



EUROPEAN  
COMMISSION

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**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of XXX**

**laying down certain uniform quality management and procedural requirements for the conformity assessment activities carried out by a notified body designated under Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council**

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.*

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**laying down certain uniform quality management and procedural requirements for the conformity assessment activities carried out by a notified body designated under Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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<sup>1</sup>, and in particular Article 36(3) thereof,

Having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU<sup>2</sup>, and in particular Article 32(3) thereof,

Whereas:

- (1) Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council establish a regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users. At the same time, those Regulations set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices.
- (2) Under Regulations (EU) 2017/745 and (EU) 2017/746, notified bodies are designated to perform conformity assessments activities for the certification of, respectively, medical devices and of *in vitro* diagnostic medical devices. For this purpose, notified bodies should comply with certain requirements that are necessary to fulfil their tasks, namely with the requirements laid down in Annex VII to Regulation (EU) 2017/745, as regards medical devices, and in Annex VII to Regulation (EU) 2017/746 as regards *in vitro* medical devices.
- (3) The application of Regulations (EU) 2017/745 and (EU) 2017/746 has shown inconsistent and divergent interpretations of certain requirements set out in Annex VII to Regulation (EU) 2017/745 and in Annex VII to Regulation (EU) 2017/746 as regards quotations provided by notified bodies to manufacturers, the timelines for completing conformity assessment activities and re-certification. Quality management and procedural requirements should be further detailed and clarified to ensure that they are implemented in a uniform manner.

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<sup>1</sup> OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

<sup>2</sup> OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

- (4) The individual practices that notified bodies apply as regards quality management and procedural requirements diverge significantly, thus putting manufacturers in unequal position across the internal market. This is particularly relevant in case of manufacturers that are small and medium-sized enterprises. Such practices have an impact on the predictability and on the timely completion of conformity assessment activities, with significant repercussions and delays for innovation and the health of patients.
- (5) Notified bodies showed significantly differing practices when issuing quotations to manufacturers for specific conformity assessments. As a result, manufacturers are not provided with a reliable estimation of the overall requested services and costs. To harmonise notified bodies' practices, this Regulation should specify the minimum information notified bodies should request to issue a quotation, to ensure that the related following applications for conformity assessment activities are not rejected because they are incomplete or because the device is outside the scope of the notified body's designation. Notified bodies should ask information on the device(s), their intended purpose, any specific characteristics or specific technologies or processes used, to allow them to verify they are designated for the corresponding codes, provided for in Commission Implementing Regulation (EU) 2017/2185<sup>3</sup>.
- (6) For the purpose of obtaining quotations, manufacturers should provide information to notified bodies which allows them to conclude whether a manufacturer is to be considered as a micro, small and medium-sized enterprise taking into consideration in the Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises<sup>4</sup>.
- (7) Based on complete information on the scope of the conformity assessment, notified bodies should issue quotations that include a clear estimation of the costs the manufacturer should expect. Such costs should be presented to the manufacturer according to a clearly presented breakdown and, possibly, include costs for the surveillance activities when such activities are required during the certification cycle.
- (8) In order to provide quotations in accordance with this Regulation based on complete information, notified bodies should make use of available opportunities to enhance the efficiency and predictability of their conformity assessment activities, such as through structured dialogues with manufacturers especially in the pre-application phase.
- (9) Notified bodies have developed varying practices for interacting with manufacturers, leading to different procedures for setting timelines for the conformity assessment activities. This results in conformity assessment activities being completed across a wide range of timelines, often lacking a clear rationale for how these timelines are determined.

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<sup>3</sup> Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 309, 24.11.2017, p. 7, [http://data.europa.eu/eli/reg\\_impl/2017/2185/oj](http://data.europa.eu/eli/reg_impl/2017/2185/oj)).

