Official Journal
of the European Union

EN
L series

2025/1234

26.6.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1234

of 25 June 2025

amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ([1]), and in particular Article 5(6) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2021/2226 ([2]) limits its application to certain medical devices and their accessories.

(2) The results of a survey on replacing paper-based instructions for use by electronic instructions for use the Commission carried out from 1 August to 10 October 2024 show a clear preference, among healthcare professionals, for receiving instructions for use in electronic form than in paper. Providing instructions for use in electronic form helps the health sector deliver better and faster solutions.

(3) The scope of application of Implementing Regulation (EU) 2021/2226 should therefore be extended to all medical devices and their accessories covered by Regulation (EU) 2017/745 that are intended for professional users, including devices that fall under the transitional provisions provided for in Article 120 of Regulation (EU) 2017/745.

(4) Implementing Regulation (EU) 2021/2226 should also apply to devices without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745, provided that they are intended for professional use. The provisions of Implementing Regulation (EU) 2021/2226 that are limited to medical devices and their accessories should therefore be amended to include also devices without an intended medical purpose.

(5) Where devices intended for professional use may also be used by lay persons, such as patients, the instructions for use intended for lay persons should be provided in paper form.

(6) From the moment in which the registration of devices in the European database on medical devices (Eudamed) becomes mandatory, manufacturers should provide to Eudamed's Unique Device Identifier ('UDI') database the internet address under which the electronic instructions for use are accessible.

(7) Having regard to experience with the application of Implementing Regulation (EU) 2021/2226, some requirements should be clarified or deleted to remove uncertainties and overlaps. For example, compliance of the requirements related to the information to be supplied by the manufacturer is part of the conformity assessment activities pursuant to Regulation (EU) 2017/745, so that a separate requirement in Implementing Regulation (EU) 2021/2226 is redundant.

(8) Implementing Regulation (EU) 2021/2226 should therefore be amended accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

([1]) OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.

([2]) Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices (OJ L 448, 15.12.2021, p. 32, ELI: http://data.europa.eu/eli/reg_impl/2021/2226/oj).

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2021/2226 is amended as follows:

(1) in Article 1, the third subparagraph is deleted;

(2) Article 2 is amended as follows:

(a) in point (2), the word 'medical' is deleted;

(b) point (3) is replaced by the following:

'(3) "fixed installed devices" means devices which are intended to be installed, fastened or otherwise secured at a specific location in a health institution so that they cannot be moved from this location or detached without using tools or apparatus, and which are not specifically intended to be used within a mobile healthcare institution.';

(3) Article 3 is amended as follows:

(a) paragraph (1) is replaced by the following:

'(1) Manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to devices referred to in Article 1(4) of Regulation (EU) 2017/745 intended for use by professional users.';

(b) paragraph (2) is replaced by the following:

'(2) Where it is reasonably foreseeable that a device intended for use by professional users is also used by lay persons, manufacturers shall provide the instructions for use intended for lay persons in paper form.';

(4) Article 5 is amended as follows:

(a) in point (6), the word 'medical' is deleted;

(b) in point (11), the words 'to the user or patient' are deleted;

(c) point (12) is deleted;

(d) point (13) is replaced by the following:

'(13) during the periods set out in points (9) and (10), all issued electronic versions of the instructions for use and their date of publication shall be available on the website or, as regards versions that are obsolete, be made available upon request.';

(5) Article 6 is amended as follows:

(a) in paragraph (1), second subparagraph, second sentence, the word 'medical' is deleted;

(b) paragraph (4) is deleted;

(6) Article 7 is amended as follows:

(a) in paragraph 2, point (f) is deleted;

(b) the following paragraph is added:

'(3) At the latest at the date from which the registration of devices in the UDI database referred to in Article 28 of Regulation (EU) 2017/745 applies in accordance with Article 123(3), point (d) or point (e), of that Regulation, as applicable, the manufacturer shall provide the internet address referred to in paragraph (2), point (e), of this Article to the UDI database in accordance with Part B, point 22, of Annex VI to Regulation (EU) 2017/745.';

(7) Article 8 is deleted;

(8) in Article 9, the second paragraph is deleted.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2025.

For the Commission
The President
Ursula VON DER LEYEN