Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (Text with EEA relevance)

Article 1

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) ‘device’ means active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC or medical devices and their accessories as defined in Article 1(2) of Directive 93/42/EEC;

(b) ‘conformity assessment body’ means a body which performs calibration, testing, certification and inspection activities under Article R1(13) in Annex I to Decision No 768/2008/EC of the European Parliament and of the Council[(1)];

(c) ‘notified body’ means a conformity assessment body which has been notified by a Member State in accordance with Article 11 of Directive 90/385/EEC or Article 16 of Directive 93/42/EEC;

(d) ‘accreditation body’ means the sole body in a Member State that performs accreditation with authority derived from the State as laid down by Article 2(10) of Regulation (EC) No 765/2008;

(e) ‘designating authority’ means the authority(ies) entrusted by a Member State to assess, designate, notify and monitor notified bodies under Directive 90/385/EEC or Directive 93/42/EEC;

(f) ‘competent authority’ means the authority(ies) in charge of market surveillance and/or of vigilance for devices;

(g) ‘on-site assessment’ means a verification in the premises of the body or of one of its subcontractors or subsidiaries by the designating authority;

(h) ‘surveillance on-site assessment’ means a periodic routine on-site assessment which is neither the on-site assessment undertaken for the initial designation, nor the on-site assessment undertaken for the renewal of the designation;

(i) ‘observed audit’ means a designating authority's assessment of the performance of a notified body’s audit team in the premises of the body's client;

(j) ‘functions’ means the tasks to be fulfilled by the body’s staff and its external experts, namely: auditing of the quality systems, product related technical documentation review, review of clinical evaluations and investigations, device testing and, for each of the previously mentioned items, the final review and decision making thereon;

(k) ‘subcontracting’ means the transfer of tasks to one of the following:

  (i) a legal person;

  (ii) a natural person who further delegates these tasks or parts thereof;

(iii) several natural or legal persons who jointly perform these tasks.

Article 2

Interpretation of designation criteria

The criteria set out in Annex 8 to Directive 90/385/EEC or in Annex XI to Directive 93/42/EEC shall be applied as laid down in Annex I.

Article 3

Procedure for the designation of notified bodies

1 When applying for designation as a notified body, a conformity assessment body shall use the application form set out in Annex II. If the conformity assessment body submits the application and documents annexed to the application on paper, it shall also submit an electronic copy of the application and its annexes.

The application shall specify the conformity assessment activities, the conformity assessment procedures and the fields of competence for which the conformity assessment body wishes to be notified, the latter by indicating the codes used in the 'New Approach Notified and Designated Organisations' Information System[(2)] and subdivisions of those fields.

2 The designating authority of the Member State where the conformity assessment body is established shall assess that body in accordance with an assessment check-list that covers at least the items listed in Annex II. The assessment shall include an on-site assessment.

Representatives of designating authorities of two other Member States shall, in coordination with the designating authority of the Member State in which the conformity assessment body is established and together with a representative of the Commission, participate to the assessment of the conformity assessment body, including the on-site assessment. The designating authority of the Member State where the conformity assessment body is established shall give those representatives timely access to the documents necessary to assess the conformity assessment body. They shall produce within 45 days after the on-site assessment a report, which shall contain at least a summary of identified non-compliances with the criteria set out in Annex I and recommendation with regard to the designation of the notified body.

3 The Member States shall make available a pool of assessors for the Commission to call upon for each assessment.

4 The designating authority of the Member State where the conformity assessment body is established shall upload into a data storage system managed by the Commission, the assessment report drafted by the representatives referred to in paragraph 2, its own assessment report and, if not contained therein, an on-site assessment report.

5 The designating authorities of all the other Member States shall be informed of the application and may request to get access to certain or all the documents referred to in paragraph 4. Those authorities and the Commission may review all the documents referred to in paragraph 4, may raise questions or concerns and may request further documentation within one month after the last upload of one of those documents. Within the same period of time, they may request an exchange of views on the application, organised by the Commission.

6 The designating authority of the Member State where the conformity assessment body is established shall respond to the questions, concerns and requests for further documentation within four weeks following their receipt.

The designating authorities of the other Member States or the Commission may individually or jointly address recommendations to the designating authority of the Member State where the conformity assessment body is established within four weeks following the receipt of the response. That designating authority shall take account of the recommendations when it takes the decision on the designation of the conformity assessment body. If it does not follow the recommendations, it shall give the reasons therefor within two weeks after its decision.

7 The Member State shall notify to the Commission its decision on the designation of a conformity assessment body by means of the 'New Approach Notified and Designated Organisations' Information System.

The validity of the designation shall be limited up to a maximum of five years.

Article 4

Extension and renewal of designation

1 An extension of the scope of the notified body's designation may be granted in accordance with Article 3.

2 A designation as notified body may be renewed in accordance with Article 3 before the end of the validity period of the previous designation.

3 For the purposes of paragraph 2, the procedure set out in Article 3(2) shall include, where appropriate, an observed audit.

4 Extension and renewal procedures may be combined.

5 Notified bodies already designated before the entry into force of this Regulation and for which the designation does not have a stated validity period or has a validity period exceeding five years, shall be subject to renewal at least within three years of entry into force of this Regulation.

[[F1]6 By way of derogation from paragraph 2, during the period from 19 May 2020 to 25 May 2021, the designating authority of a Member State, in extraordinary circumstances resulting from the COVID-19 pandemic and due to the adoption of Regulation (EU) 2020/561 of the European Parliament and of the Council[(3)] deferring the application of certain provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council[(4)], may decide to renew a designation as notified body without having recourse to the procedures laid down in Article 3.

