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# COMMISSION IMPLEMENTING DECISION (EU) 2026/197

## of 28 January 2026

## amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for sterilization of health care products and information supplied by the manufacturer (labelling)

**(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 17665-1:2006 on sterilization of health care products, and EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN ISO 18113-4:2011 and EN ISO 18113-5:2011 on information supplied by the manufacturer (labelling), the references 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) The revision of those standards resulted in the adoption of harmonised standards EN ISO 17665:2024, EN ISO 18113-1:2024, EN ISO 18113-2:2024, EN ISO 18113-3:2024, EN ISO 18113-4:2024 and EN ISO 18113-5:2024 ('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.

(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,

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, 28 January 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*

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

| No | Reference of the standard |
|---|---|
| ‘18. | EN ISO 17665:2024<br>Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024) |
| 19. | EN ISO 18113-1:2024<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022) |
| 20. | EN ISO 18113-2:2024<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022) |
| 21. | EN ISO 18113-3:2024<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2022) |
| 22. | EN ISO 18113-4:2024<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2022) |
| 23. | EN ISO 18113-5:2024<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2022)’. |