) of Section 3.2,
   - the changes referred to in Section 3.4,
   - the documentation referred to in Section 5.2, and
   - the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4. 5.3, 5.4. and 5.5.

2. Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the manufacturer, or his authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of this period.[293]

---

[292] It should be in line with the obligations of the authorised representative set out in Chapter II. It is suggested to add a reference to this Annex in Article 9.

[293] CWP should consider whether it is the right place for such provisions.

ANNEX IX[294]

CONFORMITY ASSESSEMENT BASED ON TYPE EXAMINATION

1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a ***device ~~type~~***[295]***, including its technical documentation and relevant life cycle processes and a corresponding*** representative sample of the production covered fulfil the relevant provisions of this Regulation.

2. Application

The application shall include:

– the name and address of the manufacturer and, if the application is lodged by the authorised representative[296], the name and address of the authorized representative,

– the technical documentation referred to in Annex II ~~needed ***suitable*** to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Regulation;~~[297] ~~where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.~~[298] The applicant shall make a ***representative sample of the production in question, hereinafter referred to as*** 'type' available to the notified body. The notified body may request other samples as necessary,

– a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that has been refused by another notified body ***or that has been withdrawn by the manufacturer before the other Notified Body made its final assessment.***

---

294 The text of this annex is taken from document 15296/14.

295 **Pcy** deleted here because of description added in the 2nd paragraph.

296 Might need adjustment in accordance with decisions in Article 8

297 To align with Annex VIII chapter II.

298 **DS 1784/13, 1103/14 AT** This Annex will be used for Class IIb and III devices; a full technical documentation seems more suitable in that respect.

3. Assessment[299]

The notified body shall:

3.1. ***examine the application employing staff with proven knowledge and experience regarding the technology concerned and its clinical application. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the relevant requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.***

3.1a. examine and assess the technical documentation ***for conformity with the requirements of this regulation applicable to the device, including assessment of relevant life cycle processes, as e.g. risk management, clinical evaluation and PMS***[300] and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CTS , as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

3.1b. shall review the clinical evidence presented by the manufacturer and the related clinical evaluation conducted. The notified body shall employ device reviewers with sufficient clinical expertise, including the use of external clinical expertise with direct and current experience of the device in question or the clinical condition in which it is utilised, for the purposes of this review ~~have the application reviewed by a clinical expert to verify the adequacy of the clinical evaluation;~~[301]

---

299 3.1.; 3.1b; 3.1c are added to align with Annex VIII Chapter II.

300 **DS 1784/13, 1103/14 AT** This Annex is correlated to the design phase and cannot be restricted to technical tests alone; preclinical and clinical evaluation and PMS-planning have also to be considered when assessing a type and its technical documentation towards the requirements of this regulation.

301 **DS 1769/13 UK**.

3.1c. in circumstances when the clinical evidence is based on data, in total or in part, from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of this route, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalency, the relevance and adequacy of the data to demonstrate conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess that specific claims are supported by specific preclinical and clinical data in the risk analysis.

3.1d. clearly document the outcome of its assessment in the clinical evaluation assessment report

3.2. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation if the standards referred to in Article 6 or CTS have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device(s) having the characteristics specified by the manufacturer;

3.3. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

3.4. agree with the applicant on the place where the necessary assessments and tests will be carried out***; and***

3.5. draw up an EU type-examination report on the results of the assessments and tests carried out under paragraphs 3.1 to 3.3, ~~including a clinical evaluation assessment report~~[302].

4. Certificate

If the type conforms to the provisions of this Regulation, the notified body shall issue an EU type-examination certificate. [The certificate shall contain the name and address of the manufacturer, the conclusions of the assessment, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body **/** ***The certificate shall be drawn up in accordance with Annex XII***].

5. Changes to the type

5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type ***or of its intended ~~use~~ purpose***[303].

---

[302] **DS 1784/13, 1103/14 AT** A supplement to the EU type-examination report suddenly appears in 5.2, without having been mentioned as such earlier. In order to make the assessment of the clinical evaluation transparent a clinical evaluation assessment report (CEAR) shall be issued by the NB and allow DAs and Joint Assessment Teams to have a focused look on the NBs assessment of clinical evaluation.
Pcy report reflected in the new 3.1d.

[303] **DS 1784/13, 1103/14 AT**.