In order to decide on the renewal of a designation as notified body in accordance with the first subparagraph, the designating authority shall carry out an assessment in order to verify the continuous competence of the notified body and its ability to perform the tasks for which it was designated.

The decision on the renewal of a designation as notified body in accordance with this paragraph shall be adopted before the end of the validity period of the preceding designation and shall automatically become void at the latest on 26 May 2021.

The designating authority shall notify the Commission of its decision, giving substantive reasons therefore, on the renewal of a designation as notified body in accordance with this paragraph by means of the 'New Approach Notified and Designated Organisations' Information System.

The Commission may require a designating authority to provide it with the results of the assessment supporting the decision on the renewal of a designation as notified body in accordance with this paragraph, as well as the outcome of related surveillance and monitoring activities, including those referred to in Article 5.**]**

Textual Amendments

F1 Inserted by Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies (Text with EEA relevance).

Article 5

Surveillance and monitoring

1 For the purpose of surveillance, the designating authority of the Member State where the notified body is established shall assess an appropriate number of notified body's reviews of the manufacturer's clinical evaluations and shall carry out an appropriate number of file reviews, surveillance on-site assessments and observed audits at the following intervals:

a at least every 12 months for notified bodies with more than 100 clients;

b at least every 18 months for all other notified bodies.

That designating authority shall, in particular, examine changes which have occurred since the last assessment and the work the notified body has performed since that assessment.

[[F1]By way of derogation from the first and second subparagraphs, in exceptional circumstances relating to the COVID-19 pandemic that temporarily prevent the designating authority of a Member State from carrying out surveillance on-site assessments or observed audits, it shall carry out any measures to ensure an adequate level of surveillance that remain possible under those circumstances in addition to the assessment of an appropriate number of the notified body's reviews of the manufacturer's technical documentation, including clinical evaluations. That designating authority shall examine changes to the organisational and general requirements set out in Annex II that have occurred since the last on-site assessment and the activities the notified body has performed thereafter.**]**

2 Surveillance and monitoring conducted by the designating authorities shall appropriately address subsidiaries.

3 The designating authority of the Member State where the notified body is established shall continuously monitor that body to ensure ongoing compliance with the applicable requirements. That authority shall provide for a systematic follow-up of complaints, vigilance reports and other information, including from other Member States, which might indicate the non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

In addition to surveillance or renewal on-site assessments, the designating authority of the Member State where the notified body is established shall initiate unannounced or short-notice on-site assessments if those on-site assessments are needed to verify compliance.

Textual Amendments

F1 Inserted by Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies (Text with EEA relevance).

Article 6

Investigation of the competence of a notified body

1 The Commission may investigate cases regarding the competence of a notified body or the fulfilment of the requirements and responsibilities to which a notified body is subject under Directive 90/385/EEC and Directive 93/42/EEC.

2 Investigations will start with a consultation of the designating authority of the Member State where the notified body is established. Upon request, that designating authority shall, within four weeks, provide the Commission with all relevant information concerning the relevant notified body.

3 The Commission will ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 When the notified body no longer meets the requirements for its notification, the Commission will inform the Member State where that body is established and may request the Member State to take the necessary corrective measures.

Article 7

Exchange of experience on designation and supervision of conformity assessment bodies

1 Designating authorities shall consult each other and the Commission on questions with general relevance with regard to the implementation of this Regulation and the interpretation of the provisions of Directive 90/385/EEC and of Directive 93/42/EEC in relation with conformity assessment bodies.

2 Designating authorities shall communicate to each other and the Commission by 31 December 2013 the model assessment check-list used in accordance with Article 3(2) and thereafter the adaptations made to this check-list.

3 When the assessment reports referred to in Article 3(4) indicate discrepancies in the general practice of designating authorities, Member States or the Commission may request an exchange of views, which will be organised by the latter.

Article 8

Operating of designating authorities

1 Designating authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks. Those authorities shall be established, organised and operated so as to safeguard the objectivity and impartiality of their activities and to avoid any conflicts of interests with conformity assessment bodies. The designating authorities shall be organised so that each decision relating to a notification of a conformity assessment body is not taken by the same member of personnel who carried out the assessment of that body.

2 Where designating authorities are not in charge of market surveillance and vigilance for medical devices, they shall involve the competent authorities of that Member State for all tasks incumbent to them in accordance with this Regulation. They shall in particular consult the competent authorities of that Member State prior to taking decisions and invite them to attend all types of assessments.

Article 9

Cooperation with accreditation bodies

Where designation is based on accreditation in the meaning of Regulation (EC) No 765/2008, Member States shall ensure that the accreditation body that has accredited a particular notified body is kept informed by the competent authorities on incident reports and other information that relate to matters under the control of the notified body when the information may be relevant for the assessment of the performance of the notified body. Member States shall ensure that the accreditation body in charge of the accreditation of a particular conformity assessment body is kept informed by the designating authority of the Member State where the conformity assessment body is established on findings relevant for the accreditation. The accreditation body shall inform the designating authority of the Member State where the conformity assessment body is established on its findings.

Article 10

Entry into force and date of 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 to extension of designations as from 25 December 2013.

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

(**1**) OJ L 218, 13.8.2008, p. 82.

(**2**) 'NANDO'; see http://ec.europa.eu/enterprise/newapproach/nando

(**3**) **[**[F1]Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18).**]**

(**4**) **[**[F1]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 (OJ L 117, 5.5.2017, p. 1).**]**

Textual Amendments

F1 Inserted by Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies (Text with EEA relevance).

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 25 January 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.