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 (Text with EEA relevance)

CHAPTER V

CLASSIFICATION AND CONFORMITY ASSESSMENT

Section 2

Conformity assessment

Article 48

Conformity assessment procedures

1 Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

2 Prior to putting into service a device that is not placed on the market, with the exception of in-house devices manufactured pursuant to Article 5(5), manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

3 Manufacturers of class D devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I, II except for Section 5, and in Chapter III of Annex IX.

In addition to the procedures referred to in the first subparagraph, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for technical documentation assessment set out in Section 5.1 of Annex IX.

In addition to the procedures referred to in the first and second subparagraphs, for companion diagnostics, the notified body shall consult a competent authority designated by the Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council[(1)] or the EMA, as applicable, in accordance with the procedure set out in Section 5.2 of Annex IX.

4 Manufacturers of class D devices, other than devices for performance study, may, instead of the conformity assessment procedure applicable pursuant to paragraph 3, choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI.

For companion diagnostics, the notified body shall in particular consult a competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, as applicable, in accordance with the procedure set out in point (k) of Section 3 of Annex X.

5 In particular, and without prejudice to any of the obligations pursuant to the other procedures referred to in paragraphs 3 and 4, for devices for which one or more EU reference

laboratories have been designated in accordance with Article 100, the notified body performing the conformity assessment shall request one of the EU reference laboratories to verify by laboratory testing the performance claimed by the manufacturer and the compliance of the device with the applicable CS, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 4.9 of Annex IX and in point (j) of Section 3 of Annex X. Laboratory tests performed by an EU reference laboratory shall in particular focus on analytical and diagnostic sensitivity using the best available reference materials.

6 In addition to the procedure applicable pursuant to paragraphs 3 and 4, where no CS are available for class D devices and where it is also the first certification for that type of device, the notified body shall consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 on the performance evaluation report of the manufacturer. To that end, the notified body shall provide the performance evaluation report of the manufacturer to the expert panel within five days of receiving it from the manufacturer. The relevant experts shall, under the supervision of the Commission, provide their views, in accordance with Section 4.9 of Annex IX or point (j) of Section 3 of Annex X, as applicable, to the notified body within the deadline for delivery of the scientific opinion by the EU reference laboratory as specified therein.

7 Manufacturers of class C devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex of at least one representative device per generic device group.

In addition to the procedures referred to in the first subparagraph, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for technical documentation assessment set out in Section 5.1 of Annex IX.

In addition to the procedures referred to in the first and second subparagraphs, for companion diagnostics the notified body shall for every device follow the procedure for technical documentation assessment laid down in Section 5.2 of Annex IX, and shall apply the procedure for technical documentation assessment laid down in Sections 4.1 to 4.8 of Annex IX and shall consult the competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, as applicable, in accordance with the procedure set out in Section 5.2 of Annex IX.

8 Manufacturers of class C devices, other than devices for performance study, may, instead of the conformity assessment procedure pursuant to paragraph 7, choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI except its Section 5.

For companion diagnostics the notified body shall in particular for every device consult a competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, as applicable, in accordance with the procedure set out in point (k) of Section 3 of Annex X.

9 Manufacturers of class B devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex for at least one representative device per category of devices.

In addition to the procedures referred to in the first subparagraph, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for assessment of the technical documentation set out in Section 5.1 of Annex IX.

10 Manufacturers of class A devices, other than devices for performance study, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 17, after drawing up the technical documentation set out in Annexes II and III.

However, if those devices are placed on the market in sterile condition, the manufacturer shall apply the procedures set out in Annex IX or in Annex XI. Involvement of the notified body shall be limited to the aspects relating to establishing, securing and maintaining sterile conditions.

11 Devices for performance studies shall be subject to the requirements set out in Articles 57 to 77.

12 The Member State in which the notified body is established may require that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 10 be made available in an official Union language(s) determined by that Member State. In the absence of such requirement, those documents shall be available in any official Union language acceptable to the notified body.

