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 3

Procedure for the designation of [F1approved] bodies

1 When applying for designation as **[**F2an 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 **[**F3approved**]**, the latter by indicating the codes **[**F4found in Guidance: UK approved bodies for medical devices https://www.gov.uk/publications/medical-devices-uk-approved-bodies-for-medical-devices.**]**

2 **[**F5The 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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7 F8...

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

Textual Amendments

F1 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)**

F2 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)**

F3 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)**

F4 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)**

F5 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)**

F6 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)**

F7 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)**

F8 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)**

Changes to legislation:
Commission Implementing Regulation (EU) No 920/2013, Article 3 is up to date with all changes known to be in force on or before 17 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)