5.2. Changes to the approved product [***or of its intended use / including limitations of its intended purpose and use]*** [304] shall receive further approval from the notified body which issued the EU type-examination certificate wherever the changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.

[5.3. Changes to the intended purpose and use of the approved device, with the exception of limitations of the intended purpose and use, require a new application for a conformity assessment.]

[304] **DS 1784/13, 1103/14 AT**.
DE only for limitations of the intended purpose (e.g. limitation on indications) a supplement to the certificates is considered acceptable. A change of the intended purpose and use is a substantial modification which requires a new full assessment at least of the clinical evaluation etc., Therefore replace "*or of its intended use" with including limitations of its intended purpose and use*

6. Specific procedures

The provisions regarding the specific procedures in the case of ***implantable*** **devices** ***classified as class III, or*** [305] devices incorporating a medicinal substance, or devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable***, or devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, [injected for local effect]or administered on skin or mucous membrane and that are absorbed by or locally dispersed in the human body***[306] set out in Annex VIII, Section 6, apply with the provision that any reference to an EU design-examination certificate shall be understood as reference to an EU type-examination certificate.

---

[305] **DS 1512/14 FR** proposal**.**

[306] ~~**DS 1518/14** based on work by **PT, UK**:~~
~~"The provisions regarding the specific procedures in the case of devices incorporating a medicinal substance, or devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable~~**, or devices that are composed of substances or combinations of substances** ~~*that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane*~~ **presented as one of the pharmaceutical dosage forms of the European Pharmacopoeia and that are absorbed by or** ~~*locally*~~ **dispersed in the human body set out** ~~in Annex VIII, Section 6, apply with the proviso that any reference to an EU design-examination certificate shall be understood as reference to an EU type-examination certificate.".~~

7. **Administrative provisions**

The manufacturer or his authorised representative ***where the manufacturer does not have a registered place of business in a Member State*** shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the documentation referred to in the second indent of Section 2,
- the changes referred to in Section 5,
- copies of EU type-examination certificates ***and reports*** and their additions***/supplements***[307].

Section 9 of Annex VIII shall apply.

---

[307] **DS 1784/13, 1103/14 AT** Refers to 3.5 and 5.2.

ANNEX X[308]

CONFORMITY ASSESSEMENT BASED ON PRODUCT CONFORMITY VERIFICATION

1. The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an EU type-examination certificate has been issued and meet the provisions of this Regulation which apply to them, ***including continuous life cycle processes as e.g. risk management, clinical evaluation and PMS.*** [309].

2. Where an EU type-examination certificate has been issued in accordance with Annex IX, the manufacturer can either apply the procedure set out in part A (production quality assurance) or the procedure set out in part B (product verification).

3. By way of derogation from Sections 1 and 2, this Annex can also be applied by manufacturers of devices classified as class IIa coupled with the drawing up of a technical documentation as set out in Annex II.

PART A: PRODUCTION QUALITY ASSURANCE

1. The manufacturer shall ensure application of the quality management system approved for the manufacture of the devices concerned and carry out the final inspection, as specified in Section 3, and is subject to the surveillance referred to in Section 4.

---

308 The text of this annex is taken from document 15296/14.

309 **DS 1784/13, DS 1103/14 AT** add "*including continuous life cycle processes as e.g. risk management, clinical evaluation and PMS*". This module cannot be restricted to technical and test issues, but must also address continuous compliance with life cycle processes, like those mentioned here. Otherwise those would not be continuously covered by conformity assessment. **PT, IE** support

2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 17 and Annex III for the device model covered by the conformity assessment procedure. By issuing an EU declaration of conformity the manufacturer ensures and declares that the devices concerned conform to the type described in the EU type-examination certificate and meet the provisions of this Regulation which apply to them.

3. Quality management system

3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:

- all elements listed in Section 3.1 of Annex VIII [310],
- the technical documentation as referred to in Annex II for the types approved; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request;
- a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation ***and its updates*** and the certificates issued is ~~sufficient~~ ***necessary***.

[310] **DE** suggests replacing reference with the text from mentioned paragraph.

3.2. ***Implementation*** ~~Application~~ of the quality management system shall ensure ~~that~~ the ***compliance*** ~~devices conform to~~ ***with*** the type described in the EU type-examination certificate and to the provisions of this Regulation which apply to them at every stage[311]. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of ***[a quality manual and***[312]***]*** written policies and[313] such as quality programmes, quality plans, ~~quality manuals~~ and quality records.

