

3. *The national authority responsible for notified bodies shall assess whether the assessment by the notified body was conducted appropriately and verify the procedures used, associated documentation and conclusions drawn by the notified body. This shall include the manufacturer's technical and clinical documentation upon which the notified body has based its assessment. These assessments shall be conducted utilising common technical specifications provided for in Article 7 and ~~clinical evaluation guidancee provided for in paragraph 6 (e) of Article 81a~~ in the conduct of the assessment.*
5. *These assessments shall also form part of the re-assessment of notified bodies in accordance with Article 35(4) and the joint assessment activities referred to in Article 37(2a). These assessments shall be conducted utilising appropriate expertise.*
6. *The MDCG may, based on the reports of these assessments by the national authority or joint assessment teams, and inputs from the market surveillance and post-market surveillance activities described in Chapter VII, recommend that the sampling, either by national authority or as part of a joint assessment activity, shall assess a greater or lesser proportion of the clinical evaluations and technical documentation assessed by a notified body.*
7. *The Commission may, by means of implementing acts, adopt measures setting out the modalities, associated documents for and coordination of the technical and clinical assessments referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*

Article 36

Changes to designations and notifications

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the ~~notification~~ **designation by the national authority responsible for notified bodies**. The procedures described in Article 32(2) to (6) and in Article 33 shall apply to changes where they entail an extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 33(10).

1a. Where a notified body decides to cease its conformity assessment activities it shall inform the national authority responsible for notified bodies and the manufacturers concerned as soon as possible and in case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of activities on condition that another notified body has confirmed in writing that it will assume responsibilities for these products. The new notified body shall complete a full assessment of the devices affected by the end of that time period before issuing new certificates for those devices.

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations **or has not implemented the necessary corrective measures**, the authority shall suspend, restrict, or fully or partially withdraw the **designation notification**, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are ~~either processed by another notified body or~~ kept available for the national authorities responsible for notified bodies and ***national authorities responsible*** for market surveillance at their request.
4. The national authority responsible for notified bodies shall:
- ~~assess whether the reasons which gave rise to the change to the notification have an~~ ***the*** impact on the certificates issued by the notified body ***where there is a change to the notification;*** and,
 - ***submit a report on its findings to the Commission and the other Member States*** within three months after having notified the changes to the notification; ~~shall submit a report on its findings to the Commission and the other Member States.~~
 - ***require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued*** ~~Where necessary to ensure the safety of devices on the market; that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.~~
 - ***enter into the electronic system mentioned in Article 45 paragraph 4 all certificates for which it has required suspension or withdrawal;***
 - ***inform the competent authority for medical devices of the Member State where the manufacturer or his authorised representative has his registered place of business through the electronic system referred to in Article 27 of the certificates for which it has required suspension or withdrawal. The competent authority responsible for the manufacturer of the device or his authorised representative shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.***

5. ~~The~~ ***With the exception of*** certificates, ~~other than those unduly issued, which were issued by the notified body for which the notification~~ ***and where a designation*** has been suspended, or restricted, or withdrawn ***the certificates*** shall remain valid in the following circumstances:
- (a) ~~in the case of suspension of a notification: on condition that,~~ ***the national authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue for certificates affected by the suspension or restriction;***
- and***
- the national authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction;***
- or*
- (b) ***the national authority responsible for notified bodies has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension/restriction and indicates whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In case the national authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide to the competent authority for devices within three months of the suspension or restriction, either the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or another notified body confirm in writing the written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension; or restriction.***

5a. With the exception of certificates unduly issued, and where a notification has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:

- ~~(b) - in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The~~ **Where the** competent authority for medical devices of the Member State in which the manufacturer **or the authorised representative** of the device covered by the certificate is established **has confirmed that there is no safety issue associated with the devices in question, and**
- **another notified body has confirmed in writing that it will assume immediate responsibilities for these products and will have completed assessment of the devices within twelve months, then**

then the national competent authority of the member state where the manufacturer or authorised representative is established may extend the provisional validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

~~The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.~~

Article 37

Challenge to the competence of notified bodies

1. The Commission, **in conjunction with the MDCG**, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, **or of one or more of its subsidiaries or subcontractors**, of the requirements set out in Annex VI or the obligations to which it is subject. **It shall ensure that the concerned national authority responsible for notified bodies is informed and is given opportunity to investigate these concerns** ~~It may also commence such investigations on its own initiative.~~
2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.

