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COMMISSION IMPLEMENTING DECISION (EU) 2025/2078

of 17 October 2025

amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for surgical clothing and drapes, medical face masks and sterilizers for medical purposes

(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').

(4) On the basis of the request, CEN and CENELEC revised the harmonised standards EN 13795-1:2019 and EN 13795-2:2019 on surgical clothing and drapes, EN 14683:2019+AC:2019 on medical face masks, and EN 14180:2014 on sterilizers for medical purposes, 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) This resulted in the adoption of the harmonised standards EN 13795-1:2025, EN 13795-2:2025, EN 14683:2025 and EN 14180:2025 ('the standards').

([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.

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

(7) 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 the standards 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 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.

(12) The harmonised standards adopted in response to standardisation requests may be subject to access to documents requests in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council ([7]). In its judgment of 5 March 2024, in Case C-588/21 P ([8]), the Court of Justice recognised that there is an overriding public interest, within the meaning of Article 4(2) of Regulation (EC) No 1049/2001, justifying the disclosure of harmonised standards,

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, 17 October 2025.

For the Commission
The President
Ursula VON DER LEYEN

([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]) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43, ELI: http://data.europa.eu/eli/reg/2001/1049/oj).

([8]) Judgment of the Court of Justice of the European Union of 5 March 2024 *Public.Resource.Org and Right to Know* v *Commission and Others*, C-588/21 P, ECLI:EU:C:2024:201.

ANNEX

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

No	Reference of the standard
‘33.	EN 13795-1:2025 Surgical clothing and drapes – Requirements and test methods – Part 1: Surgical drapes and gowns
34.	EN 13795-2:2025 Surgical clothing and drapes – Requirements and test methods – Part 2: Clean air suits
35.	EN 14683:2025 Medical face masks – Requirements and test methods
36.	EN 14180:2025 Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing’

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Legislation	ESO	Reference and title Provision	Start of legal eff	Publicatior	Publication Deci	Publication OJ dat	End of legal e	Withdrawa	Withdrawal	Withdrawal OJ date
2017/745 - Medical Devices	CEN	EN 13795-1:2025 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	20.10.2025	OJ L	2025/2078	20.10.2025				
2017/745 - Medical Devices	CEN	EN 13795-2:2025 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits	20.10.2025	OJ L	2025/2078	20.10.2025				
2017/745 - Medical Devices	CEN	EN 14180:2025 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing	20.10.2025	OJ L	2025/2078	20.10.2025				
2017/745 - Medical Devices	CEN	EN 14683:2025 Medical face masks - Requirements and test methods	20.10.2025	OJ L	2025/2078	20.10.2025				
2017/745 - Medical Devices	CEN	EN 1865-2:2024 Patient handling equipment used in ambulances - Part 2: Power assisted stretcher	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 1865-6:2024 Patient handling equipment used in ambulances - Part 6: Powered chairs	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 285:2015+A1:2021 Sterilization - Steam sterilizers - Large sterilizers	17.05.2022	OJ L 138	2022/757	17.05.2022				
2017/745 - Medical Devices	CEN	EN 455-1:2020+A2:2024 Medical gloves for single use - Part 1: Requirements and testing for freedom of holes	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 455-2:2024 Medical gloves for single use - Part 2: Requirements and testing for physical properties	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 455-3:2023 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	08.03.2024	OJ L	2024/815	08.03.2024				

2017/745 - Medical Devices	CEN	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	Cenelec	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#IEC 60601-2-83:2019 EN IEC 60601-2-83:2020/A11:2021	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 10993-10:2023 Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)	05.07.2023	OJ L 170	2023/1410	05.07.2023				
2017/745 - Medical Devices	CEN	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 10993-15:2023 Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2019)	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	CEN	EN ISO 10993-17:2023 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)	08.03.2024	OJ L	2024/815	08.03.2024				

2017/745 - Medical Devices	CEN	EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020) EN ISO 10993-18:2020/A1:2023	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	CEN	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	19.07.2021	OJ L 256	2021/1182	19.07.2021				
2017/745 - Medical Devices	CEN	EN ISO 10993-9:2021 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014) EN ISO 11135:2014/A1:2019	19.07.2021	OJ L 256	2021/1182	19.07.2021				
2017/745 - Medical Devices	CEN	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019	19.07.2021	OJ L 256	2021/1182	19.07.2021				
2017/745 - Medical Devices	CEN	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013) EN ISO 11137-2:2015/A1:2023	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	CEN	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019) EN ISO 11607-1:2020/A1:2023	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	CEN	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019) EN ISO 11607-2:2020/A1:2023	08.03.2024	OJ L	2024/815	08.03.2024				

2017/745 - Medical Devices	CEN	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) EN ISO 11737-1:2018/A1:2021	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	19.07.2021	OJ L 256	2021/1182	19.07.2021				
2017/745 - Medical Devices	CEN	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2023)	09.10.2024	OJ L	2024/2631	09.10.2024				
2017/745 - Medical Devices	CEN	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 14160:2021 Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2020)	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021	17.05.2022	OJ L 138	2022/757	17.05.2022				

2017/745 - Medical Devices	CEN	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)	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 17664-2:2023 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices (ISO 17664-2:2021)	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	CEN	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)	19.07.2021	OJ L 256	2021/1182	19.07.2021	05.07.2023	OJ L 170	2023/1410	05.07.2023
2017/745 - Medical Devices	CEN	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018) EN ISO 25424:2019/A1:2022	05.07.2023	OJ L 170	2023/1410	05.07.2023				