(c) to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations ~~to be conducted in more than one Member State~~ to comply with ~~information~~ obligations under Articles 50 to 60;

(d) to enable manufacturers to comply with information obligations under Articles 61 to 66;

(e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well informed basis and to enhance the cooperation between them.

2. Eudamed shall include the following ~~as integral parts~~:

(a) the electronic system on UDI referred to in Article 24***a***;

(b) the electronic system on registration of ~~devices and~~ economic operators referred to in Article 25;

***(ba) the electronic system on notified bodies referred to in Article 33(9);***

(c) the electronic system on information ***on applications for conformity assessment and*** on certificates referred to in Article ***43(1) and Article*** 45(4) ***and on Summaries of safety and clinical performance referred to in Article 26***;

(d) the electronic system on clinical investigations referred to in Article 53,

(e) the electronic system on vigilance ***and post-market surveillance*** referred to in Article ~~62~~ ***66a***;

(f) the electronic system on market surveillance referred to in Article ~~68~~ ***75b***.

***2a. In the design of Eudamed the Commission shall give due consideration to the compatibility of national databases and national web-interfaces to allow for import and export of data.***

3. The data shall be entered into Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions concerning the electronic systems referred to in paragraph 2. ***The Commission shall provide for technical and administrative support to users of Eudamed.***

4. All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent defined in the provisions referred to in paragraph 2.

5. Eudamed shall contain personal data only insofar as this is necessary for the electronic systems referred to in paragraph 2 to collate and process the information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of the data subjects for no longer than the periods referred to in Article 8(4).

6. The Commission and the Member States shall ensure that the data subjects may effectively exercise their rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall ensure that the data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than within 60 days after a request is made by a data subject.

7. The Commission shall, by means of implementing acts, lay down the modalities necessary for the development and management of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). ***When adopting these implementing acts, the Commission shall ensure that, to the extent possible, the system develops so as to avoid any requirement of double entries of the same information within the same module or in different modules of the system.***

8. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered controller of Eudamed and its electronic systems.

*Article 27a*

***Functionality of the European database portal and the Electronic system on UDI***

***1. The Commission shall, in collaboration with MDCG, draw up the functional specifications for the European database referred to in article 27a and the Electronic system on UDI referred to in article 24a, together with the time frame for their implementation.***

***2. The Commission shall, on the basis of an independent audit report, inform the MDCG when it has verified that the European database and the Electronic system on UDI have achieved full functionality and the systems meet the functional specifications drawn up pursuant to paragraph 1.***

***3. The Commission shall, after consultation with MDCG and when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the Official Journal of the European Union.***

# Chapter IV
# Notified bodies

*Article 28*

*National authorities responsible for notified bodies* ***for medical devices***

1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out ~~third-party~~ conformity assessment ~~tasks~~ ***activities*** under this Regulation shall ***nominate*** ~~designate~~ an authority, ***which may consist of separate constituent entities under national law,*** that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors ~~or~~ ***and*** subsidiaries of those bodies, hereinafter referred to as the 'national authority responsible for notified bodies'.

2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.

3. ***The national authority responsible for notified bodies*** ~~It~~ shall be organised so that each decision relating to ***designation or*** notification ~~of a conformity assessment body~~ is taken by personnel different from those who carried out the assessment ~~of the conformity assessment body~~.

4. ***The national authority responsible for notified bodies*** ~~It~~ shall not perform any activities that ~~conformity assessment~~ ***notified*** bodies perform ~~nor provide consultancy services~~ on a commercial or competitive basis.

5. The national authority responsible for notified bodies shall safeguard the confidentiality of the information it obtains. However, it shall exchange information on a notified body with other Member States, ~~and~~ the Commission ***and, when required, with other regulatory authorities***.

6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

***Where*** ~~Without prejudice to Article 33(3), where a~~ ***the*** national authority ~~is~~ responsible for ~~the designation of~~ notified bodies ~~in the field of products other than medical devices,~~ ***is a different authority than*** the ***national*** competent authority for medical devices***, it shall ensure that the national competent authority responsible for medical devices is*** ~~shall be~~ consulted on ~~all~~ ***relevant*** aspects ~~specifically related to medical devices~~.

7. Member States shall ***make publicly available general*** ~~provide the Commission and the other Member States with~~ information on their ~~procedures for~~ ***provisions on*** the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and ***on*** ~~of any~~ changes ***which have a significant impact on these tasks*** ~~thereto~~.

8. The national authority responsible for notified bodies shall ~~be peer-reviewed every second year~~ ***participate in the oversight activities laid down in Article 38***. ~~The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.~~

~~The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer-review shall be communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.~~

*Article 29*

*Requirements relating to notified bodies*

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary ***so they are qualified*** to fulfil the~~ir~~ tasks for which they are designated in accordance with this Regulation. ~~Minimum~~ ***The*** requirements to be met by notified bodies are set out in Annex VI.

