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) 2017/746[1] of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

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which, when the summary was generated, still provided a presumption of conformity together with references already withdrawn from the OJ.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)
2017/746	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)	20/07/2021	OJ L 258 - 20/07/2021	-		-		-
2017/746	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)	20/07/2021	OJ L 258 - 20/07/2021	-		-		-

[1] OJ L 117 5.5.2017, p. 176-332

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)
2017/746	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, 2024/817 - 08/03/2024	-		-		-
2017/746	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, 2024/817 - 08/03/2024	-		-		-
2017/746	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, 2024/817 - 08/03/2024	-		-		-
2017/746	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)	07/01/2022	OJ L 4 - 07/01/2022	-		-		-
2017/746	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)	20/07/2021	OJ L 258 - 20/07/2021	-		-		-
2017/746	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, 2024/2625 - 09/10/2024	-		-		-
2017/746	CEN	EN ISO 13408-6:2021	Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)	07/01/2022	OJ L 4 - 07/01/2022	-		-		-
2017/746	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)	07/01/2022	OJ L 4 - 07/01/2022	-		-		-
2017/746	CEN	EN ISO 14971:2019, EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	12/05/2022	OJ L 135 - 12/05/2022	-		-		-
2017/746	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)	07/01/2022	OJ L 4 - 07/01/2022	-		-		-
2017/746	CEN	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)	07/01/2022	OJ L 4 - 07/01/2022	-		-		-
2017/746	CEN	EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)	09/10/2024	OJ L, 2024/2625 - 09/10/2024	-		-		-
2017/746	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)	20/07/2021	OJ L 258 - 20/07/2021	-		-	05/07/2023	OJ L 170 - 05/07/2023

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)
2017/746	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	-		-		-

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