It shall, in particular, include an adequate description of all elements listed in points (a), (b)[314], (d) and (e) of Section 3.2 of Annex VIII.

3.3. The provisions of points (a) and (b) of Section 3.3 of Annex VIII apply.

If the quality management system ensures that the devices conform to the type described in the EU type-examination certificate and conforms to the relevant provisions of this Regulation[315]**,** the notified body shall issue an EU quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the inspection and a reasoned assessment.

3.4. The provisions of Section 3.4 Annex VIII apply.

---

311 **DS 1784/13, 1103/14 AT** add "*including the continuous life cycle processes*". **IE, PT** support.
312 **DE** current state of the art is that the QMS is documented in a quality manual.
313 **DS 1784/13, 1103/14 AT** add "*Standard Operating Procedures (SOPs)*"
314 **DS 1784/13, 1103/14 AT** See changes suggested for Annex VIII.
315 **DS 1784/13, 1103/14 AT** add "*including the continuous life cycle processes*". **IE, PT** support

4. Surveillance

The provisions of Section 4.1, the first, second and fourth indents of Section 4.2, Section 4.3, Section 4.4, Section 4.6 and Section 4.7 of Annex VIII apply[316].

In the case of devices classified as class III, the surveillance shall also include a check of the coherence between the quantity of produced or purchased raw material or crucial components approved for the type and the quantity of finished products.

5. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)

Upon completing the manufacture of each batch of devices that incorporate a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(4), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

[316] **DE** suggests replacing references with the text from mentioned paragraphs.

6. Administrative provisions

The manufacturer or ***where the manufacturer does not have a registered place of business in a Member State*** his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the documentation referred to in the fourth indent of Section 3.1 of Annex VIII,
- the documentation referred to in the seventh indent of Section 3.1 of Annex VIII, including the EU type-examination certificate referred to in Annex IX,
- the changes referred to in Section 3.4 of Annex VIII, and
- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3 and 4.4 of Annex VIII.

Section 9 of Annex VIII shall apply.

7. Application to devices classified as class IIa[317]

7.1. By way of derogation from Section 2, by virtue of the EU declaration of conformity the manufacturer ensures and declares that the devices in class IIa are manufactured in conformity with the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them.

7.2. For devices in class IIa the notified body shall assess, as part of the assessment in Section 3.3, [on a representative basis][318], the technical documentation as referred in Annex II ***for the selected devices*** for compliance with the provisions of this Regulation; [where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.][319]

---

317 Depending on the decisions in Article 42, class IIb might also need to be addressed here.

318 Will be deleted if MS opt for "*selected devices*".

319 **DE** delete: "*where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request*"

In choosing representative sample(s) ***of devices*** the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (*e.g.* with regard to physical, chemical**,** ~~or~~ biological ***or clinical*** properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample(s) ***of devices*** taken[320].

7.3. If the assessment in accordance with Section 7.2. confirms that the devices in class IIa conform to the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this section of this Annex.

7.4. Further samples ***of devices/device types***[321] shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.

7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the technical documentation referred to in Annex II,
- the certificate referred to in Section 7.3.

Section 9 of Annex VIII shall apply.

---

320 **DS 1784/13, 1103/14 AT** Samples would relate to devices/device types, not to parts/chapters of the technical documentation!

321 **DS 1784/13, 1103/14 AT** The granularity of device sampling is not made clear!

PART B: PRODUCT VERIFICATION

1. Product verification is the procedure whereby after examination of every manufactured device the manufacturer, by issuing a EU declaration of conformity in accordance with Article 17 and Annex III, ensures and declares that the devices which have been subject to the procedure set out in Sections 4 and 5 conform to the type described in the EU type-examination certificate and meet the requirements of this Regulation which apply to them***, including continuous life cycle processes*** [322].

2. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which conform to the type described in the EU type-examination certificate and to the requirements of the Regulation which apply to them. Before the start of manufacture, the manufacturer shall prepare documents defining the manufacturing process, in particular as regards sterilisation where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

   In addition, for devices placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 3 and 4 of Part A of this Annex.

