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

Article 8

Except for medical devices of Class I, as defined in Annex IX to Directive 93/42/EEC, the fulfilment of the obligations laid down in Articles 4 to 7 of this Regulation shall be reviewed by a notified body during the procedure applicable for conformity assessment as referred to in Article 9 of Directive 90/385/EEC or Article 11 of Directive 93/42/EEC. The review shall be based on a specific sampling method adapted to the class and the complexity of the product.

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. 8 substituted by S.I. 2021/873 Sch. 2 para. 7

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)