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COMMISSION IMPLEMENTING DECISION (EU) 2026/760

of 1 April 2026

amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for sterilizers for medical purposes – small steam sterilizers, stainless steel steam boilers and electroacoustics – hearing aids

(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) 2017/745 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) In 2021, 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 medical devices developed in support of Council Directives 90/385/EEC ([3]) and 93/42/EEC ([4]), and for the drafting of new harmonised standards in support of Regulation (EU) 2017/745 ('the request').

(3) On the basis of the request, CEN and Cenelec revised harmonised standards EN 13060:2014+A1:2018 on small steam sterilizers and EN 60118-0:2015 on electroacoustics – hearing aids, and drafted a new harmonised standard on stainless steel steam boilers, in order to take into account the latest technical and scientific progress.

(4) The revision of those standards resulted in the adoption of harmonised standards EN 13060:2025, EN 14222:2021 +A1:2025 and EN IEC 60118-0:2024 ('the standards').

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

(6) The standards satisfy the requirements which they aim to cover, and which are set out in Regulation (EU) 2017/745. It is therefore appropriate to publish the references of those standards 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) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj).
([3]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17, ELI: http://data.europa.eu/eli/dir/1990/385/oj).
([4]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1, ELI: http://data.europa.eu/eli/dir/1993/42/oj).

(7) The Annex to Commission Implementing Decision (EU) 2021/1182 ([5]) lists the references of harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745.

(8) Implementing Decision (EU) 2021/1182 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 day of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2021/1182 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, 1 April 2026.

For the Commission
The President
Ursula VON DER LEYEN

([5]) Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ L 256, 19.7.2021, p. 100, ELI: http://data.europa.eu/eli/dec_impl/2021/1182/oj).

ANNEX

In the Annex to Implementing Decision (EU) 2021/1182, the following entries are added:

No	Reference of the standard
‘49.	EN 13060:2025 Sterilizers for medical purposes – Small steam sterilizers – Requirements and testing
50.	EN 14222:2021+A1:2025 Stainless steel steam boilers
51.	EN IEC 60118-0:2024 Electroacoustics – Hearing aids – Part 0: Measurement of the performance characteristics of hearing aids’