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COMMISSION IMPLEMENTING DECISION (EU) 2024/2625

of 8 October 2024

amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for aseptic processing of health care products and clinical performance studies using specimens from human subjects

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([1]), and in particular Article 10(6) thereof,

Whereas:

(1) In accordance with Article 8(1) of Regulation (EU) 2017/746 of the European Parliament and of the Council ([2]), devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, are to be presumed to be in conformity with the requirements of that Regulation covered by those standards or parts thereof.

(2) Regulation (EU) 2017/746 replaced Directive 98/79/EC of the European Parliament and of the Council ([3]) with effect from 26 May 2022.

(3) By Implementing Decision C(2021) 2406 ([4]), the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) for the revision of existing harmonised standards on *in vitro* diagnostic medical devices developed in support of Directive 98/79/EC and for the drafting of new harmonised standards in support of Regulation (EU) 2017/746 (the 'request').

(4) On the basis of the request, CEN and Cenelec revised the harmonised standards EN ISO 13408-1:2015 for aseptic processing of health care products, and drafted a new harmonised standard for clinical performance studies using specimens from human subjects, the reference of which are not published in the *Official Journal of the European Union*, in order to take into account the latest technical and scientific progress and the need to support the requirements of Regulation (EU) 2017/746.

(5) This resulted in the adoption of the harmonised standards EN ISO 13408-1:2024 and EN ISO 20916:2024 ('the standards').

(6) The Commission together with CEN and Cenelec has assessed whether the standards comply with the request.

([1]) OJ L 316, 14.11.2012, p. 12, ELI: http://data.europa.eu/eli/reg/2012/1025/oj.

([2]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj).

([3]) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1, ELI: http://data.europa.eu/eli/dir/1998/79/oj).

([4]) Commission Implementing Decision C(2021) 2406 of 14 April 2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council. Available online on: https://ec.europa.eu/growth/tools-databases/enorm/mandate/575_en.

(7) The standards satisfy the requirements which they aim to cover, and which are set out in Regulation (EU) 2017/746. It is therefore appropriate to publish the references of the standards in the *Official Journal of the European Union*.

(8) The Annex to Commission Implementing Decision (EU) 2021/1195 ([5]) lists the references of harmonised standards drafted in support of Regulation (EU) 2017/746.

(9) In order to ensure that the references of harmonised standards drafted in support of Regulation (EU) 2017/746 are listed in one act, the references of the standards should be included in Implementing Decision (EU) 2021/1195.

(10) Implementing Decision (EU) 2021/1195 should therefore be amended accordingly.

(11) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the day of its publication.

(12) The harmonised standards adopted in response to standardisation requests may be subject to access to documents requests in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council ([6]). In its judgment of 5 March 2024 *Public.Resource.Org and Right to Know v. Commission and Others* ([7]), the Court of Justice of the European Union recognised that there is an overriding public interest, within the meaning of Article 4(2) of Regulation (EC) No 1049/2001, justifying the disclosure of harmonised standards,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2021/1195 is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 8 October 2024.

For the Commission
The President
Ursula VON DER LEYEN

([5]) Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 258, 20.7.2021, p. 50, ELI: http://data.europa.eu/eli/dec_impl/2021/1195/oj).

([6]) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43, ELI: http://data.europa.eu/eli/reg/2001/1049/oj).

([7]) Judgment of the Court of Justice of the European Union of 5 March 2024 *Public.Resource.Org and Right to Know v. Commission and Others*, C-588/21 P, ECLI:EU:C:2024:201.

ANNEX

In the Annex to Implementing Decision (EU) 2021/1195, the following entries are added:

No	Reference of the standard
'14.	EN ISO 13408-1:2024 Aseptic processing of health care products – Part 1: General requirements (ISO 13408-1:2023)
15.	EN ISO 20916:2024 *In vitro* diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice (ISO 20916:2019)'.