Summary of references of harmonised European standards published in the *Official Journal of the European Union* in support of Regulation (EU) 2017/746 on *in vitro* medical devices

1st publication (basic act): Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 258, 20.7.2021, p. 50) http://data.europa.eu/eli/dec_impl/2021/1195/oj
Consolidated version: http://data.europa.eu/eli/dec_impl/2021/1195/2023-07-05

2nd publication (1st amendment to the basic act): Commission Implementing Decision (EU) 2022/15 of 6 January 2022 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for 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 and requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (OJ L 4, 7.1.2022, p. 16) http://data.europa.eu/eli/dec_impl/2022/15/oj

3rd publication (2nd amendment to the basic act): Commission Implementing Decision (EU) 2022/729 of 11 May 2022 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for quality management systems and for application of risk management to medical devices (OJ L 135, 12.5.2022, p. 31) http://data.europa.eu/eli/dec_impl/2022/729/oj

4th publication (3rd amendment to the basic act): Commission Implementing Decision (EU) 2023/1411 of 4 July 2023 amending Implementing Decision (EU) 2021/1195 as regards a harmonised standard for sterilization of health care products (OJ L 170, 5.7.2023, p. 105) https://eur-lex.europa.eu/eli/dec_impl/2023/1411/oj

Reference of the standard	Publication	No
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 258, **20.7.2021**, p. 50	1
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 258, **20.7.2021**, p. 50	2
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 4, **7.1.2022**, p. 16	5
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 258, **20.7.2021**, p. 50	3
EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)	OJ L 4, **7.1.2022**, p. 16	6
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**	OJ L 4, **7.1.2022**, p. 16 OJ L 135, 12.5.2022, p. 31	7
EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/**A11:2021**	OJ L 135, **12.5.2022**, p. 31	10
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 4, **7.1.2022**, p. 16	8
EN ISO 17511:2021 *In vitro* diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020)	OJ L 4, **7.1.2022**, p. 16	9

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 258, **20.7.2021**, p. 50 OJ L 170, 5.7.2023, p. 105	4

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 > *In vitro* diagnostic medical devices - Regulation (EU) 2017/746: https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en