

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...
- Article 2 For the purposes of this Regulation, the following definitions shall...
- Article 3 (1) Subject to the conditions set out in paragraph 2,...
- Article 4 (1) Manufacturers of devices referred to in Article 3 that...
- Article 5 Manufacturers of devices referred to in Article 3 may provide...
- Article 6 (1) Manufacturers shall clearly indicate that the instructions for use...
- Article 7 (1) Where manufacturers provide the instructions for use in electronic...
- Article 8 Except for medical devices of Class I, as defined in...
- Article 9 Instructions for use in electronic form which are provided in...
- Article 10 This Regulation shall enter into force on the 20th day...
- Signature

**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. (See end of Document for details) [View outstanding changes](#)

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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 281, 23.11.1995, p. 31.

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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.

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**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](#)
- 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\(b\)](#)