EU DECLARATION OF CONFORMITY

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

EU DECLARATION OF CONFORMITY

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The application allows you to:

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- Store all declarations on a secure server;
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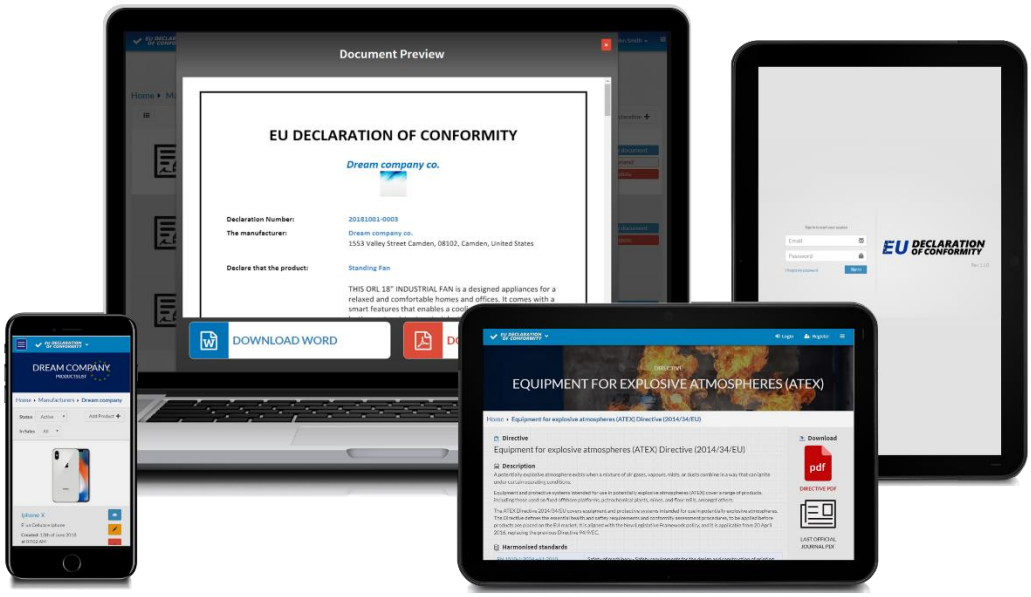

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COMMISSION IMPLEMENTING DECISION (EU) 2026/1231

of 11 June 2026

amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, symbols to be used with information to be supplied by the manufacturer, medical electrical equipment, transfusion equipment for medical use, ophthalmic optics, non-active surgical implants, washer-disinfectors, prosthetics and sharps injury protection

(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, CEN and CENELEC revised harmonised standards EN ISO 10993-23:2021, EN ISO 10993-12:2021 and EN ISO 10993-17:2023 on biological evaluation of medical devices, EN IEC 60601-2-83:2020 with its amendment EN IEC 60601-2-83:2020/A11:2021 on medical electrical equipment, and EN ISO 15223-1:2021 on symbols to be used with information to be supplied by the manufacturer, the references of which are published in the *Official Journal of the European Union* in support of Regulation (EU) 2017/745, in order to take into account the latest technical and scientific progress.

[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 amendments EN ISO 10993-23:2021/A1:2025 on additional *in vitro* reconstructed human epidermis models, EN ISO 10993-12:2021/A1:2025, EN ISO 10993-17:2023/A1:2025, EN IEC 60601-2-83:2020/A1:2025 and EN ISO 15223-1:2021/A1:2025 on addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific ('the amendments').

(5) Also on the basis of the request, CEN and CENELEC revised harmonised standards EN ISO 1135-4:2015 and EN ISO 1135-5:2015 on transfusion equipment for medical use, EN ISO 10993-1:2020 and EN ISO 10993-5:2009 on biological evaluation of medical devices, EN ISO 12870:2018 and EN ISO 14889:2013 with its amendment EN ISO 14889:2013/A1:2017 on ophthalmic optics, EN ISO 14607:2018 on non-active surgical implants, EN ISO 15883-1:2009 with its amendment EN ISO 15883-1:2009/A1:2014, EN ISO 15883-2:2009, EN ISO 15883-3:2009 and EN ISO 15883-7:2016 on washer-disinfectors, EN ISO 22675:2016 on prosthetics, EN ISO 23908:2013 on sharps injury protection and EN 60601-1:2006 on medical electrical equipment, the references of which are not published in the *Official Journal of the European Union* in support of Regulation (EU) 2017/745, in order to take into account the latest technical and scientific progress.

