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

COMMISSION REGULATION (EU) No 207/2012

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on electronic instructions for use of medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[(1)], and in particular Article 9(10) thereof,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(2)], and in particular Article 11(14) thereof,

Whereas:

(1) For some medical devices the provision of instructions for use in electronic form instead of in paper form can be beneficial for professional users. It can reduce the environmental burden and improve the competitiveness of the medical devices industry by reducing costs, while maintaining or improving the level of safety.

(2) Such possibility of providing instructions for use in electronic form instead of in paper form should be limited to certain medical devices and accessories intended to be used in specific conditions. In any case, for reasons of safety and efficiency users should always have the possibility to obtain those instructions for use in paper form on request.

(3) In order to reduce potential risks as far as possible, the appropriateness of the provision of instructions for use in electronic form should be subject to a specific risk assessment by the manufacturer.

(4) In order to ensure that users have access to the instructions for use, appropriate information about access to those instructions for use in electronic form and about the right to request the instructions for use in paper form, should be provided.

(5) To ensure unconditional access to the instructions for use in electronic form and to facilitate the communication of updates and of product alerts, the instructions for use in electronic form should also be available through a website.

(6) Regardless of the language obligations imposed on manufacturers by the law of the Member States, manufacturers who provide instructions for use in electronic form should indicate on their website in which Union languages those instructions are available.

(7) 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 this Regulation should be reviewed by a notified body during the procedure applicable for conformity assessment based on a specific sampling method.

(8) As the protection of the right to privacy of natural persons with respect to the processing of personal data should be ensured by manufacturers and notified bodies as well, it is appropriate to provide that websites containing instructions for use of a medical device fulfil the requirements of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[(3)].

(9) In order to ensure safety and consistency, instructions for use in electronic form which are provided in addition to complete instructions for use in paper form should be covered by this Regulation as regards limited requirements in relation to their contents and websites.

(10) It is appropriate to provide for a deferred application of this Regulation so as to facilitate the smooth transition to the new system and to allow all operators and Member States time to adapt to it.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up by Article 6(2) of Directive 90/385/EEC,

HAS ADOPTED THIS REGULATION:

(**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.

Status:
Point in time view as at 26/05/2020.

Changes to legislation:
Commission Regulation (EU) No 207/2012, Introductory Text is up to date with all changes known to be in force on or before 18 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.