2026/2481

10.11.2026

COMMISSION IMPLEMENTING DECISION (EU) 2026/2481

of 9 November 2026

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

(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 covered by those standards or parts thereof set out in that Regulation.

(2) By Implementing Decision C(2021) 2406 ([3]), 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 of the European Parliament and the Council ([4]) ('the request').

(3) On the basis of the request and, in order to take into account the latest technical and scientific progress, CEN and Cenelec revised the harmonised standard EN ISO 11137-1:2015 on sterilization of health care products together with its amendment EN ISO 11137-1:2015/A2:2019, the reference of which is published in the *Official Journal of the European Union* in support of Regulation (EU) 2017/746.

(4) The revision of that standard resulted in the adoption of the superseding harmonised standard EN ISO 11137-1:2026 ('the superseding standard').

(5) The Commission has assessed, together with CEN and Cenelec, whether the superseding standard complies with the request.

(6) The superseding standard 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 the superseding standard in the *Official Journal of the European Union*.

([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]) 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 (https://ec.europa.eu/growth/tools-databases/enorm/mandate/575_en).

([4]) 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).

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

(8) As the harmonised standard EN ISO 11137-1:2015 together with its amendment EN ISO 11137-1:2015/A2:2019 has been revised, the reference to its previous version should be deleted from the Annex to Implementing Decision (EU) 2021/1195.

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

(10) In order to give manufacturers and other economic operators sufficient time to adapt their processes and devices that are covered by the harmonised standard EN ISO 11137-1:2015 together with its amendment EN ISO 11137-1:2015/A2:2019, it is necessary to defer the withdrawal of the reference of that harmonised standard.

(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,

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*.

Point (1) of the Annex shall apply from 10 May 2028.

Done at Brussels, 9 November 2026.

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).

ANNEX

The Annex to Implementing Decision (EU) 2021/1195 is amended as follows:

(1) entry No 2 is deleted;

(2) the following entry is inserted between entries 2 and 3:

'2a.	EN ISO 11137-1:2026 Sterilization of health care products – Radiation – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2025)'