COMMISSION IMPLEMENTING DECISION (EU) 2022/15

of 6 January 2022

amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer and requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

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 will replace 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 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 revised the existing harmonised standards EN ISO 11737-1:2018, EN ISO 13408-6:2011, EN ISO 13485:2016, EN ISO 15223-1:2016 and EN ISO 17511:2003, in order to take into account the latest technical and scientific progress and to adapt them to the requirements of Regulation (EU) 2017/746. This resulted in the adoption of the revised harmonised standards EN ISO 13408-6:2021 on aseptic processing of health care products, EN ISO 15223-1:2021 on symbols to be used with information to be supplied by the manufacturer and EN ISO 17511:2021 on requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples and of amendment EN ISO 11737-1:2018/A1:2021 to harmonised standard EN ISO 11737-1:2018 on sterilization of health care products and amendment EN ISO 13485:2016/A11:2021 to harmonised standard EN ISO 13485:2016 on quality management systems.

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[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.

(5) The Commission together with CEN and Cenelec has assessed whether the harmonised standards revised by CEN and Cenelec comply with the request set out in Implementing Decision C(2021) 2406.

(6) The harmonised standards EN ISO 13408-6:2021, EN ISO 15223-1:2021 and EN ISO 17511:2021 and the amendments EN ISO 11737-1:2018/A1:2021 and EN ISO 13485:2016/A11:2021 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 those standards in the *Official Journal of the European Union*.

(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. 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 standards EN ISO 13408-6:2021, EN ISO 15223-1:2021 and EN ISO 17511:2021 and the amendments EN ISO 11737-1:2018/A1:2021 and EN ISO 13485:2016/A11:2021 should be included in that Implementing Decision.

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

(9) 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 date 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, 6 January 2022.

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

No	Reference of the standard
‘5.	EN ISO 11737-1:2018 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) EN ISO 11737-1:2018/A1:2021
6.	EN ISO 13408-6:2021 Aseptic processing of health care products – Part 6: Isolator systems (ISO 13408-6:2021)
7.	EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/A11:2021
8.	EN ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements (ISO 15223-1:2021)
9.	EN ISO 17511:2021 *In vitro* diagnostic medical devices – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020)’.