Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (Text with EEA relevance)

Article 1

This Regulation establishes the conditions under which the instructions for use of medical devices referred to in point 15 of Annex 1 to Directive 90/385/EEC and in point 13 of Annex I to Directive 93/42/EEC may be provided in electronic form instead of in paper form.

It also establishes certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form relating to their contents and websites.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 207/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Regulation applied (with modifications) by S.I. 2002/618, reg. 4J(2) (as inserted) by S.I. 2019/791 reg. 3(7)
- Regulation applied (with modifications) by S.I. 2002/618, reg. 4J(3) (as inserted) by S.I. 2019/791 reg. 3(7)
- Regulation revoked by S.I. 2002/618, reg. 4J (as substituted) by S.I. 2021/873 Sch. 1 para. 3
- Art. 1 words inserted by S.I. 2021/873 Sch. 2 para. 4

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2021/873 Sch. 2 para. 8
- Art. 3(1)(a) words substituted by S.I. 2021/873 Sch. 2 para. 5(a)
- Art. 3(1)(b) words substituted by S.I. 2021/873 Sch. 2 para. 5(b)
- Art. 3(1)(c) words substituted by S.I. 2021/873 Sch. 2 para. 5(b)
- Art. 3(1)(d) words substituted by S.I. 2021/873 Sch. 2 para. 5(c)
- Art. 3(1)(e) words substituted by S.I. 2021/873 Sch. 2 para. 5(b)
- Art. 7(2)(e) words substituted by S.I. 2021/873 Sch. 2 para. 6(a)
- Art. 7(3) inserted by S.I. 2021/873 Sch. 2 para. 6(b)