

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

*Article 7*

1 Where manufacturers provide the instructions for use in electronic form on an electronic storage medium together with the device or where the device itself is fitted with a built-in system visually displaying the instructions for use, the instructions for use in electronic form shall also be made accessible to the users through a website.

2 Any website containing instructions for use of a device which are provided in electronic form instead of in paper form shall comply with the following requirements:

- a the instructions for use shall be provided in a commonly used format that can be read with freely available software;
- b it shall be protected against hardware and software intrusion;
- c it shall be provided in such a way that the server downtime and display errors are reduced as far as possible;
- d it shall mention in which Union languages the manufacturer provides the instructions for use in electronic form;
- e it shall fulfil the requirements of Directive 95/46/EC;
- f the Internet address as displayed in accordance with Article 6(2) shall be stable and directly accessible during the periods set out in points (9) and (10) of Article 5;
- g all previous versions of the instructions for use issued in electronic form and their date of publication shall be available on the website.

**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](#)

**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\(b\)](#)