Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)

CHAPTER IV

NOTIFIED BODIES

Article 35

Authorities responsible for notified bodies

1 Any Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall appoint an authority (‘authority responsible for notified bodies’), which may consist of separate constituent entities under national law and 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 and subsidiaries of those bodies.

2 The 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 authority responsible for notified bodies shall be organised in a manner such that each decision relating to designation or notification is taken by personnel different from those who carried out the assessment.

4 The authority responsible for notified bodies shall not perform any activities that notified bodies perform on a commercial or competitive basis.

5 The authority responsible for notified bodies shall safeguard the confidential aspects of the information it obtains. However, it shall exchange information on notified bodies with other Member States, the Commission and, when required, with other regulatory authorities.

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

Where the authority responsible for notified bodies is a different authority from the national competent authority for medical devices, it shall ensure that the national authority responsible for medical devices is consulted on relevant matters.

7 Member States shall make publicly available general information on their measures governing the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on such tasks.

8 The authority responsible for notified bodies shall participate in the peer-review activities provided for in Article 48.

Article 36

Requirements relating to notified bodies

1 Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil those tasks. In particular, notified bodies shall comply with Annex VII.

In order to meet the requirements referred to in the first subparagraph, notified bodies shall have permanent availability of sufficient administrative, technical and scientific personnel in accordance with Section 3.1.1 of Annex VII and personnel with relevant clinical expertise in accordance with Section 3.2.4 of Annex VII, where possible employed by the notified body itself.

The personnel referred to in Sections 3.2.3 and 3.2.7 of Annex VII shall be employed by the notified body itself and shall not be external experts or subcontractors.

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

3 In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt implementing acts, to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 37

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 applicable requirements set out in Annex VII and shall inform the 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 Notified bodies shall make publicly available a list of their subsidiaries.

4 Conformity assessment activities may be subcontracted or carried out by a subsidiary provided that the legal or natural person that applied for conformity assessment has been informed accordingly.

5 Notified bodies shall keep at the disposal of the authority responsible for notified bodies all 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 38

Application by conformity assessment bodies for designation

1 Conformity assessment bodies shall submit an application for designation to the authority responsible for notified bodies.

2 The application shall specify the conformity assessment activities as defined in this Regulation, and the types of devices for which the body is applying to be designated, and shall be supported by documentation demonstrating compliance with Annex VII.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VII, a valid accreditation certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted and shall be taken into consideration during the assessment described in Article 39. However, the applicant shall make available all the documentation referred to in the first subparagraph to demonstrate compliance with those requirements upon request.

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

Article 39

Assessment of the application

1 The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 38 is complete and shall request the applicant to provide any missing information. Once the application is complete that authority shall send it to the Commission.

The authority responsible for notified bodies shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.

2 The authority responsible for notified bodies shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the MDCG.

3 Within 14 days of the submission referred to in paragraph 2 of this Article, the Commission, in conjunction with the MDCG, shall appoint a joint assessment team made up of three experts, unless the specific circumstances require a different number of experts, chosen from the list referred to in Article 40(2). One of the experts shall be a representative of the Commission who shall coordinate the activities of the joint assessment team. The other two experts shall come from Member States other than the one in which the applicant conformity assessment body is established.

The joint assessment team shall be comprised of experts who are competent to assess the conformity assessment activities and the types of devices which are the subject of the application or, in particular when the assessment procedure is initiated in accordance with Article 47(3), to ensure that the specific concern can be appropriately assessed.

4 Within 90 days of its appointment, the joint assessment team shall review the documentation submitted with the application in accordance with Article 38. The joint assessment team may provide feedback to, or require clarification from, the authority responsible for notified bodies on the application and on the planned on-site assessment.

The 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 subcontractor, located inside or outside the Union, to be involved in the conformity assessment process.

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

5 Findings regarding non-compliance of an applicant conformity assessment body with the requirements set out in Annex VII shall be raised during the assessment process and discussed between the authority responsible for notified bodies and the joint assessment team with a view to reaching consensus and resolving any diverging opinions, with respect to the assessment of the application.