13 The Commission may, by means of implementing acts, specify the detailed arrangements and procedural aspects with a view to ensuring the harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects:

a the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in third paragraph of Section 2.3. and in Section 3.5 of Annex IX, in the case of class C devices;

b the minimum frequency of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

c the frequency of samples of the manufactured devices or batches of class D devices to be sent to an EU reference laboratory designated under Article 100 in accordance with Section 4.12 of Annex IX and Section 5.1 of Annex XI; or

d the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of technical documentation and type examination in accordance with Sections 3.4 and 4.3 of Annex IX and points (f) and (g) of Section 3. of Annex X.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 49

Involvement of notified bodies in conformity assessment procedures

1 Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned. The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

2 The notified body concerned shall, by means of the electronic system referred to in Article 52, inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment.

3 When applying to a notified body under paragraph 1, manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body and provide information about any previous application for the same conformity assessment that has been refused by another notified body.

4 The notified body may require any information or data from the manufacturer, which is necessary in order to properly conduct the chosen conformity assessment procedure.

5 Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

Article 50

Mechanism for scrutiny of conformity assessments of class D devices

1 A notified body shall notify the competent authority of certificates it has granted for class D devices, with the exception of applications to supplement or renew existing certificates. Such notification shall take place through the electronic system referred to in Article 52 and shall include the instructions for use referred to in Section 20.4 of Annex I, the summary of safety and performance referred to in Article 29, the assessment report by the notified body, and, where applicable, the laboratory tests and the scientific opinion by the EU reference laboratory pursuant to the second subparagraph of Article 48(3), and where applicable the views expressed in accordance with Article 48(4) by the experts referred to in Article 106 of Regulation (EU) 2017/745. In the case of divergent views between the notified body and the experts, a full justification shall also be included.

2 A competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures in accordance with Article 40, 41, 42, 43 or 89 and, where deemed necessary, take appropriate measures in accordance with to Articles 90 and 92.

3 The MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device.

Article 51

Certificates of conformity

1 The certificates issued by the notified bodies in accordance with Annexes IX, X and XI shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates shall be as set out in Annex XII.

2 The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

3 Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or users or require manufacturers to undertake specific PMPF studies pursuant to Part B of Annex XIII.

4 Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

5 The notified body shall enter in the electronic system referred to in Article 52 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public.

6 In the light of technical progress, the Commission is empowered to adopt delegated acts in accordance with Article 108 amending the minimum content of the certificates set out in Annex XII.

Article 52

Electronic system on notified bodies and on certificates of conformity

For the purposes of this Regulation, the following information shall be collated and processed pursuant to Article 57 of Regulation (EU) 2017/745 in the electronic system set up in accordance with that Article:

(a) the list of subsidiaries referred to in Article 33(2);

(b) the list of experts referred to in Article 36(2);

(c) the information relating to the notification referred to in Article 38(10) and the amended notifications referred to in Article 42(2);

(d) the list of notified bodies referred to in Article 39(2);

(e) the summary of the report referred to in Article 40(12);

(f) the notifications for conformity assessments and certificates referred to in Article 50(1);

(g) withdrawal or refusals of applications for the certificates as referred to in Article 49(2) and Section 4.3 of Annex VII;

(h) the information regarding certificates referred to in Article 51(5);

(i) the summary of safety and performance referred to in Article 29.

Article 53

Voluntary change of notified body

1 In cases where a manufacturer terminates its contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the detailed arrangements for the change of notified body shall be clearly defined in

an agreement between the manufacturer, the incoming notified body and, where practicable the outgoing notified body. That agreement shall cover at least the following aspects:

a the date on which the certificates issued by the outgoing notified body become invalid;

b the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;

c the transfer of documents, including confidentiality aspects and property rights;

d the date after which the conformity assessment tasks of the outgoing notified body is assigned to the incoming notified body;

e the last serial number or lot number for which the outgoing notified body is responsible.

2 The outgoing notified body shall withdraw the certificates it has issued for the device concerned on the date on which they become invalid.

Article 54

Derogation from the conformity assessment procedures

1 By way of derogation from Article 48, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the procedures referred to in that Article have not been carried out but use of which is in the interest of public health or patient safety or health.

2 The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

3 Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(4).

Article 55

Certificate of free sale

1 For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the CE-marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall set out the Basic UDI-DI of the device as provided to the UDI database under Article 26. Where a notified body has issued a certificate

pursuant to Article 51, the certificate of free sale shall set out the unique number identifying the certificate issued by the notified body, as referred to in Section 3 of Chapter II of Annex XII.

2 The Commission may, by means of implementing acts, establish a model for certificates of free sale, taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 107(2).

(**1**) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).