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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

(Text with EEA relevance)

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 ([1]), 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 ([2]), and in particular Article 32(3) thereof,

Whereas:

(1) Regulations (EU) 2017/745 and (EU) 2017/746 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.

(4) The individual practices that notified bodies apply as regards quality management and procedural requirements diverge significantly, thus putting manufacturers in unequal positions 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 assessment activities. 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

([1]) OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.
([2]) OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj.

conformity assessment activities are not rejected because they are incomplete or because the device is outside the scope of the notified body's designation. Notifies 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 ([3]).

(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 Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises ([4]).

(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 sufficiently detailed 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.

(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. Where a framework agreement exists between the notified body and the manufacturer, the signature of the contract should be understood as the signature of the contract for the specific conformity assessment activity.

(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.

([3]) 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, ELI: http://data.europa.eu/eli/reg_impl/2017/2185/oj).

([4]) 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).

(14) Timelines for product verification should be specific to class III or class IIb implantable devices and to class D *in vitro* diagnostic medical 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, as well as for class B and class C devices and for specific *in vitro* diagnostic medical devices, such as companion diagnostics, near-patient testing and self-testing 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 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 the timeline of a conformity assessment activity where the completion of such an activity depends upon further information to be provided by the manufacturer. The timeline 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 publish the reports on their websites, to ensure transparency on their performances and to allow manufacturers to compare information between notified bodies, and inform the authority responsible for the notified body and the Commission.

(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 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, 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 or 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 that are relevant for the conformity assessment 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 conformity assessment procedure(s) for which the manufacturer applies;

(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 possible scope change(s) described as referred to in point (h);

(j) any other information regarding the manufacturer, such as its organisational structure or valid certificates, and regarding the device, which are necessary to estimate the activities to be performed.

For the purpose of issuing quotations for conformity assessment activities related to changes and modifications as referred to in points (h) or re-certification referred to in point (i), the notified body shall refrain from seeking the information referred to in points (b) to (g), provided that the manufacturer confirms there have been no changes to the information submitted.

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) the estimated timeline(s).

4. The notified body shall inform the manufacturer in advance about any increase above 10 % of the estimated costs, giving 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.

2. The notified body shall 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 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 or 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 each device or each 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) 20 days for the 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 and entered in the European database on medical devices ('Eudamed') in accordance with Section 4.8 of Annex VII to Regulation (EU) 2017/745 or 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 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.

Unless otherwise agreed between the notified body and the manufacturer, the activities referred to in points (b) and (c) of the first subparagraph of this paragraph shall start the day after the signature of the contract referred to in point (a) of the first subparagraph of this paragraph.

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) 20 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 the supplement to the concerned certificate(s) is issued and entered in Eudamed, in accordance with Section 4.8 of Annex VII to Regulation (EU) 2017/745 or Section 4.8 of Annex VII to Regulation (EU) 2017/746, as applicable.

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

4. The notified body shall continue the conformity assessment activities until a decision on issuing or refusing a certificate is made. Expiry of the maximum timelines referred to in paragraphs 2 and 3 or the use of the maximum number of interruptions referred to in Article 3 shall not be sufficient reason for the notified body to refuse issuing a certificate or refuse approving a change.

Article 3

Interruption of timeline

1. Where there is a need for a manufacturer to address non-compliances, or duly justified questions and requests from the notified body that are necessary for its assessment, the notified body may interrupt the timeline of the conformity assessment activities for a maximum of:

(a) one time for the phase referred to in Article 2(2), point (a);

(b) four times for the phase referred to in Article 2(2), point (b);

(c) four times for the phase referred to in Article 2(2), point (c);

(d) five times in total for the phases referred to in Article 2(3), points (a) and (b);

(e) three times in total for the reviews and verifications referred to in Articles 5 and 6;

(f) one time for the phase referred to in Article 2(2), point (d), Article 2(3), point (c), and Article 7(2), where the notified body asks the manufacturer to verify the correctness of the information on the certificate(s) and, if necessary, to enter in Eudamed the relevant information on the device(s) covered.