- 2a. The Commission in conjunction with the MDCG may initiate, as applicable, the assessment process described in Article 32(3) and (4) when there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VI and when the investigation of the national authority is not deemed to have fully addressed the concerns or upon request of the national authority. The reporting and outcome of this assessment process shall follow the principles of Article 32. Alternatively, depending on the severity of the issue, the Commission in conjunction with the MDCG may request that the national authority responsible for notified bodies allow for participation of up to two experts from the list established pursuant to Article 32a in an on-site assessment as part of the planned monitoring and surveillance activities in accordance with Article 35 and as outlined in the annual plan described in paragraph 3 therein.**
3. Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the ~~notification~~ **designation** if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.

- 3a. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.**

Article 38

Exchange Peer review and exchange of experience between national authorities responsible for notified bodies

1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation. ***This shall address elements including:***
 - (a) ***Development of best practice documents relating to the activities of the national authorities responsible for notified bodies;***
 - (b) ***Development of guidance documents for notified bodies in relation to the implementation of this Regulation;***
 - (c) ***Training and qualification of the experts referred to in Article 32a;***
 - (d) ***Monitoring of trends relating to changes to notified body designations and notifications and trends in certificate withdrawals and transfers between notified bodies;***
 - (e) ***Monitoring of the application and applicability of scope codes referred to in Article 33(4a);***
 - (f) ***Development of a mechanism for peer review between authorities and the Commission;***
 - (g) ***Methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies for medical devices.***

2. ***The national authorities responsible for notified bodies shall participate in a peer review every third year in accordance with the mechanism agreed in Article 38(1). These reviews shall normally be conducted during on-site joint assessments described in Article 32 but alternatively on a voluntary basis may take place as part of the national authority's monitoring activities in Article 35.***

3. ***The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism, including coordinating the peer review component. The Commission shall report on the Member States implementation of the requirements in Article 28, taking best practice in the Union into consideration.***

3a. The Commission shall compile a report of the peer review for the national authority being reviewed. The report documenting the outcome of the peer-review shall be communicated to the Member State concerned and, with the consent of the national authority being reviewed, to all other Member States.

The Commission shall also compile an annual summary report of the peer review activities which shall be made publicly available.

4. The Commission may, by means of implementing acts, adopt measures setting out the modalities and associated documents for the peer review, training and qualification mechanisms referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Article 39

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices.

The bodies notified under this Regulation shall participate in the work of that group.

Article 40

Fees

1. ~~The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.~~
2. ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 89 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 31(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.~~

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 their intended purpose *intended by the manufacturer* and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.

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 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.**

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

3. ~~At The Commission may, at the~~ **a** request of a Member State **the Commission shall** ~~or on its own initiative~~ **after consulting the MDCG, 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 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 activities by way of derogation from the classification criteria set out in Annex VII, be reclassified.**

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).

3b. These The implementing acts referred to in paragraphs 3 and 3a shall be 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 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 in accordance
with Article 898(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 the classification criteria set out in Annex VII.~~

Section 2 – Conformity assessment

Article 42

Conformity assessment procedures

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI.
 - 1a. ***Prior to putting into service devices that are not placed on the market, with the exception of devices manufactured pursuant to Article 4(5), manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI.***
2. Manufacturers of devices classified as class III, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality *management system* assurance and ~~design dossier examination~~ *assessment of the technical documentation* 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.

2a. For implantable ~~and invasive~~ devices classified as class III ~~which are listed in Annex XVa~~, the notified body shall follow the procedure regarding clinical evaluation consultation as specified in section 6.0 of Chapter II of annex VIII or Section 6 of Annex IX, as applicable.

This procedure is not required where

- (a) 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***
- (b) the principles of the clinical evaluation of the device type or category have been addressed in a common specification referred to in Article 7 and the NB confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant common specification for clinical evaluation of that kind of device.***

2b. Any notified body that takes a decision in accordance with ~~the previous sub-paragraph 2a~~ shall notify the competent authorities and the Commission accordingly through the system referred to in Article 27. That notification shall be accompanied by the clinical evaluation assessment report.

2c. The Commission shall by ~~[date 5 year after the date of application of this regulation]~~ draw up a report on the operation of Article 42(2a) and submit it to the European Parliament and to the Council. On the basis of this report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.

2d. 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.

