Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (Text with EEA relevance)

Article 3

[F1 1 Before lodging an application for a conformity assessment for the purpose of complying with regulation 13 or regulation 27 of the Medical Devices Regulations 2002, the manufacturer of medical devices referred to in Article 1(1) of this Regulation or their UK responsible person must carry out the risk analysis and risk management scheme set out in Annex I to this Regulation.**]**

2 For custom-made devices and devices intended for clinical investigation which fall under Article 1(1), the statement of the manufacturer or his authorised representative and the documentation in accordance with Annex 6 to Directive 90/385/EEC or Annex VIII to Directive 93/42/EEC, respectively, shall also address compliance with the particular requirements set out in section 1 of Annex I to this Regulation.

Textual Amendments

F1 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. 10**

Changes to legislation:
Commission Regulation (EU) No 722/2012, Article 3 is up to date with all changes known to be in force on or before 08 August 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 applied by S.I. 2002/618, reg. 4K(2)(4) (as inserted) by S.I. 2019/791 reg. 3(7) (This amendment not applied to legislation.gov.uk. The affecting text in reg. 3(7) is omitted (31.12.2020 immediately before IP completion day) by virtue of S.I. 2020/1478, reg. 1(3), Sch. 2 para. 9(h))
- Regulation applied by S.I. 2002/618, reg. 4K(3) (as inserted) by S.I. 2019/791 reg. 3(7) (This amendment not applied to legislation.gov.uk. The affecting text in reg. 3(7) is omitted (31.12.2020 immediately before IP completion day) by virtue of S.I. 2020/1478, reg. 1(3), Sch. 2 para. 9(h))
- Regulation revoked by S.I. 2002/618, reg. 4K (as substituted) by S.I. 2021/873 Sch. 1 para. 4