***1a. Notified bodies shall make available and submit upon request, all relevant documentation, including the manufacturer's documentation to the national authority responsible for notified bodies to allow it to conduct its assessment, designation, notification and monitoring and surveillance activities outlined within this Chapter.***

2. ~~The~~ ***In order to ensure the uniform application of the requirements set out in Annex VI, the*** Commission ~~shall be empowered to~~ ***may*** adopt ~~delegated~~ ***implementing*** acts in accordance with Article 8~~9~~***9(3)*** ~~amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices~~.

*Article 30*

*Subsidiaries and subcontracting*

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the ~~relevant~~ ***applicable*** requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary ~~only with the agreement of~~ ***provided that*** the legal or natural person that applied for conformity assessment ***has been informed of this***.

4. Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

*Article 31*

*Application by a conformity assessment body for ~~notification~~ **designation***

1. A conformity assessment body shall submit an application for ~~notification~~ ***designation*** to the national authority responsible for notified bodies of the Member State in which it is established.

2. The application shall specify the conformity assessment activities ***as defined in this Regulation***, ~~the conformity assessment procedures~~ and the ***types of*** devices for which the body ***applies to be designated and for which involvement of a notified body is required*** ~~claims to be competent~~, supported by documentation proving compliance with all the requirements set out in Annex VI.

   In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, ~~the relevant documentation may be submitted in form of~~ a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 ***may be submitted in support of these requirements and shall be taken into consideration during the assessment described in Article 32. However, the applicant shall make available the full documentation to demonstrate conformity with these requirements upon request.*** ~~The conformity assessment body shall be presumed to be in conformity with the requirements covered by the certificate delivered by such accreditation body.~~

3. After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.

*Article 32*

*Assessment of the application*

1. The national authority responsible for notified bodies shall ***within 30 days*** check that the application referred to in Article 31 is complete and ***shall request the applicant to provide any missing information. Once the application is complete the national authority shall send it to the Commission along with a proposed timeframe for preliminary review and an indicative date for an on-site assessment.***

   ***The national authority shall review the application and supporting documentation in accordance with its own procedures and shall*** draw up a preliminary assessment report.

2. ~~It~~ ***The national authority responsible for notified bodies*** shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group established by Article 78 ('MDCG'). ***The national authority responsible for notified bodies shall also indicate based on their assessment whether the on-site assessment date proposed in paragraph 1 remains valid.*** ~~Upon request by the Commission, the report shall be submitted by the authority in up to three official Union languages.~~

   ***Documents to support the application described in Article 31 shall be made available upon request.***

3. Within 14 days of the submission referred to in paragraph 2, the Commission, ***in conjunction with the MDCG,*** shall ~~designate~~ ***assign*** a joint assessment team made up of ~~at least two~~ ***three*** experts, ***unless the specific circumstances require another number of experts,*** chosen from ~~a~~ ***the*** list ~~of experts who are qualified in the assessment of conformity assessment bodies~~ ***referred to in Article 32a***. ~~The list shall be drawn up by the Commission in cooperation with the MDCG.~~ ***One*** ~~At least one~~ of these experts shall be a representative of the Commission who shall ~~lead~~ ***coordinate*** the ***activities of the*** joint assessment team.

***The joint assessment team shall be comprised of competent experts which reflect the conformity assessment activities and the types of devices which are subject to the application or, in particular when this procedure is initiated in accordance with Article 37 to ensure that the specific concern can be appropriately assessed.***

4. Within 90 days after ~~designation~~ ***assignment*** ~~of the joint assessment team, the national authority responsible for notified bodies and~~ the joint assessment team shall review the documentation submitted with the application in accordance with Article 31. ***The joint assessment team may feedback to or require clarification from the national authority responsible for notified bodies on the application and on the planned on-site assessment.***

***The national authority responsible for notified bodies together with the joint assessment team shall plan*** and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process.