At the end of the on-site assessment, the authority responsible for notified bodies shall list for the applicant conformity assessment body the non-compliances resulting from the assessment and summarise the assessment by the joint assessment team.

Within a specified timeframe, the applicant conformity assessment body shall submit to the national authority a corrective and preventive action plan to address the non-compliances.

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

7 The 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 indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

The authority responsible for notified bodies shall having confirmed the corrective and preventive action plan forward it and its opinion thereon to the joint assessment team. The joint assessment team may request of the authority responsible for notified bodies further clarification and modifications.

The 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.

8 The authority responsible for notified bodies shall submit its final assessment report and, if applicable, the draft designation to the Commission, the MDCG and the joint assessment team.

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

10 The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements specifying procedures and reports for the application for designation referred to in Article 38 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 114(3).

Article 40

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 referred to in Articles 39 and 48.

2 The Commission shall maintain a list of the experts nominated pursuant to paragraph 1 of this Article, together with information on their specific field of competence and expertise. That list shall be made available to Member States competent authorities through the electronic system referred to in Article 57.

Article 41

Language requirements

All documents required pursuant to Articles 38 and 39 shall be drawn up in a language or languages which shall be determined by the Member State concerned.

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

The Commission shall provide translations of the documentation pursuant to Articles 38 and 39, or parts thereof into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team appointed in accordance with Article 39(3).

Article 42

Designation and notification procedure

1 Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 39 was completed and which comply with Annex VII.

2 Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool within the database of notified bodies developed and managed by the Commission (NANDO).

3 The notification shall clearly specify, using the codes referred to in paragraph 13 of this Article, the scope of the designation indicating the conformity assessment activities as defined in this Regulation and the types of devices which the notified body is authorised to assess and, without prejudice to Article 44, any conditions associated with the designation.

4 The notification shall be accompanied by the final assessment report of the authority responsible for notified bodies, the final opinion of the joint assessment team referred to in Article 39(9) 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.

5 The notifying Member State shall, without prejudice to Article 44, inform the Commission and the other Member States of any conditions associated with the designation and 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 VII.

6 Within 28 days of the notification referred to in paragraph 2, 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 authority responsible for notified bodies. Where no objection is raised, the Commission shall publish in NANDO the notification within 42 days of its having been notified as referred to in paragraph 2.

7 When a Member State or the Commission raises objections in accordance with paragraph 6, the Commission shall bring the matter before the MDCG within 10 days of the expiry of the period referred to in paragraph 6. After consulting the parties involved, the MDCG shall give its opinion at the latest within 40 days of the matter having been brought before it. Where the MDCG is of the opinion that the notification can be accepted, the Commission shall publish in NANDO the notification within 14 days.

8 Where the MDCG, after having been consulted in accordance with paragraph 7, 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 the notifying Member State decides to uphold its decision to designate the conformity assessment body, having given its reasons in accordance with paragraph 8, the Commission shall publish in NANDO the notification within 14 days of being informed thereof.

10 When publishing the notification in NANDO, the Commission shall also add to the electronic system referred to in Article 57 the information relating to the notification of the notified body along with the documents mentioned in paragraph 4 of this Article and the opinion and responses referred to in paragraphs 7 and 8 of this Article.

11 The designation shall become valid the day after the notification is published in NANDO. The published notification shall state the scope of lawful conformity assessment activity of the notified body.

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

13 The Commission shall by 26 November 2017, by means of implementing acts, draw up a list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). The Commission, after consulting

the MDCG, may update this list based, *inter alia*, on information arising from the coordination activities described in Article 48.

Article 43

Identification number and list of notified bodies

1 The Commission shall assign an identification number to each notified body for which the notification becomes valid in accordance with Article 42(11). It shall assign a single identification number even when the body is notified under several Union acts. If they are successfully designated in accordance with this Regulation, bodies notified pursuant to Directives 90/385/EEC and 93/42/EEC shall retain the identification number assigned to them pursuant to those Directives.