<sup>4</sup> Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

- (10) In the interest of promoting the safe and continuous supply of the public, notified bodies should complete the conformity assessment activities for a medical device or for an *in vitro* diagnostic medical device in the shortest feasible timeline needed for the required assessment or, at the latest, within a maximum timeline.
- (11) Based on the individual conformity assessment activities required for device certification, notified bodies and manufacturers should agree on timelines for completing these activities, ensuring they do not exceed maximum limits.
- (12) Maximum timelines should be set taking into consideration the variety of devices and specificities of the conformity assessment activities that notified bodies have to carry out. A maximum timeline should be set for the assessment of the application for a conformity assessment procedure and the signature of the contract between the notified body and the manufacturer.
- (13) Due to the need to carry out activities at the manufacturer's premises or, where relevant, at the premises of certain suppliers or sub-contractors of the manufacturer, timelines for quality management system auditing should be differentiated from those for the product verification. Such differentiation should not prevent that conformity assessment activities for product verification and for quality management system are conducted in parallel when carried out in accordance with Annex IX to Regulation (EU) 2017/745 and Annex IX to Regulation (EU) 2017/746, provided that the required input from the assessment of the technical documentation is taken into account when developing the audit programme.
- (14) Timelines for product verification should be specific to class III or class IIb devices. Timelines should also apply in case of assessment of the technical documentation for a representative device on a sampling basis for other class IIb or IIa devices.
- (15) Maximum timelines for quality management system auditing and product verification, including product review, should also take into account the need to properly follow up on potential non-compliances raised during the assessment.
- (16) Timelines should be set for the conformity assessment of planned substantial changes to the quality management system or the range and type of the devices and to the changes to the approved device. A maximum timeline should be set for the notified body's assessment of the notification to decide if additional conformity assessment activities are to be carried out. A maximum timeline should be set also for those eventual additional conformity assessment activities to be performed.
- (17) A maximum timeline should be set also for the final decision and for the issuance of the certificate(s) or the supplement(s) to already issued certificate(s) for which the manufacturer informed notified bodies of a planned change. This timeline should allow notified bodies to issue their decision based on the assessment performed.
- (18) Notified bodies should interrupt further work on a conformity assessment activity where the completion of such an activity depends upon further information to be provided by the manufacturer. Work on the conformity assessment activity should also be interrupted where the completion of the activity depends on the contribution of the European Medicinal Agency (EMA), a regulatory authority, an expert panel or of an EU reference laboratory, as long as the notified bodies' activities depend exclusively on those contributions.
- (19) Notified bodies should have appropriate arrangements, within their quality management systems, to monitor their performances on timelines and on how predicted costs in quotations correspond to actual costs charged for conformity

assessment activities. To ensure that such information of public interest is available and presented in a clear and harmonised manner, notified bodies should prepare reports that provide data on the monitoring of timelines and costs. Notified bodies should send the reports to the Commission and publish them, to ensure transparency on their performances and to allow manufacturers to compare information between notified bodies.

- (20) Notified bodies perform the re-certification of medical devices and of *in vitro* medical devices in a divergent manner. The practical application of requirements related to the relevant manufacturer documentation and to the extent of the related review results in a wide range of practices from targeted assessment of limited documentation to more comprehensive assessments that have comparable extent of those for the initial product verification. This results in huge differences in re-certification processes and relevant timelines and costs thereof.
- (21) Notified bodies should perform re-certification according to predictable timelines, suitable for the certificate(s) to be renewed before their expiry date and without repeating the assessment performed during the initial certification. Information and extracts of the technical documentation that should be subject to assessment should be clearly identified both for the renewal of quality management system and product certificates.
- (22) Notified bodies should focus the assessment of the quality management system subject to re-certification in particular on information related to surveillance activities, changes, compliance with applicable sampling plans, non-compliances and corrective or preventive actions and eventual conditions to the certificate. The assessment should take into consideration also the state of the art.
- (23) Notified bodies should focus the assessment of information related to the device subject to re-certification in particular on information provided by the manufacturer on post market surveillance, changes to the device, also related to the evolution of the state of the art, and updates to the risk analysis.
- (24) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

#### **Quotations**

- 1. For the purpose of issuing quotations to manufacturers as referred to in Section 4.2, point (d), of Annex VII to Regulation (EU) 2017/745 or in Section 4.2, point (d) of Annex VII to Regulation (EU) 2017/746, as the case may be, the notified body shall have documented procedures that ensure that it only issues quotations where it has received from the manufacturer the following information:
  - (a) the manufacturer's identification, namely its name and address;
  - (b) the information necessary for the notified body to determine if the manufacturer is a micro, small and medium-sized enterprise as defined in Commission Recommendation 2003/361/EC, namely the number of employees and the annual turnover;