3. The manufacturer shall undertake to institute and keep up to date a post-market surveillance plan, including a post-market clinical follow-up, and the procedures ensuring compliance with the obligations ***of the manufacturer*** emanating from the provisions on vigilance ***and post-market surveillance*** set out in ~~Articles 61 to 66~~ ***Chapter VII***.[323]

---

[322] **DS 1784/13, DS 1103/14 AT** add "*including continuous life cycle processes*". This module cannot be restricted to technical and test issues, but must also address continuous compliance with life cycle processes, like those mentioned here. Otherwise those would not be continuously covered by conformity assessment. **IE, PT** support.

[323] **DS 1103/14 AT**.

4. The notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the device[324], with the requirements of the Regulation by examining and testing every product as specified in Section 5.[325]

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

5. Verification by examination and testing of every product

5.1. Every device is examined individually and the appropriate physical or laboratory tests defined in the relevant standard(s) referred to in Article 6 or equivalent tests ***and assessments*** shall be carried out in order to verify, where appropriate, the conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.[326]

5.2. The notified body shall affix, or have affixed its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests ***and assessments***[327] carried out.

---

[324] **DS 1784/13, DS 1103/14 AT** add "*and of relevant life cycle processes, as e.g. risk management, clinical evaluation and PMS*".

[325] **DS 1103/14 AT** add "*and by assessing the life cycle process results and conclusions*".

[326] **DS 1784/13, DS 1103/14 AT** add "*including assessment of relevant life cycle processes as e.g. risk management, clinical evaluation and PMS*".

[327] **DS 1784/13, DS 1103/14 AT**.

6. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)

Upon completing the manufacture of each batch of devices that incorporate a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(4), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

7. Administrative provisions

The manufacturer or his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the documentation referred to in Section 2,
- the certificate referred to in Section 5.2,
- the EU type-examination certificate referred to in Annex IX.

Section 9 of Annex VIII shall apply.

8. Application to devices classified as class IIa

8.1. By way of derogation from Section 1, by virtue of the EU declaration of conformity the manufacturer ensures and declares that the devices in class IIa are manufactured in conformity with the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them.

8.2. The verification conducted by the notified body in accordance with Section 4 is intended to confirm the conformity of the devices in class IIa with the technical documentation referred to in Annex II and with the requirements of this Regulation which apply to them.

8.3. If the verification in accordance with Section 8.2. confirms that the devices in class IIa conform to the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them**,** the notified body shall issue a certificate pursuant to this section of this Annex.

8.4. By way of derogation from Section 7, the manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the technical documentation referred to in Annex II,
- the certificate referred to in Section 8.3.

Section 9 of Annex VIII shall apply.

ANNEX XI

[~~CONFORMITY ASSESSMENT~~] PROCEDURE FOR CUSTOM-MADE DEVICES [328] [329]

1. For custom-made devices***, other than implantable class III devices,*** the manufacturer or his authorised representative shall draw up the statement containing the following information:
   - the name and address of the manufacturer, and of any additional manufacturing sites,
   - if applicable, the name and address of the authorised representative,
   - data allowing identification of the device in question,
   - a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code,
   - the name of the ~~***medical*** doctor of medicine, dental practitioner or any other~~ person authorised by national law by virtue of this person's professional qualifications who made out the prescription and, where applicable, the name of the health institution concerned,
   - the specific characteristics of the product as indicated by the prescription,
   - a statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds,
   - where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Commission Regulation (EU) No 722/2012.

---

[328] **DE, LT, PT** the title of the Annex does not conform to its content.

[329] **FR** suggests using FR proposal regarding specific procedures for these devices;
DK certificates regarding QMS should be issued, requirement for NB should be elaborated;
NL suggests implementing regulation.

2. The manufacturer shall undertake to keep available for the competent national authorities the documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Regulation.

   The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph;

3. The information contained in the ~~declaration~~ ***statement***[330] concerned by this Annex shall be kept for a period of time of at least five years after the device has been placed on the market. In the case of implantable devices the period shall be at least 15 years.

   Section 9 of Annex VIII shall apply.

4. The manufacturer shall undertake to review and document experience gained in the post-production phase, including a PMCF referred to in Part B of Annex XIII, and to implement appropriate means to apply any necessary corrective action. This undertaking shall include an obligation for the manufacturer to notify, in accordance with Article 61(4) the competent authorities of any serious incidents and/or field safety corrective actions immediately on learning of them.

---

[330] **LT** replace "*declaration*" with "*statement*".