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 5

Surveillance and monitoring

1 For the purpose of surveillance, the **[**F1Secretary of State**]** shall assess an appropriate number of **[**F2approved**]** 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 **[**F2approved**]** bodies with more than 100 clients;

b at least every 18 months for all other **[**F2approved**]** bodies.

That designating authority shall, in particular, examine changes which have occurred since the last assessment and the work the **[**F2approved**]** body has performed since that assessment.

[F3By 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 **[**F2approved**]** body's reviews of the manufacturer's technical documentation, including clinical evaluations. **[**F4The 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 **[**F2approved**]** body has performed thereafter.**]**

2 Surveillance and monitoring conducted by the **[**F5Secretary of State**]** shall appropriately address subsidiaries.

3 **[**F6The 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 **[**F7Secretary of State**]** shall initiate unannounced or short-notice on-site assessments if those on-site assessments are needed to verify compliance.

Textual Amendments

F1 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)**

F2 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)**

F3 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).

F4 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)**

F5 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)**

F6 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)**

F7 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)**

Changes to legislation:
Commission Implementing Regulation (EU) No 920/2013, Article 5 is up to date with all changes known to be in force on or before 12 March 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)