- (c) name and address of the manufacturer's authorised representative, where applicable;
  - (d) addresses, number of employees, number of work shifts and descriptions of activities performed for each site covered by the manufacturer's quality management system;
  - (e) name and address of the manufacturer's suppliers and sub-contractors where design and manufacture activities are performed, including a description of the activities performed by those entities;
  - (f) description of the device(s), their intended purpose, any specific characteristics or specific technologies or processes used, and the risk-classification;
  - (g) the desired conformity assessment procedure(s);
  - (h) for the changes and modifications referred to in Section 4.9 of Annex VII to Regulation (EU) 2017/745 or Section 4.9 of Annex VII to Regulation (EU) 2017/746, as applicable, a detailed description of the planned changes or modifications;
  - (i) for re-certification, identification of affected certificate(s), including scope change(s);
  - (j) any other information regarding the manufacturer, such as its organisational structure, and regarding the device, which are necessary to estimate the activities to be performed.
2. The notified body shall ensure that, in the documented procedures referred to in paragraph 1, the exchanges of technical information and regulatory guidance, namely the structured dialogue with manufacturers, cover aspects relevant to issue quotations, including the information listed in paragraph 1.
3. The notified body shall issue a quotation which includes at least the following:
- (a) the estimated overall costs, which are detailed for the assessment of the quality management system and the technical documentation, as applicable and include, typical costs for surveillance activities and unannounced audits;
  - (b) an estimation of potential extra costs arising during the assessment activities; such estimations may refer to hourly fees only when the duration of the specific activity cannot be predetermined;
  - (c) a separate estimation of travel and accommodation costs.
4. The notified body shall inform the manufacturer, in a timely manner, about any increase of the initially estimated costs and justify the reason of such an increase.

## *Article 2*

### **Timelines**

1. For the purposes of Section 4.5.1, second paragraph, third indent, of Annex VII to Regulation (EU) 2017/745 and Section 4.5.1, second paragraph, third indent, of Annex VII to Regulation (EU) 2017/746, the notified body shall have documented procedures to ensure that the shortest possible timeline is agreed with the manufacturer, taking into consideration the following:

- (a) the range and type(s) of the devices;
- (b) the specific characteristics of the devices and technologies used;
- (c) the devices' risk class(es);
- (d) the conformity assessment activities the notified body is to perform.

In the quotation, the notified body shall specify the agreed timeline.

2. The notified body shall in any case ensure that conformity assessment activities are completed according to the following maximum timelines:

- (a) 30 days for the application review and the signature of the contract, starting on the day on which the notified body receives the complete application and ending on the day the contract with the manufacturer is signed in accordance with Section 4.3, second paragraph, of Annex VII to Regulation (EU) 2017/745 or with Section 4.3, second paragraph, of Annex VII to Regulation (EU) 2017/746, as applicable;
- (b) 120 days for the quality management system auditing in accordance with Section 4.5.2 of Annex VII to Regulation (EU) 2017/745 or with Section 4.5.2 of Annex VII to Regulation (EU) 2017/746, as applicable, starting on the date the notified body initiates the audit programme's first activity and ending on the day in which the final review referred to in Section 4.7 of Annex VII to Regulation (EU) 2017/745 or in Section 4.7 of Annex VII to Regulation (EU) 2017/746, as applicable, is completed;
- (c) 90 days for the product verification in accordance with Section 4.5.3 of Annex VII to Regulation (EU) 2017/745 and Section 4.5.3 of Annex VII to Regulation (EU) 2017/746, starting on the day the notified body initiates the assessment of the technical documentation of the device or the representative device and ending on the day in which the final review referred to in Section 4.7 of Annex VII to Regulation (EU) 2017/745 or in Section 4.7 of Annex VII to Regulation (EU) 2017/746, as applicable, is completed;
- (d) 15 days for the final decision and certification, starting on the day after the completion of the last relevant final review referred to in point (b) or (c), depending on the conformity assessment procedure requested, and ending on the day the certificates are issued in accordance with Section 4.8 of Annex VII to Regulation (EU) 2017/75 or with Section 4.8 of Annex VII to Regulation (EU) 2017/746, as applicable.

The conformity assessment activities referred to in points (b) and (c) of the first subparagraph of this paragraph shall be conducted in parallel when carried out in accordance with Annex IX to Regulation (EU) 2017/745 or with Annex IX to Regulation (EU) 2017/746, as applicable, provided that the required input from the assessment of the relevant technical documentation is taken into account when developing the audit programme.