2e. 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 *management system* 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 per generic device group. By way of derogation, the assessment of the technical documentation as specified in Chapter II of Annex VIII shall be applicable for Class IIb implantable devices.*** 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 *management system* 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 for each category of devices.*** 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.

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 concerned with *establishing* 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.
- ~~6. Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.~~
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. *Manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment procedure based on quality management system assurance as specified in Annex VIII, except for its Chapter II with assessment of the technical documentation.*
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(s) *determined by the Member State concerned*. Otherwise they shall be available in an official Union language acceptable to the notified body.
9. Investigational devices shall be subject to the requirements set out in Articles 50 to 60.

10. The Commission may, by means of implementing acts, specify *or modify* 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~~ *assessment of the technical documentation* 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 in accordance with Article 89 amending or ~~supplementing~~ *updating* the conformity assessment procedures set out in Annexes VIII to XI.

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, the conformity assessment procedures and the devices concerned. 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 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.*
- 2a. ***Manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body or provide information about any previous application for the same type that has been refused by another notified body.***
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.
4. 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*** 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.

Article 44

Mechanism for scrutiny of certain conformity assessments

1. ~~With~~ Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class III, with the exception of applications to supplement or renew existing certificates., ***A notified body shall notify the competent authorities of certifications it has granted to implantable devices classified as class III devices, the conformity assessment of which has been performed pursuant to Article 42(2a). The Such notification shall be accompanied by the draft instructions for use referred to in Section 19.3 of Annex I take place automatically through the electronic system referred to in Article 27 and shall include the draft summary of safety and clinical performance information pursuant referred to in Article 26, the assessment report by the notified body, the draft instructions for use referred to in Section 19.3 of Annex I, and, where applicable, the scientific opinion report of the expert panels referred to in section 6.0 of Chapter II of annex VIII or section 6.1 of Annex IX, as applicable, including, where applicable, a justification in case of divergent views between notified body and expert panel. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.***

A competent authority and, where applicable, the Commission may, based on reasonable concerns, apply further procedures according to articles 35, 35a, 36, 37, 69 and, when deemed necessary, take appropriate measures according to Article 70.

- ~~1a.~~ ***A competent authority may request further information from notified bodies about the conformity assessments of such devices pursuant to Article 35(2).***

~~1b. Where one of the competent authorities has reasonable concerns about the conformity assessment it may inform the Commission which shall bring the matter before the MDCG. The MDCG shall evaluate and comment on the conformity assessment. In the context of this evaluation, the MDCG may request via the competent authority responsible for the notified body additional information that is necessary for the analysis of the notified body's conformity assessment. It may also consult the expert panels referred to in article 81a with regard to its scientific opinion report.~~

~~For reasons of protection of public health, the Member state concerned may suspend the making available on the market of a device referred to in the first paragraph on its territory until the evaluation has been carried out by the MDCG.~~

~~1e. The MDCG shall send its evaluation report to the competent authority concerned. The competent authority shall transmit the report to the notified body. The notified body shall give due consideration to the report and shall convey to the competent authority a written explanation of how it has been taken into consideration.~~

~~If the evaluation report of the MDCG confirms the concerns expressed by the competent authority, the notified body shall ensure that all the relevant measures are taken by the manufacturer in order to address these concerns or, if necessary, impose restrictions or remove the certificate delivered in accordance with Article 45.~~

~~1d. The competent authority shall, through the electronic system referred to in Article 45(4), make the evaluation report of the MDCG, the written explanation of the notified body, and its own conclusion accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.~~

1e. Where deemed necessary for the protection of patient safety and public health, a competent authority may raise concerns on specific devices or categories of devices, other than implantable devices classified as class III, to the Commission, which shall bring the matter to the MDCG pursuant to paragraph 3. The procedure of paragraphs 3 to 5 shall apply accordingly.

Where necessary, the MDCG may consult the expert panels referred to in article 81a during this procedure.

2. Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4). In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.

Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.

3. The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. ~~The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.~~
5. ~~Where deemed necessary for the protection of patient safety and public health, the Commission, may determine, by means of implementing acts, specific categories or groups of devices, other than devices of class III, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).~~

~~Measures pursuant to this paragraph may be justified only by one or more of the following criteria:~~

- ~~(a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;~~
 - ~~(b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;~~
 - ~~(c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;~~
 - ~~(d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;~~
 - ~~(e) public health concerns regarding a specific category or group of devices or the technology on which they are based.~~
6. ~~The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.~~
 7. ~~The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between notified bodies and MDCG for the purposes of this Article.~~