COMMISSION IMPLEMENTING DECISION (EU) 2023/1411

of 4 July 2023

amending Implementing Decision (EU) 2021/1195 as regards a harmonised standard for sterilization of health care products

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]) 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.

(4) On the basis of the request set out in Implementing Decision C(2021) 2406, CEN and Cenelec further revised the harmonised standard EN ISO 25424:2019, the reference of which is 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. This resulted in the adoption of amendment EN ISO 25424:2019/A1:2022 to harmonised standard EN ISO 25424:2019 on sterilization of health care products.

(5) The Commission together with CEN and Cenelec has assessed whether amendment EN ISO 25424:2019/A1:2022 to harmonised standard EN ISO 25424:2019 complies with the request set out in Implementing Decision C(2021) 2406.

(6) Amendment EN ISO 25424:2019/A1:2022 to harmonised standard EN ISO 25424:2019 satisfies the requirements which it aims to cover and which are set out in Regulation (EU) 2017/746. It is therefore appropriate to publish the reference of amendment EN ISO 25424:2019/A1:2022 to harmonised standard EN ISO 25424:2019 in the *Official Journal of the European Union*.

([1]) OJ L 316, 14.11.2012, p. 12.

([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).

([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).

([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.

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

(8) In order to ensure that the references of harmonised standards drafted in support of Regulation (EU) 2017/746 are listed in one act, the reference of amendment EN ISO 25424:2019/A1:2022 to harmonised standard EN ISO 25424:2019 should be included in Implementing Decision (EU) 2021/1195.

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

(10) 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,

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, 4 July 2023.

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).

ANNEX

In the Annex, entry No 4 is replaced by the following:

No	Reference of the standard
‘4.	EN ISO 25424:2019 Sterilisation of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilisation process for medical devices (ISO 25424:2018) EN ISO 25424:2019/A1:2022’.