3. The notified body shall complete the assessment of a planned substantial change to the quality management system or to the device range covered by an EU quality management system certificate or an EU quality assurance certificate, and the assessment of a change to the approved device covered by an EU technical documentation assessment certificate or an EU type-examination certificate, in the following maximum timelines:

- (a) 30 days for reviewing the proposed planned change, starting on the day the notified body receives from the manufacturer information on the planned change with completed documentation, and ending on the day in which the notified body notifies the manufacturer of the decision on whether any additional conformity assessment activities are needed or of the approval of the planned change;
- (b) 90 days for the additional conformity assessment activities of the planned change, starting on the day the notified body initiates, where necessary, the audit programme's first activity or on the day the notified body initiates the assessment of the technical documentation, whichever is the earlier, and ending the day the notified body notifies the manufacturer of the approval of the planned change;
- (c) 15 days for issuing the supplement to the concerned certificate(s), where necessary, starting on the day following that of the notification of the approval of the planned change as referred to in point (a) or (b), and ending on the date of issuance of the supplement to the concerned certificate(s).

Where a new conformity assessment procedure is necessary, the timelines referred to in paragraph 2 shall apply.

### *Article 3*

#### **Interruption of work on conformity assessments**

1. Where there is a need for a manufacturer to address non-compliances, questions and other requests from the notified body, the notified body may interrupt the work on the conformity assessment activities for a maximum of:
  - (a) one time for the phase referred to in Article 2(2), point (a);
  - (b) three times for the phase referred to in Article 2(2), point (b);
  - (c) three times for the phase referred to in Article 2(2), point (c);
  - (d) four times in total for the phases referred to in Article 2(3), points (a) and (b);
  - (e) twice in total for the reviews and verifications referred to in Articles 6 and 7.

The notified body shall agree with the manufacturer on the duration of the interruption and inform the manufacturer in writing.

2. The timeline is interrupted on the day the notified body informs the manufacturer of its requests and resumes on the day when the notified body receives the requested information from the manufacturer.
3. In addition to the interruptions referred to in paragraph 1, the notified body shall interrupt the work on the conformity assessment where an opinion of the EMA, a regulatory authority, an expert panel or an EU reference laboratory is needed.

Such interruption shall not be counted and cumulated with those referred to in paragraph 1.

The notified body shall inform the manufacturer in writing about the reason for the interruption referred to in the first subparagraph and its expected duration.



4. The duration of any of the interruptions referred to in paragraph 1 shall be extended only if duly justified and the notified body and the manufacturer agree on the extension in writing.

#### *Article 4*

##### **Monitoring of the duration and costs**

1. The notified body shall establish, document and implement, as part of its quality management system, a system to monitor the duration of conformity assessment activities and their costs, to ensure that those activities meet the requirements referred to in Section 2.1 of Annex VII of Regulation (EU) 2017/745 and in Section 2.1 of Annex VII of Regulation (EU) 2017/746.
2. The monitoring system referred to in paragraph 1 shall provide the following information:
  - (a) on the duration of conformity assessment activities:
    - (i) percentage of conformity assessment activities completed in accordance with the maximum timelines set out in Article 2;
    - (ii) minimum, maximum and median duration of conformity assessment activities from the date of application to the date of certification, in days;
    - (iii) percentage of conformity assessment activities for which a specific procedure referred to in Section 4.5.6 of Annex VII to Regulation (EU) 2017/745 and in Section 4.5.5 of Annex VII to Regulation (EU) 2017/746 was carried out;
  - (b) on the costs of conformity assessment activities:
    - (i) minimum, maximum and median total cost of completed conformity assessment activities, in Euro;
    - (ii) median of the percentage of extra costs not estimated by the initial quotation, calculated on the total cost;
    - (iii) percentage of travel and accommodation costs, calculated on the total cost.

The total cost of a conformity assessment activities shall be understood as the sum of all the fees applied by a notified body to a manufacturer for the activities performed during the timeline.

3. The monitoring system referred to in paragraph 1 shall provide the information referred to in paragraph 2, points (a) and (b), for the following activities:
  - (a) conformity assessment activities carried out in accordance with Chapters I and II of Annex IX, Annex X and Parts A or B of Annex XI to Regulation (EU) 2017/745, or Chapters I and II of Annex IX, Annex X and Annex XI to Regulation (EU) 2017/746;
  - (b) the assessment of the changes referred to in Article 2(3).
4. By 30 April of every year, the notified body shall draw up an annual report on timelines and costs of conformity assessment activities that presents the information referred to in paragraphs 2 and 3. It shall consider, in the report, the conformity

assessment activities it completed during the previous year. The notified body shall publish the report on its website and provide it to the Commission.