~~Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 31(2), unless the Commission representative mentioned in Article 32(3) requests the on-site assessment.~~

***The on-site assessment of the applicant body shall be led by the national authority responsible for notified bodies.***

*4a.* Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team with a view to finding common agreement ***and resolution of any diverging opinions,*** with respect to the assessment of the application. ~~Divergent opinions shall be identified in the assessment report of the national authority responsible.~~

***A list of non-compliances resulting from the assessment shall be presented by the national authority responsible for notified bodies to the applicant body at the end of the on-site assessment including a summary of the assessment delivered by the joint assessment team.***

***The national authority shall request a corrective and preventive action plan from the applicant body to be submitted within a specified timeframe to address the non-compliances.***

*4aa.* ***The joint assessment team shall within 30 days of completion of the on-site assessment document any remaining diverging opinions with respect to the assessment and send these to the national authority responsible for notified bodies.***

*4b. The national authority responsible for notified bodies shall following receipt of a corrective and preventive action plan from the applicant body assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall include an indication of the root cause of the finding and a timeframe for implementation of the actions therein.*

*The national authority shall having confirmed the corrective and preventive action plan forward this plan and its opinion on this plan to the joint assessment team. The joint assessment team may request further clarification and modifications from the national authority responsible for notified bodies.*

*The national authority responsible for notified bodies shall draw up its final assessment report which shall include:*

- *the result of the assessment,*
- *confirmation that the corrective and preventive actions have been appropriately addressed and, where required, implemented,*
- *any remaining diverging opinion with the joint assessment team, and, where applicable,*
- *the recommended scope of designation.*

5. The national authority responsible for notified bodies shall submit its ***final*** assessment report and***, if applicable, the*** ~~its~~ draft ~~notification~~ ***designation*** to the Commission***,*** ~~which shall immediately transmit those documents to~~ the MDCG and ~~to the members of~~ the joint assessment team. ~~Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.~~

6. The joint assessment team shall provide its opinion ***in a final report*** regarding the assessment report ***prepared by the national authority responsible for notified bodies*** and, ***if applicable,*** the draft ~~notification~~ ***designation*** within 21 days of receipt of those documents ~~and~~ ***to*** the Commission, ***which*** shall immediately submit this opinion to the MDCG. Within ~~21~~ ***42*** days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft ~~notification~~ ***designation*** which the ~~relevant~~ national authority ***responsible for notified bodies*** shall duly take into consideration for its decision on the designation of the notified body.

7. The Commission may, by means of implementing acts, adopt measures setting out the modalities ***specifying procedures and reports*** for the application for ~~notification~~ ***designation*** referred to in Article 31 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

***Article 32a***

***Nomination of experts for joint assessment of applications for notification***

***1. The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of medical devices to participate in the activities outlined in Article 32 and Article 38.***

***2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1, together with information on their specific competence and expertise. This list shall be made available to Member States competent authorities through the electronic system referred to in Article 27.***

*Article 32b*

***Language requirements***

***All documents required pursuant to Articles 31 and 32 shall be drawn up in a language or languages which shall be determined by the Member State concerned.***

***Member States, in applying the first sub-paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documents concerned.***

***The Commission shall provide necessary translations of the documentation pursuant to Article 31 and 32, or parts thereof into an official Union language such that the documents can be readily understood by the joint assessment team designated in accordance with Article 32(3).***

*Article 33*

~~*Notification*~~ ***Designation and notification*** *procedure*

***0.*** Member States may ~~notify~~ only ***designate*** conformity assessment bodies which satisfy the requirements set out in Annex VI ***and for which the assessment pursuant to Article 32 was completed***.

1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool developed and managed by the Commission.

~~2. Member States may notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.~~

~~3. Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.~~

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities ***as defined in this Regulation***~~, the conformity assessment procedures~~ and the type of devices which the notified body is authorised to assess ***and, without prejudice to Article 35, any conditions associated with the designation***.

***4a.*** The Commission ***shall within six months of the entry into force of this Regulation*** ~~may~~, by means of implementing acts, ~~set~~ ***draw*** up a list of codes and ~~the~~ corresponding types of devices to ~~define~~ ***describe*** the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 88(~~2~~ ***3***). ***The Commission, after consulting the MDCG, may update this list*** **inter alia** ***based on information arising from the coordination activities described in Article 38.***

5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the ~~opinion~~ ***final report*** of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.

6. The notifying Member State shall***, without prejudice to Article 35,*** ~~provide~~ ***inform*** the Commission and the other Member States ***of any conditions associated with the designation and*** ~~with~~ ***provide*** documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI. ~~It shall furthermore submit evidence of the availability of competent personnel for monitoring the notified body in accordance with Article 28(6).~~

7. Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.

8. When a Member State or the Commission raises objections in accordance with paragraph 7, ~~the effect of the notification shall be suspended. In this case,~~ the Commission shall bring the matter before the MDCG within ~~15~~ ***10*** days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within ***40*** ~~28~~ days after the matter has been brought before it. ~~If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.~~

***8a. Where the MDCG, after having been consulted in accordance with paragraph 8, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.***

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG ~~or the Commission~~, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted ~~fully or partially~~, ***or where the notifying Member State having responded in accordance with paragraph 8a, decides to notify the designation of the conformity assessment body*** the Commission shall publish the notification ~~accordingly~~ ***within 14 days of receipt.***

***When publishing the notification in the database of notified bodies developed and managed by the Commission, the Commission shall also add the information relating to the notification of the notified body to the electronic system referred to in Article 27 along with the documents mentioned in paragraph 5 and the opinion and responses referred to in paragraphs 8 and 8a of this Article.***

10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.

