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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

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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

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)
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)
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

▼M1

No	Reference of the standard
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)
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

▼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)

▼**M4**

No	Reference of the standard
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
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)