Information referred to in paragraph 2 as regards minimum and maximum timeline and minimum and maximum costs referred to in point (a)(ii) and (b)(i), respectively, shall not be included in the annual report where the number of conformity assessment activities in the previous year is equal to or lower than five.

## *Article 5*

### **Launch of re-certification**

1. For the purpose of re-certification reviews, renewal of certificates and assessment of information received from the manufacturer referred to in Section 4.11, first, second and third paragraphs, of Annex VII to Regulation (EU) 2017/745 or in Section 4.11, first, second and third paragraphs of Annex VII to Regulation (EU) 2017/746, as applicable, the notified body shall have documented procedures that ensure that manufacturers are informed that the EU quality management system certificate or the EU quality assurance certificate, the EU technical documentation assessment certificates or the EU type-examination certificates is expiring and that the manufactures are to lodge an application for the re-certification reviews.
2. The notified body shall inform manufacturers at least one year before the date of expiry of the certificates referred to in paragraph 1.

## *Article 6*

### **Re-certification for product certificates**

1. The notified body shall ensure that the documented procedures for the renewal of product certificates referred to in Section 4.11, second paragraph, of Annex VII to Regulation (EU) 2017/745 or Section 4.11, second paragraph, of Annex VII to Regulation (EU) 2017/746, as applicable, require the manufacturer to lodge an application for the re-certification reviews and to provide the following information from the initial certification or the last re-certification:
  - (a) a list that describes the changes, notified or not, referred to in Section 4.11, second paragraph, points (a) and (f), of Annex VII to Regulation (EU) 2017/745 or Section 4.11, second paragraph, of Annex VII to Regulation (EU) 2017/746, as applicable, to the originally approved device, including those to the device requirements and the device components;
  - (b) the most recent periodic safety update report of the device and a summary of the field safety corrective actions taken on the device, following the experience from post-market surveillance referred to in Section 4.11, second paragraph, point (b), of Annex VII to Regulation (EU) 2017/745 or Section 4.11, second paragraph, point (b), of Annex VII to Regulation (EU) 2017/746, as applicable;
  - (c) a summary of changes of the risk evaluation of a device, including those related to the field safety corrective actions taken following the experience from the risk management referred to in Section 4.11, second paragraph, point (c), of Annex VII to Regulation (EU) 2017/745 or Section 4.11, second paragraph, point (c), of Annex VII to Regulation (EU) 2017/746, as applicable;

- (d) identification of the changes made to the device to take into account the state of the art, following the experience referred to in Section 4.11, second paragraph, point (d), of Annex VII to Regulation (EU) 2017/745 or Section 4.11, second paragraph, point (d), of Annex VII to Regulation (EU) 2017/746, as applicable;
  - (e) the most recent clinical evaluation report or performance evaluation report of the device, following the experience referred to in Section 4.11, second paragraph, point (e), of Annex VII to Regulation (EU) 2017/745 or Section 4.11, second paragraph, point (e), of Annex VII to Regulation (EU) 2017/746, as applicable;
  - (f) identification of the changes referred to in Section 4.11, second paragraph, point (g), of Annex VII to Regulation (EU) 2017/745 or Section 4.11, second paragraph, point (g), of Annex VII to Regulation (EU) 2017/746, as applicable, made to the device.
2. The notified body shall ensure that the documented procedures referred to in paragraph 1 require the manufacturer to provide also a list of changes to the approved device which are not yet notified and are necessary to:
- (a) ensure the device complies with new regulatory requirements or new common specifications;
  - (b) take into consideration new scientific findings and new standards including harmonised standards, as referred to in Section 4.11, second paragraph, points (g) and (h) of Annex VII to Regulation (EU) 2017/745 or Section 4.11, second paragraph, points (g) and (h), of Annex VII to Regulation (EU) 2017/746, as applicable.