***11. The conformity assessment body concerned may perform the activities of a notified body only after the notification has become valid in accordance with paragraph 10.***

*Article 34*

*Identification number and list of notified bodies*

1. The Commission shall assign an identification number to each notified body for ~~which~~ the notification ~~is accepted~~ ***as it becomes valid*** in accordance with Article 33***(10)***. It shall assign a single identification number even when the body is notified under several Union acts.

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the ***conformity assessment*** activities ***as defined in this Regulation and the types of devices*** for which they have been notified, accessible to the public ***in the database of notified bodies developed and managed by the Commission. It shall also make this list available on the electronic system referred to in Article 27***. The Commission shall ensure that the list is kept up to date.

*Article 35*

*Monitoring **and assessment** of notified bodies*

***0. Notified bodies shall, without delay, inform the national authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.***

1. The national authority responsible for notified bodies shall ~~continuously~~ ***conduct*** monitor***ing of*** the notified bodies ***based on its territory and of their subsidiaries and subcontractors*** to ensure ongoing compliance with the requirements ***and the fulfilment of its obligations*** set out in ***this Regulation*** ~~Annex VI~~. The notified bodies shall, on request ***from the national authority responsible for notified bodies***, supply all relevant information and documents, required to enable the authority***, the Commission and other Member States*** to verify compliance with those criteria.

~~Notified bodies shall, without delay, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.~~

2. ***The national authority responsible for notified bodies shall receive a copy of all requests submitted by the Commission or by another Member State authority to notified bodies on its territory relating to conformity assessments such notified bodies have carried out.*** Notified bodies shall respond without delay to ***such*** requests ~~relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission~~. The national authority responsible for notified bodies of the Member State in which the body is established shall ~~enforce~~ ***ensure that*** requests submitted by authorities of any other Member State or by the Commission ***are resolved*** unless there is a legitimate reason for not doing so in which case both sides may consult the MDCG. ~~The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated confidential.~~

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body ***and, when appropriate, the subsidiaries and subcontractors*** under its responsibility still ~~satisfies~~ ***satisfy*** the requirements ***and fulfil their obligations*** set out in Annex VI. This ~~assessment~~ ***review*** shall include an on-site visit to each notified body ***and, when necessary, to its subsidiaries and subcontractors***.

***The national authority shall conduct its monitoring and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. This plan shall provide a reasoned schedule for the frequency of assessment of the notified body and, in particular, associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.***

***3a. The national authority's monitoring of notified bodies shall include witnessed audits of the notified body personnel, including when necessary, the personnel from subsidiaries and subcontractors, when conducting quality system assessments at a manufacturer's facility.***

*3c. The monitoring of notified bodies conducted by national authorities responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance systems to help guide its activities.*

*The authority shall provide for a systematic follow-up of complaints and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.*

*3ca. The national authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance.*

*3cb. The national authority responsible for notified bodies shall assess the notified body assessments of manufacturers' technical and clinical documentation as further outlined in Article 35a.*

*3d. The national authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VI and shall monitor the timely implementation of corrective and preventive actions.*

4. Three years after notification of a notified body, and again every ~~third~~ *fourth* year thereafter, ~~the~~ *a complete re-*assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article *31 and* 32~~(3) and (4)~~. ~~At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.~~

*4a. The Commission may, by means of implementing acts, modify the frequency of complete re-assessment referred to in the previous sub-paragraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*

5. The Member States shall report to the Commission and to the ***MDCG*** ~~other Member States~~, at least once a year, on their monitoring activities ***regarding their notified bodies and, where applicable, subsidiaries and subcontractors. This report shall provide details of the outcome of the monitoring activities.*** This report ***shall be treated as confidential by the MDCG and the Commission however it*** shall contain a summary which shall be made publicly available.

***The summary report shall be uploaded to the European databank referred to in Article 27.***

***Article 35a***

***Review of Notified Body assessment of technical documentation and clinical evaluation documentation***

*1. The national authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies shall assess an appropriate number of notified body assessments of manufacturers' technical documentation and clinical evaluations to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. These assessments shall be conducted both off site and during on-site assessments.*

*2. The sample of files assessed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body and in particular high risk devices, appropriately justified and documented in a sampling plan, which shall be available from the national authority responsible for notified bodies upon request of the MDCG.*