Summary of references of harmonised European standards published in the *Official Journal of the European Union* in support of Regulation (EU) 2017/745 on medical devices

1st publication (basic act): 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) http://data.europa.eu/eli/dec_impl/2021/1182/oj
Consolidated version: http://data.europa.eu/eli/dec_impl/2021/1182/2023-07-05

2nd publication (1st amendment to the basic act): Commission Implementing Decision (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment (OJ L 1, 5.1.2022, p. 11) http://data.europa.eu/eli/dec_impl/2022/6/oj

3rd publication (2nd amendment to the basic act): Commission Implementing Decision (EU) 2022/757 of 11 May 2022 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for quality management systems, sterilisation and application of risk management to medical devices (OJ L 138, 17.5.2022, p. 27) http://data.europa.eu/eli/dec_impl/2022/757/oj

4th publication (3rd amendment to the basic act): Commission Implementing Decision (EU) 2023/1410 of 4 July 2023 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for sterilization of health care products and biological evaluation of medical devices (OJ L 170, 5.7.2023, p. 102) https://eur-lex.europa.eu/eli/dec_impl/2023/1410/oj

Reference of the standard	Publication	No
EN 285:2015+A1:2021 Sterilization - Steam sterilizers - Large sterilizers	OJ L 138, **17.5.2022**, p. 27	15
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)	OJ L 1, **5.1.2022**, p. 11	6
EN ISO 10993-10:2023 Biological evaluation of medical devices - Part 10: Tests for skin sensitisation (ISO 10993-10:2021)	OJ L 170, **5.7.2023**, p. 102	17
EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	OJ L 1, **5.1.2022**, p. 11	7
EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	OJ L 256, **19.7.2021**, p. 100	1
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**	OJ L 256, **19.7.2021**, p. 100	2
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**	OJ L 256, **19.7.2021**, p. 100	3
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**	OJ L 1, **5.1.2022**, p. 11	8
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)	OJ L 256, **19.7.2021**, p. 100	4
EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)	OJ L 1, **5.1.2022**, p. 11	9
EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO	OJ L 1, **5.1.2022**, p. 11	10

13485:2016) EN ISO 13485:2016/**AC:2018** EN ISO 13485:2016/**A11:2021**	OJ L 138, 17.5.2022, p. 27	
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)	OJ L 1, **5.1.2022**, p. 11	11
EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/**A11:2021**	OJ L 138, **17.5.2022**, p. 27	16
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)	OJ L 1, **5.1.2022**, p. 11	12
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)	OJ L 1, **5.1.2022**, p. 11	13
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**	OJ L 256, **19.7.2021**, p. 100 OJ L 170, 5.7.2023, p. 102	5
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**	OJ L 1, **5.1.2022**, p. 11	14

Webpage on Public Health > Medical Devices - Topics of Interest > Harmonised standards: https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en

Webpage on Single market and standards > European standards > Harmonised standards > Medical devices - Regulation (EU) 2017/745: https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/medical-devices_en