Where such changes are necessary on the basis of new scientific findings, the manufacturer shall indicate, in the list referred to in the first subparagraph, if that basis is:

- (a) new medical, scientific and technical knowledge, such as new medical procedures;
  - (b) new or revised testing methods of the properties and performances of the device;
  - (c) scientific findings on materials, including findings on their physical, chemical and microbiological characteristics and biocompatibility;
  - (d) results of clinical investigations on equivalent devices and publicly available data from registers and registries.
3. The notified body shall review the documentation referred to in paragraphs 1 and 2, received from the manufacturer, within 60 days at the maximum from the date of its receipt. In that review, the notified body shall verify:
- (a) that the changes to the device are coherent with the information gathered from the post-market surveillance;
  - (b) that the changes to the device are coherent with the changes to the state of the art and the outcome of the updated risk analysis;
  - (c) that all non-compliances identified are either resolved or followed up by adequate and accepted corrective actions and preventive actions plan with appropriate timelines;

- (d) where the certification was subject to conditions or limitations, whether those conditions or limitations are still valid, need to be amended or have become obsolete;
- (e) whether the scope of the certificate needs to be amended.

#### *Article 7*

##### **Re-certification for quality management system certificates**

The notified body shall ensure that the documented procedures for the renewal of the quality management system certificates referred to in Section 4.11, first paragraph, of Annex VII to Regulation (EU) 2017/745 or Section 4.11, first paragraph, of Annex VII to Regulation (EU) 2017/746, as applicable, shall require the manufacturers to lodge an application for the re-certification and the notified body to verify, within 60 days at the maximum from the date of receipt of such application:

- (a) that all the relevant requirements for conducting audits provided for in Section 4.5.2 of Annex VII and Sections 2.2 and 2.3 of Annex IX to Regulation (EU) 2017/745 or in Section 4.5.2 of Annex VII and Sections 2.2 and 2.3 of Annex IX to Regulation (EU) 2017/746, as applicable, have been fully assessed at least once after the date of issuance of the certificates and before their expiry date.
- (b) that the results of all surveillance activities carried out, announced or unannounced, in accordance with Section 4.10 of Annex VII to Regulation (EU) 2017/745 or with Section 4.10 of Annex VII to Regulation (EU) 2017/746, as applicable, during the certification cycle, especially on-site audits of the manufacturer, its subcontractors / suppliers, and product tests carried out, as well as the outcome of technical documentation assessments on a sampling basis, still comply with the relevant provisions of Regulation (EU) 2017/745 or Regulation (EU) 2017/746, as applicable;
- (c) whether the audit programme and the sampling plan drawn up according to Section 4.5.2 (a) of Annex VII to Regulation (EU) 2017/745 or according to Section 4.5.2 (a) of Annex VII to Regulation (EU) 2017/746, as applicable, are still up to date or need to be amended;
- (d) that all non-compliances identified are either resolved or followed up by an adequate and accepted corrective actions and preventive actions plan with appropriate timelines;
- (e) where the certification was subject to conditions or limitations, whether those conditions or limitations are still valid, need to be amended or have become obsolete;
- (f) whether the scope of the certificate needs to be amended.

#### *Article 8*

##### **Decision on re-certification**

1. For the purpose of taking the decision on re-certification referred to in Section 4.11, fourth paragraph, of Annex VII to Regulation (EU) 2017/745 and in Section 4.11, fourth paragraph, of Annex VII to Regulation (EU) 2017/746, the notified body shall limit, within its documented procedures, re-certification activities to assessing the documentation referred to in Article 6(1) and (2) and Article 7, as applicable. If the

notified body finds that the documentation received for the re-certification reviews is not sufficient to complete the assessment, it shall ask the manufacturer to provide clarification. Requests to provide additional technical documentation to that specified in Article 6(1) and (2) shall be limited to the specific evidence necessary to complete the assessment.

2. The notified body shall ensure that, within its documented procedures, the certificates are re-issued within a maximum period of 15 days, starting on the day after that of the positive decision on recertification and ending on the day the certificates are issued.

## *Article 9*

### **Transitional provisions**

1. Articles 2 and 3 shall not apply to conformity assessment procedures for which the notified body and the manufacturer signed a written agreement before [*OP please insert the date: date of entry into force of this Regulation + 3 months*].
2. Article 4(1), (2) and (3) shall apply to conformity assessment procedures for which the notified body and the manufacturer signed a written agreement after [*OP please insert the date: date of entry into force of this Regulation + 12 months*].
3. Articles 5, 6 and 7 shall not apply to re-certification reviews of certificates expiring before [*OP please insert the date: date of entry into force of this Regulation + 6 months + 365 days*].

## *Article 10*

### **Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*OP please insert the date: date of entry into force of this Regulation + 3 months*].

However, Article 4(4) shall apply from 1 January 2028.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*