

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
Article 1a	In this Regulation, any reference to Annex 8 to Directive...
Article 2	Interpretation of designation criteria
Article 3	Procedure for the designation of approved bodies
Article 4	Extension and renewal of designation
Article 5	Surveillance and monitoring
Article 6	Investigation of the competence of an approved body
Article 7	Exchange of experience on designation and supervision of conformity assessment bodies
Article 8	Operating of designating authorities
Article 9	Cooperation with accreditation bodies
Article 10	Entry into force and date of application
	Signature

ANNEX I

Interpretation of the criteria set out in Annex 8 to Directive 90/385/EEC and in Annex XI to Directive 93/42/EEC

1. Sections 1 and 5 of Annex 8 to Directive 90/385/EEC...
2. The second paragraph of Section 2 of Annex XI to...
3. Sections 3 and 4 of Annex 8 to Directive 90/385/EEC...
4. Sections 6 of Annex 8 to Directive 90/385/EEC and of...
5. Sections 7 of Annex 8 to Directive 90/385/EEC and of...

ANNEX II

Application form to be submitted when applying for designation as an approved body

Designating authority: ...
Name of the applying conformity assessment body: ...
Previous name (if applicable): ...
Approved Body number (if applicable): ...
Address: ...
...
...
...
Contact person: ...

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 23 August 2023. 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. (See end of Document for details) [View outstanding changes](#)

E-mail: ...

Telephone: ...

Legal form of the conformity assessment body: ...

Company registration number: ...

At company register: ...

...

...

The following documents shall be added. In case of extension...

Item/issue Corresponding Annex I section Attachment number +

Reference(Section/page) ORGANISATIONAL...

Name and signature of an authorised representative of the applicant...

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- (1) OJ L 189, 20.7.1990, p. 17.
- (2) OJ L 169, 12.7.1993, p. 1.
- (3) OJ L 218, 13.8.2008, p. 30.

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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)