

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 notified body's designation may be granted in accordance with Article 3.
- 2 A designation as notified 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.
- 5 Notified bodies already designated before the entry into force of this Regulation and for which the designation does not have a stated validity period or has a validity period exceeding five years, shall be subject to renewal at least within three years of entry into force of this Regulation.