Where the notified body and the manufacturer agree on a rolling review of the technical documentation, they shall also agree on a plan for submitting parts of the technical documentation and possible additional interruptions to those referred to in points (b) and (c) of the first subparagraph.

The notified body may use two additional interruptions to those referred to in point (b) of the first subparagraph for each additional site covered by the manufacturer's quality management system to be audited on-site.

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

2. The timeline of the conformity assessment activity is interrupted on the day the notified body informs the manufacturer of its requests and resumes, unless otherwise agreed, on the day after 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 timeline of the conformity assessment activity 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 as referred to in Section 2.1 of Annex VII to Regulation (EU) 2017/745 and in Section 2.1 of Annex VII to Regulation (EU) 2017/746, a system to monitor the duration of conformity assessment activities and their costs.

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) median duration of conformity assessment activities from the date of application to the date of certification, in days;

(b) on the costs of conformity assessment activities, the median total cost of completed conformity assessment activities, in euro.

The total costs of 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 including any administrative charges.

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 inform the authority responsible for the notified body and the Commission.

Article 5

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 that resulted in a different benefit-risk ratio 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.

3. Where the changes referred to in paragraph 2 are necessary on the basis of new scientific findings, the manufacturer shall indicate, in the list referred to in that paragraph, 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 or performance evaluations on equivalent devices and publicly available data from registers and registries.

4. The notified body shall assess the documentation referred to in paragraphs 1 and 2, received from the manufacturer, within 90 days at the maximum from the date of its receipt. As part of that assessment, the notified body shall:

(a) verify that the changes to the device are coherent with the information gathered from the post-market surveillance;

(b) verify 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) verify that all non-compliances identified are either resolved or followed up by an adequate and accepted corrective actions and preventive actions plan within an appropriate period of time;

(d) where the certification was subject to conditions or limitations, verify whether those conditions or limitations are still valid, need to be amended or have become obsolete;

(e) verify whether the scope of the certificate needs to be amended;

(f) complete 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.

5. 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 paragraphs 1 and 2 shall be limited to the specific information necessary to complete the assessment.

Article 6

Re-certification for quality management system certificates

1. 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, within 90 days at the maximum from the date of receipt of such application, the notified body to:

(a) verify 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) verify 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) verify 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) verify that all non-compliances identified are either resolved or followed up by an adequate and accepted corrective actions and preventive actions plan within an appropriate period of time;

(e) where the certification was subject to conditions or limitations, verify whether those conditions or limitations are still valid, need to be amended or have become obsolete;

(f) verify whether the scope of the certificate needs to be amended;

(g) complete 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.

2. If the notified body finds that information from the manufacturer, additional to that referred to in paragraph 1, points (b) to (f), is necessary to complete the assessment for the re-certification reviews, it shall ask the manufacturer to provide such information. Requests to provide that additional information shall be limited to the specific information necessary to complete the assessment.

Article 7

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 5(1) and (2) and Article 6(1), as applicable.

2. The notified body shall ensure that, within its documented procedures, the decision is made and the certificates are re-issued within a maximum period of 20 days, starting on the day after the final review referred to in Article 5(4), point (f), or Article 6(1), point (g), of this Regulation, as applicable, is completed and ending on the day the certificates are issued and entered in Eudamed, in accordance with Section 4.8 of Annex VII to Regulation (EU) 2017/745 or Section 4.8 of Annex VII to Regulation (EU) 2017/746, as applicable.

3. Where the decision on the renewal of the certificate is made earlier than three months before the expiry date of the certificate, by way of derogation from paragraph 2 the maximum period of 20 days shall start three months before the expiry date of such certificate.

Article 8

Transitional provisions

1. Articles 1, 2 and 3 shall not apply to conformity assessment procedures for which the notified body and the manufacturer signed a written agreement before 25 February 2027.

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 25 May 2027.

3. Articles 5, 6 and 7 shall not apply to re-certification reviews of certificates expiring before 25 November 2027.

Article 9

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 25 February 2027.

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, 4 May 2026.

For the Commission
The President
Ursula VON DER LEYEN