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 4

Extension and renewal of designation

1 An extension of the scope of the **[**F1approved**]** body's designation may be granted in accordance with Article 3.

2 A designation as **[**F2an 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.

[F35 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**]**

[F46 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(1) deferring the application of certain provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council(2), 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 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)**

F2 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)**

F3 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)**

F4 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).

(1) **[**[F4]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).**]**

(2) **[**[F4]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

F4 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).

Changes to legislation:
Commission Implementing Regulation (EU) No 920/2013, Article 4 is up to date with all changes known to be in force on or before 22 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.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation revoked by S.I. 2002/618, reg. 4L(1)(2) (as inserted) by S.I. 2019/791 reg. 3(7)