EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Ecosystems III: Construction, Machinery and Standardisation
Standards Policy

Brussels, 9.10.2024

Summary of references of harmonised standards published in the Official Journal – Regulation (EU) 2017/745[1] 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

The summary below consolidates the references of harmonised standards published by the Commission in the *Official Journal of the European Union* (OJ). It reproduces information already published in the L or C series of the OJ as indicated in columns (2), (5) and/or (7). It contains all references which, when the summary was generated, still provided a presumption of conformity together with references already withdrawn from the OJ.

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This summary was generated on 9 October 2024.

Legislation reference (A)	ESO (B)	Reference number of the standard (C)	Title of the standard (D)	Date of start of presumption of conformity (1)	OJ reference for publication in OJ (2)	Restriction (3)	Date of start of presumption of conformity with restriction (4)	OJ reference for publication of a restriction in OJ (5)	Date of withdrawal from OJ (end of presumption of conformity) (6)	OJ reference for withdrawal from OJ (7)
2017/745	CEN	EN 285:2015+A1:2021	Sterilization - Steam sterilizers - Large sterilizers	17/05/2022	OJ L 138 - 17/05/2022	-		-		-
2017/745	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	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 - 05/01/2022	-		-		-

[1] OJ L 117 5.5.2017, p. 1-175

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2017/745	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 - 05/07/2023	-		-		-
2017/745	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 - 05/01/2022	-		-		-
2017/745	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	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	CEN	EN ISO 10993-18:2020, EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)	08/03/2024	OJ L, 2024/815 - 08/03/2024	-		-		-
2017/745	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 - 19/07/2021	-		-		-
2017/745	CEN	EN ISO 11135:2014, EN ISO 11135:2014/A1:2019	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)	19/07/2021	OJ L 256 - 19/07/2021	-		-		-
2017/745	CEN	EN ISO 11137-1:2015, EN ISO 11137-1:2015/A2:2019	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)	19/07/2021	OJ L 256 - 19/07/2021	-		-		-
2017/745	CEN	EN ISO 11137-2:2015, EN ISO 11137-2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	08/03/2024	OJ L, 2024/815 - 08/03/2024	-		-		-
2017/745	CEN	EN ISO 11607-1:2020, EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	08/03/2024	OJ L, 2024/815 - 08/03/2024	-		-		-
2017/745	CEN	EN ISO 11607-2:2020, EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	08/03/2024	OJ L, 2024/815 - 08/03/2024	-		-		-
2017/745	CEN	EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	05/01/2022	OJ L 1 - 05/01/2022	-		-		-

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2017/745	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 - 19/07/2021	-		-		-
2017/745	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	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 - 05/01/2022	-		-		-
2017/745	CEN	EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	05/01/2022	OJ L 1 - 05/01/2022	-		-		-
2017/745	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 - 05/01/2022	-		-		-
2017/745	CEN	EN ISO 14971:2019, EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	17/05/2022	OJ L 138 - 17/05/2022	-		-		-
2017/745	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 - 05/01/2022	-		-		-
2017/745	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 - 05/01/2022	-		-		-
2017/745	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	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 - 19/07/2021	-		-	05/07/2023	OJ L 170 - 05/07/2023

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2017/745	CEN	EN ISO 25424:2019, EN ISO 25424:2019/A1:2022	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)	05/07/2023	OJ L 170 - 05/07/2023	-		-		-
2017/745	Cenelec	EN IEC 60601-2-83:2020, EN IEC 60601-2-83:2020/A11:2021	Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	05/01/2022	OJ L 1 - 05/01/2022	-		-		-

Column legend

Reference information on legislation and standards

(A) Reference number of a relevant Directive or Regulation under which it was published in the OJ

(B) European standardisation organisation that adopted the relevant standard

(C) Reference number of a relevant European standard or of a European standard and its amendment(s)

(D) Title of a European standard

Dates and OJ references for establishing a presumption of conformity

(1) Date when a presumption of conformity starts or started in cases where a reference was published in the OJ without restriction. This date is usually, but not always, the same as the OJ reference date in column (2)

(2) Reference number and date of a relevant publication in the L or C series of the OJ in cases where a reference was published in the OJ without restriction

Dates and OJ references for establishing a presumption of conformity with restriction

(3) Restriction published in the OJ to restrict a presumption of conformity – this includes restrictions on the basis of formal objections

(4) Date when a presumption of conformity with restriction starts or started in cases where a reference was published in the OJ with restriction. This date is usually, but not always, the same as the date in column (5)

(5) Reference number and date of a relevant publication in the L or C series of the OJ in cases where a reference was published in the OJ with restriction

Dates and OJ references for ending a presumption of conformity

(6) Date when a presumption of conformity ends or ended

(7) Reference number and date of a relevant publication in the L or C series of the OJ where the date of withdrawal from the OJ (date in column (6)) was published