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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)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Decision (EU) 2022/6 of 4 January 2022	L 1	11	5.1.2022
►M2	Commission Implementing Decision (EU) 2022/757 of 11 May 2022	L 138	27	17.5.2022
►M3	Commission Implementing Decision (EU) 2023/1410 of 4 July 2023	L 170	102	5.7.2023
►M4	Commission Implementing Decision (EU) 2024/815 of 6 March 2024	L 815	1	8.3.2024
►M5	Commission Implementing Decision (EU) 2024/2631 of 8 October 2024	L 2631	1	9.10.2024
►M6	Commission Implementing Decision (EU) 2025/681 of 8 April 2025	L 681	1	9.4.2025
►M7	Commission Implementing Decision (EU) 2025/2078 of 17 October 2025	L 2078	1	20.10.2025
►M8	Commission Implementing Decision (EU) 2026/193 of 28 January 2026	L 193	1	30.1.2026
►M9	Commission Implementing Decision (EU) 2026/760 of 1 April 2026	L 760	1	7.4.2026
►M10	Commission Implementing Decision (EU) 2026/1231 of 11 June 2026	L 1231	1	17.6.2026

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COMMISSION IMPLEMENTING DECISION (EU) 2021/1182

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on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council

Article 1

The references of harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 and listed in the Annex to this Decision are hereby published in the *Official Journal of the European Union*.

Article 2

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

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ANNEX

No	Reference of the standard
1.	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
▼M10	
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
▼B	
2.	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
3.	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
4.	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)
▼M3	
5.	EN ISO 25424:2019 Sterilisation of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilisation process for medical devices (ISO 25424:2018) EN ISO 25424:2019/A1:2022
▼M1	
6.	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)
7.	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
▼M10	
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

▼M1

No	Reference of the standard
8.	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
9.	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)
▼M2 10.	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
11.	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)
12.	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)
▼M10 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
▼M1 13.	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)
14.	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
▼M10 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

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No	Reference of the standard
▼M2	
15.	EN 285:2015+A1:2021 Sterilization – Steam sterilizers – Large sterilizers
16.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021
▼M3	
17.	EN ISO 10993-10:2023 Biological evaluation of medical devices – Part 10: Tests for skin sensitisation (ISO 10993-10:2021)
▼M4	
18.	EN 455-3:2023 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation
19.	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)
20.	EN ISO 10993-17:2023 Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)
▼M10	
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
▼M4	
21.	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
22.	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
23.	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

▼M4

No	Reference of the standard
24.	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
25.	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)

▼M5

26.	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2023)

▼M6

27.	EN 455-1:2020+A2:2024 Medical gloves for single use – Part 1: Requirements and testing for freedom of holes
28.	EN 455-2:2024 Medical gloves for single use – Part 2: Requirements and testing for physical properties
29.	EN 556-1:2024 Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices
30.	EN 556-2:2024 Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 2: Requirements for aseptically processed medical devices
31.	EN 1865-2:2024 Patient handling equipment used in ambulances – Part 2: Power assisted stretcher
32.	EN 1865-6:2024 Patient handling equipment used in ambulances – Part 6: Powered chairs

▼M7

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

▼M7

No	Reference of the standard
36.	EN 14180:2025 Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing

▼M8

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)

▼M8

No	Reference of the standard
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)

▼M9

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

▼M10

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)
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)

▼**M10**

No	Reference of the standard
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