(6) The revision of those standards resulted in the adoption of harmonised standards EN ISO 1135-4:2025, EN ISO 1135-5:2025, EN ISO 10993-1:2025, EN ISO 10993-5:2009 with its amendment EN ISO 10993-5:2009/A11:2025, EN ISO 12870:2025, EN ISO 14889:2025, EN ISO 14607:2025, EN ISO 15883-1:2025, EN ISO 15883-2:2025, EN ISO 15883-3:2025, EN ISO 15883-7:2025, EN ISO 22675:2025, EN ISO 23908:2025 and EN 60601-1:2006 with its amendment EN 60601-1:2006/A13:2024 ('the standards').

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

(8) The amendments and 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 amendments and 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 10993-23:2021, EN ISO 10993-12:2021, EN ISO 10993-17:2023, EN IEC 60601-2-83:2020 with its amendment EN IEC 60601-2-83:2020/A11:2021 and EN ISO 15223-1:2021 have been amended, the reference 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 harmonised standards EN ISO 10993-23:2021, EN ISO 10993-12:2021, EN ISO 10993-17:2023, EN IEC 60601-2-83:2020 with its amendment EN IEC 60601-2-83:2020/A11:2021 and EN ISO 15223-1:2021, it is necessary to defer the withdrawal of the references of those harmonised standards. In particular, for EN ISO 15223-1:2021, it is necessary to allow for a period of 5 years, as information provided by the sectorial interested parties in the Subgroup on Standards of the Medical Device Coordination Group shows the significant impact on economic operators in terms of costs and timing to implement labelling changes in manufacturing and distribution of devices, taking into account the processes involved, both at EU and international levels ([7]).

([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).

([7]) See the documents related to the meeting of the Subgroup on Standards of the Medical Device Coordination Group, held on 4 February 2026: https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=69791.

(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.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Points (1), (3), (7) and (9) of the Annex shall apply from 15 December 2027.

Point (5) of the Annex shall apply from 15 June 2031.

Done at Brussels, 11 June 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 1 is deleted;

(2) the following entry is inserted:

‘1a.	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021) EN ISO 10993-23:2021/A1:2025’

(3) entry No 7 is deleted;

(4) the following entry is inserted:

‘7a.	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993 12:2021) EN ISO 10993-12:2021/A1:2025’

(5) entry No 12 is deleted;

(6) the following entry is inserted:

‘12a.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) EN ISO 15223-1:2021/A1:2025’

(7) entry No 14 is deleted;

(8) the following entry is inserted:

‘14a.	EN IEC 60601-2-83:2020 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment EN IEC 60601-2-83:2020/A11:2021 EN IEC 60601-2-83:2020/A1:2025’

(9) entry No 20 is deleted;

(10) the following entry is inserted:

‘20a.	EN ISO 10993-17:2023 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023) EN ISO 10993-17:2023/A1:2025’

(11) the following entries are added:

No	Reference of the standard
‘52.	EN ISO 1135-4:2025 Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed (ISO 1135-4:2025)
53.	EN ISO 1135-5:2025 Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus (ISO 1135-5:2025)

No	Reference of the standard
54.	EN ISO 10993-1:2025 Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process (ISO 10993-1:2025)
55.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009) EN ISO 10993-5:2009/A11:2025
56.	EN ISO 12870:2025 Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2024)
57.	EN ISO 14607:2025 Non-active surgical implants - Mammary implants - Specific requirements (ISO 14607:2024)
58.	EN ISO 14889:2025 Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses (ISO 14889:2025)
59.	EN ISO 15883-1:2025 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2024)
60.	EN ISO 15883-2:2025 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices (ISO 15883-2:2024)
61.	EN ISO 15883-3:2025 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2024)
62.	EN ISO 15883-7:2025 Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment (ISO 15883-7:2025)
63.	EN ISO 22675:2025 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2024)
64.	EN ISO 23908:2025 Sharps injury protection - Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration - Requirements and test methods (ISO 23908:2024)
65.	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1:2006/A13:2024’