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 NANDO. It shall also make this list available on the electronic system referred to in Article 57. The Commission shall ensure that the list is kept up to date.

Article 44

Monitoring and re-assessment of notified bodies

1 Notified bodies shall, without delay, and at the latest within 15 days, inform the authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VII or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.

2 The authorities responsible for notified bodies shall monitor the notified bodies established on their territory and their subsidiaries and subcontractors to ensure ongoing compliance with the requirements and the fulfilment of its obligations set out in this Regulation. Notified bodies shall, upon request by their 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.

3 Where the Commission or the authority of a Member State submits a request to a notified body established on the territory of another Member State relating to a conformity assessment carried out by that notified body, it shall send a copy of that request to the authority responsible for notified bodies of that other Member State. The notified body concerned shall respond without delay and within 15 days at the latest to the request. The authority responsible for notified bodies of the Member State in which the body is established shall ensure that requests submitted by authorities of any other Member State or by the Commission are resolved by the notified body unless there is a legitimate reason for not doing so in which case the matter may be referred to the MDCG.

4 At least once a year, the authorities responsible for notified bodies shall re-assess whether the notified bodies established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in Annex VII. That review shall include an on-site audit of each notified body and, where necessary, of its subsidiaries and subcontractors.

The authority responsible for notified bodies 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. That 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.

5 The monitoring of notified bodies by the authority responsible for notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, as that personnel is in the process of conducting quality management system assessments at a manufacturer's facility.

6 The monitoring of notified bodies conducted by the authority responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance to help guide its activities.

The authority responsible for notified bodies 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.

7 The 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.

8 The authority responsible for notified bodies shall review the assessments by notified bodies of manufacturers' technical documentation, in particular the clinical evaluation documentation as further outlined in Article 45.

9 The 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 VII and shall monitor the timely implementation of corrective and preventive actions.

10 Three years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VII shall be conducted by the authority responsible for notified bodies of the Member State in which the body is established and by a joint assessment team appointed for the purpose of the procedure described in Articles 38 and 39.

11 The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend paragraph 10 to modify the frequency at which the complete re-assessment referred to in that paragraph is to be carried out.

12 The Member States shall report to the Commission and to the MDCG, at least once a year, on their monitoring and on-site assessment activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. The report shall provide details of the outcome of those activities, including activities pursuant to paragraph 7, and 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 of the report shall be uploaded to the electronic system referred to in Article 57.

Article 45

Review of notified body assessment of technical documentation and clinical evaluation documentation

1 The authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies, shall review an appropriate number of notified body assessments of manufacturers' technical documentation, in particular the clinical evaluation documentation as referred to in points (c) and (d) of Section 6.1 of Annex II to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. The reviews by the authority responsible for notified bodies shall be conducted both off-site and on-site.

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

3 The authority responsible for notified bodies shall review whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such checking shall include the technical documentation and clinical evaluation documentation of the manufacturer upon which the notified body has based its assessment. Such reviews shall be conducted utilising CS.

4 Those reviews shall also form part of the re-assessment of notified bodies in accordance with Article 44(10) and the joint assessment activities referred to in Article 47(3). The reviews shall be conducted utilising appropriate expertise.

5 Based on the reports of the reviews and assessments by the authority responsible for notified bodies or joint assessment teams, on input from the market surveillance, vigilance and post-market surveillance activities described in Chapter VII, on the continuous monitoring of technical progress, or on the identification of concerns and emerging issues concerning the safety and performance of devices, the MDCG may recommend that the sampling, carried out under this Article, cover a greater or lesser proportion of the technical documentation and clinical evaluation documentation assessed by a notified body.

6 The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements, associated documents for, and coordination of, the review of assessments of technical documentation and clinical evaluation documentation, as referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 46

Changes to designations and notifications

1 The authority responsible for notified bodies shall notify the Commission and the other Member States of any relevant changes to the designation of a notified body.

The procedures described in Article 39 and in Article 42 shall apply to extensions of the scope of the designation.

