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 **[**F1regulation 2(1) of the Medical Devices Regulations 2002**]**;

(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) **[**F2“approved body” has the same meaning as in regulation 2(1) of the Medical Devices Regulations 2002;**]**

(d) **[**F3“accreditation” means an attestation by a national accreditation body conveying formal recognition that a conformity assessment body is competent to carry out a specific activity;**]**

(e) F4...

(f) F5...

(g) ‘on-site assessment’ means a verification in the premises of the body or of one of its subcontractors or subsidiaries by the **[**F6Secretary of State**]**;

(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 **[**F7the Secretary of State’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.

Textual Amendments

F1 Words in Art. 1(a) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 17**

F2 Art. 1(c) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 18**

F3 Art. 1(d) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 19**

F4 Art. 1(e) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 20**

F5 Art. 1(f) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 20**

F6 Words in Art. 1(g) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 21**

F7 Words in Art. 1(i) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 22**

[F8 Article 1a

In this Regulation, any reference to Annex 8 to Directive 90/385 or to Annex XI to Directive 93/42 is to be construed as a reference to those Annexes as they applied immediately before IP completion day and as modified by Schedule 2A to the Medical Devices Regulations 2002.**]**

Textual Amendments

F8 Art. 1a inserted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 23**

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 [F9approved] bodies

1 When applying for designation as **[**F10an approved 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 **[**F11approved**]**, the latter by indicating the codes **[**F12found

in Guidance: UK approved bodies for medical devices https://www.gov.uk/publications/medical-devices-uk-approved-bodies-for-medical-devices.**]**

2 **[**F13The Secretary of State**]** 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.

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F15 3 . . . . . .

F15 4 . . . . . .

F15 5 . . . . . .

F15 6 . . . . . .

7 F16...

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

Textual Amendments

F9 Word in Art. 3 heading substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(a)**

F10 Words in Art. 3(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(b)**

F11 Word in Art. 3(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(c)(i)**

F12 Words in Art. 3(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(c)(ii)**

F13 Words in Art. 3(2) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(d)(i)**

F14 Words in Art. 3(2) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(d)(ii)**

F15 Art. 3(3)-(6) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(e)**

F16 Words in Art. 3(7) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(f)**

Article 4

Extension and renewal of designation

1 An extension of the scope of the **[**F17approved**]** body's designation may be granted in accordance with Article 3.

2 A designation as **[**F18an approved**]** 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.

[F19 5 An approved body, within the meaning of regulation A45(1)(b) of the Medical Devices Regulations 2002, whose designation does not have a stated validity period or has a validity period exceeding five years, is to be subject to a renewal within five years of IP completion day**]**

[F20 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(2) deferring the application of certain provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council(3), 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

F17 Word in Art. 4(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 25(a)**

F18 Words in Art. 4(2) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 25(b)**

F19 Art. 4(5) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 25(c)**

F20 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 **[**F21 Secretary of State**]** shall assess an appropriate number of **[**F22 approved**]** 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 **[**F22 approved**]** bodies with more than 100 clients;

b at least every 18 months for all other **[**F22 approved**]** bodies.

That designating authority shall, in particular, examine changes which have occurred since the last assessment and the work the **[**F22approved**]** body has performed since that assessment.

[F20By 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 **[**F22approved**]** body's reviews of the manufacturer's technical documentation, including clinical evaluations. **[**F23The Secretary of State**]** 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 **[**F22approved**]** body has performed thereafter.**]**

2 Surveillance and monitoring conducted by the **[**F24Secretary of State**]** shall appropriately address subsidiaries.

3 **[**F25The Secretary of State shall continuously monitor that body to ensure ongoing compliance with the applicable requirements. The Secretary of State shall provide for a systematic follow-up of complaints, vigilance reports and other information, including from outside the United Kingdom, which might indicate the non-fulfilment of the obligations by an approved body or its deviation from common or best practice.**]**

In addition to surveillance or renewal on-site assessments, the **[**F26Secretary of State**]** shall initiate unannounced or short-notice on-site assessments if those on-site assessments are needed to verify compliance.

Textual Amendments

F20 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).

F21 Words in Art. 5(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(a)(ii)**

F22 Word in Art. 5(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(a)(i)**

F23 Words in Art. 5(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(a)(iii)**

F24 Words in Art. 5(2) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(b)**

F25 Words in Art. 5(3) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(c)(i)**

F26 Words in Art. 5(3) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(c)(ii)**

[F27*Article 6*

Investigation of the competence of an approved body

The Secretary of State may investigate cases regarding the competence of an approved body or the fulfilment of the requirements and responsibilities to which an approved body is subject under the Medical Devices Regulations 2002.**]**

Textual Amendments

F27 Art. 6 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 27**

F28 Article 7

Exchange of experience on designation and supervision of conformity assessment bodies

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Textual Amendments

F28 Art. 7 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 28**

F29 Article 8

Operating of designating authorities

. . . . . .

Textual Amendments

F29 Art. 8 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 28**

F30 Article 9

Cooperation with accreditation bodies

Where designation is based on accreditation within the meaning of Regulation (EC) No 765/2008, the Secretary of State shall ensure that the accreditation body that has accredited a particular approved body is kept informed of incident reports and other information that relate to matters under the control of the approved body when the information may be relevant for the assessment of the performance of the approved body. The Secretary of State must ensure that the accreditation body in charge of the accreditation of a particular conformity assessment body is kept informed of findings relevant for the accreditation. The accreditation body shall inform the Secretary of State of its findings.

Textual Amendments

F30 Art. 9 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 29**

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.

F31 …

Textual Amendments

F31 Words in Signature omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 30**

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

(**2**) **[**[F20]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).**]**

(**3**) **[**[F20]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

F20 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 11/08/2021.

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 04 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.