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COMMISSION IMPLEMENTING DECISION (EU) 2026/193

of 28 January 2026

amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for neurosurgical implants, biological evaluation of medical devices, clinical investigation of medical devices for human subjects, non-active surgical implants, sterilization of health care products, biocompatibility evaluation of breathing gas pathways in healthcare applications and small-bore connectors for liquids and gases in healthcare applications

(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 of that Regulation covered by those standards or parts thereof.

(2) Regulation (EU) 2017/745 replaced Council Directives 90/385/EEC ([3]) and 93/42/EEC ([4]) with effect from 26 May 2021.

(3) By Implementing Decision C(2021) 2406 ([5]), 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 Directives 90/385/EEC and 93/42/EEC, and for the drafting of new harmonised standards in support of Regulation (EU) 2017/745 ('the request').

([1]) OJ L 316, 14.11.2012, p. 12, ELI: http://data.europa.eu/eli/reg/2012/1025/oj.

([2]) Regulation (EU) 2017/745 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).

([5]) 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.

(4) On the basis of the request, CEN and Cenelec revised the harmonised standards EN ISO 7197:2009 on neurosurgical implants, EN ISO 10993-4:2017 on biological evaluation of medical devices, EN ISO 14155:2020 on clinical investigation of medical devices for human subjects, EN ISO 14630:2012, EN ISO 21535:2009 and EN ISO 21536:2009 on non-active surgical implants, EN ISO 17665-1:2006 on sterilization of health care products, and EN ISO 18562-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020 and EN ISO 18562-4:2020 on biocompatibility evaluation of breathing gas pathways in healthcare applications, and drafted a new harmonised standard on small-bore connectors for liquids and gases in healthcare applications, 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) 2017/745.

(5) The revision of those standards resulted in the adoption of harmonised standards EN ISO 7197:2024, EN ISO 14630:2024, EN ISO 17665:2024, EN ISO 18562-1:2024, EN ISO 18562-2:2024, EN ISO 18562-3:2024, EN ISO 18562-4:2024, EN ISO 21535:2024, EN ISO 21536:2024 and EN ISO 80369-2:2024 ('the standards'), and of the amendments to harmonised standards EN ISO 10993-4:2017/A1:2025 and EN ISO 14155:2020/A11:2024 ('the amendments').

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

(7) The standards and the amendments 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 the standards and of the amendments in the *Official Journal of the European Union*.

(8) The Annex to Commission Implementing Decision (EU) 2021/1182 ([6]) lists the references of harmonised standards drafted in support of Regulation (EU) 2017/745.

(9) In order to ensure that the references of harmonised standards drafted in support of Regulation (EU) 2017/745 are listed in one act, the references of the standards and of the amendments should be included in Implementing Decision (EU) 2021/1182.

(10) Implementing Decision (EU) 2021/1182 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) 2021/1182 is amended in accordance with the Annex to this Decision.

([6]) 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).

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

ANNEX

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

No	Reference of the standard
‘37.	EN ISO 7197:2024 Neurosurgical implants – Sterile, single-use hydrocephalus shunts (ISO 7197:2024)
38.	EN ISO 10993-4:2017 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017) EN ISO 10993-4:2017/A1:2025
39.	EN ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155:2020) EN ISO 14155:2020/A11:2024
40.	EN ISO 14630:2024 Non-active surgical implants – General requirements (ISO 14630:2024)
41.	EN ISO 17665:2024 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)
42.	EN ISO 18562-1:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process (ISO 18562-1:2024)
43.	EN ISO 18562-2:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter (ISO 18562-2:2024)
44.	EN ISO 18562-3:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic substances (ISO 18562-3:2024)
45.	EN ISO 18562-4:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate (ISO 18562-4:2024)
46.	EN ISO 21535:2024 Non-active surgical implants – Joint replacement implants – Specific requirements for hip-joint replacement implants (ISO 21535:2023)
47.	EN ISO 21536:2024 Non-active surgical implants – Joint replacement implants – Specific requirements for knee-joint replacement implants (ISO 21536:2023)
48.	EN ISO 80369-2:2024 Small-bore connectors for liquids and gases in healthcare applications – Part 2: Connectors for respiratory applications (ISO 80369-2:2024, Corrected version 2025-06)’