For changes to the designation other than extensions of its scope, the procedures laid down in the following paragraphs shall apply.

2 The Commission shall immediately publish the amended notification in NANDO. The Commission shall immediately enter information on the changes to the designation of the notified body in the electronic system referred to in Article 57.

3 Where a notified body decides to cease its conformity assessment activities it shall inform the authority responsible for notified bodies and the manufacturers concerned as soon as possible and in the 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 the notified body's activities on condition that another notified body has confirmed in writing that it will assume responsibilities for the devices covered by those certificates. The new notified body shall complete a full assessment of the devices affected by the end of that period before issuing new certificates for those devices. Where the notified body has ceased its activity, the authority responsible for notified bodies shall withdraw the designation.

4 Where a authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VII, 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, 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.

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

5 Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the manufacturers concerned at the latest within 10 days.

6 In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall take appropriate steps to ensure that the files of the notified body concerned are kept and make them available to authorities in other Member States responsible for notified bodies and to authorities responsible for market surveillance at their request.

7 In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall:

a assess the impact on the certificates issued by the notified body;

b submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the designation;

c require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued to ensure the safety of devices on the market;

d enter into the electronic system referred to in Article 57 information in relation to certificates of which it has required their suspension or withdrawal;

e inform the competent authority for medical devices of the Member State in which the manufacturer has its registered place of business through the electronic system referred to in Article 57 of the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.

8 With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in the following circumstances:

a the authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue in relation to certificates affected

by the suspension or restriction, and the authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction; or

b the 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 or restriction, and states 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 the event that the 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 medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business, within three months of the suspension or restriction, a 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.

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

a where the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business has confirmed that there is no safety issue associated with the devices in question; and

b another notified body has confirmed in writing that it will assume immediate responsibilities for those devices and will have completed assessment of them within twelve months of the withdrawal of the designation.

In the circumstances referred to in the first subparagraph, the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its place of business may extend the provisional validity of the certificates for further periods of three months, which altogether shall not exceed twelve months.

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

Article 47

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 VII or the obligations to which they are subject. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.

2 The notifying Member State shall provide the Commission, on request, with all information regarding the designation of the notified body concerned.

3 The Commission, in conjunction with the MDCG, may initiate, as applicable, the assessment procedure described in Article 39(3) and (4), where 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 VII and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns

or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles of Article 39. Alternatively, depending on the severity of the issue, the Commission, in conjunction with the MDCG, may request that the authority responsible for notified bodies allow the participation of up to two experts from the list established pursuant to Article 40 in an on-site assessment as part of the planned monitoring and assessment activities in accordance with Article 44 and as outlined in the annual assessment plan described in Article 44(4).

4 Where the Commission ascertains that a notified body no longer meets the requirements for its designation, 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 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 designation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). It shall notify the Member State concerned of its decision and update NANDO and the electronic system referred to in Article 57.

5 The Commission shall ensure that all confidential information obtained in the course of its investigations is treated accordingly.

Article 48

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

1 The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the authorities responsible for notified bodies. Such exchange shall cover elements including:

a development of best practice documents relating to the activities of the 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 40;

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 42(13);

f development of a mechanism for peer reviews 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.

2 The authorities responsible for notified bodies shall participate in a peer review every third year through the mechanism developed pursuant to paragraph 1 of this Article. Such reviews shall normally be conducted in parallel with the on-site joint assessments described in Article 39. Alternatively, an authority may make the choice of having such reviews take place as part of its monitoring activities referred to in Article 44.

3 The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism.

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

5 The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements and related documents for the peer review mechanism and training and qualification as referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 49

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. This group shall meet on a regular basis and at least annually.

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

The Commission may establish the specific arrangements for the functioning of the coordination group of notified bodies.

Article 50

List of standard fees

Notified bodies shall establish lists of their standard fees for the conformity assessment activities that they carry out and shall make those lists publicly available.

Status:
Point in time view as at 05/04/2017.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council, CHAPTER IV.