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OFFICIAL JOURNAL OF MEDICAL DEVICES REGULATION (EU) 2017/745

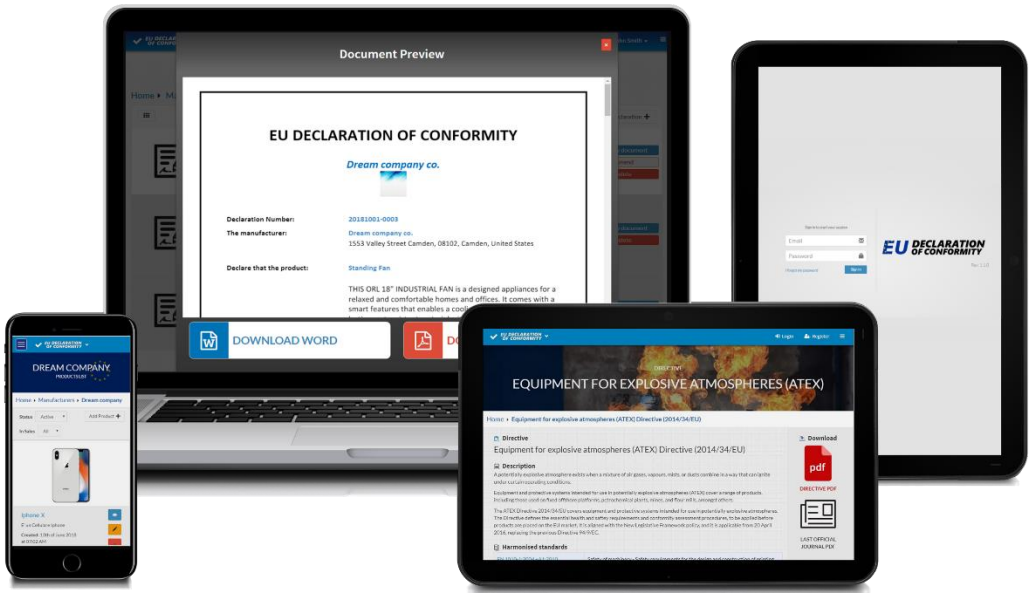
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EU DECLARATION OF CONFORMITY

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2026/2479

10.11.2026

COMMISSION IMPLEMENTING DECISION (EU) 2026/2479

of 9 November 2026

amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for sterilization of health care products, clinical investigation of medical devices for human subjects, natural rubber latex male condoms, biological evaluation of medical devices, washer-disinfectors, medical electrical equipment 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 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 medical devices developed in support of Council Directives 90/385/EEC ([4]) and 93/42/EEC ([5]) ('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 harmonised standards EN ISO 11137-1:2015 on sterilization of health care products together with its amendment EN ISO 11137-1:2015/A2:2019 and EN ISO 14155:2020 on clinical investigation of medical devices for human subjects together with its amendment EN ISO 14155:2020/A11:2024, the references of which are published in the *Official Journal of the European Union* in support of Regulation (EU) 2017/745.

([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]) 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]) 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).

([5]) 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).

(4) The revision of those standards resulted in the adoption of the superseding harmonised standards EN ISO 11137-1:2026 and EN ISO 14155:2026 ('the superseding standards').

(5) Also on the basis of the request and, in order to take into account the latest technical and scientific progress, CEN and CENELEC revised harmonised standards EN ISO 4074:2015 on natural rubber latex male condoms, EN ISO 10993-6:2016 and EN ISO 10993-7:2008 together with its amendment EN ISO 10993-7:2008/A1:2022 and corrigendum EN ISO 10993-7:2008/AC:2009 on biological evaluation of medical devices, EN ISO 15883-6:2015 on washer-disinfectors, EN IEC 60601-2-22:2020 and EN 60601-2-57:2011 on medical electrical equipment and EN ISO 80369-1:2018 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 support of Regulation (EU) 2017/745.

(6) The revision of those standards resulted in the adoption of the new harmonised standards EN ISO 4074:2026, EN ISO 10993-6:2026, EN ISO 10993-7:2026, EN ISO 15883-6:2026, EN IEC 60601-2-22:2020 with its amendment EN IEC 60601-2-22:2020/A11:2026, EN IEC 60601-2-57:2026 with its amendment EN IEC 60601-2-57:2026/A11:2026 and EN ISO 80369-1:2026 ('the new standards').

(7) The Commission has assessed, together with CEN and CENELEC, whether the superseding standards and the new standards comply with the request.

(8) The superseding standards and the new 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 superseding standards and new standards in the *Official Journal of the European Union*.

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

(10) As the harmonised standards EN ISO 11137-1:2015 together with its amendment EN ISO 11137-1:2015/A2:2019 and EN ISO 14155:2020 together with its amendment EN ISO 14155:2020/A11:2024 have been revised, the references to their previous versions should be deleted from the Annex to Implementing Decision (EU) 2021/1182.

(11) Implementing Decision (EU) 2021/1182 should therefore be amended accordingly.

(12) In order to give manufacturers and other economic operators sufficient time to adapt their processes and devices that are covered by the harmonised standards EN ISO 11137-1:2015 together with its amendment EN ISO 11137-1:2015/A2:2019 and EN ISO 14155:2020 together with its amendment EN ISO 14155:2020/A11:2024, it is necessary to defer the withdrawal of the references of those harmonised standards.

(13) 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*.

Points (1) and (3) of the Annex shall apply from 10 May 2028.

Done at Brussels, 9 November 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Decision (EU) 2021/1182 is amended as follows:

(1) entry No 3 is deleted;

(2) the following entry is inserted between entries 3 and 4:

'3a.	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)';

(3) entry No 39 is deleted;

(4) the following entry is inserted between entries 39 and 40:

'39a.	EN ISO 14155:2026 Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155:2026)';

(5) the following entries are added:

No	Reference of the standard
'66.	EN ISO 4074:2026 Natural rubber latex male condoms – Requirements and test methods (ISO 4074:2026)
67.	EN ISO 10993-6:2026 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation (ISO 10993-6:2026)
68.	EN ISO 10993-7:2026 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2026)
69.	EN ISO 15883-6:2026 Washer-disinfectors – Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-critical medical devices and health care equipment (ISO 15883-6:2026)
70.	EN IEC 60601-2-22:2020 Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment EN IEC 60601-2-22:2020/A11:2026
71.	EN IEC 60601-2-57:2026 Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring, cosmetic and aesthetic use EN IEC 60601-2-57:2026/A11:2026
72.	EN ISO 80369-1:2026 Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements (ISO 80369-1:2025)'.