SNAPSHOT

Medical Devices – List of European Standards intended to be cited in the *Official Journal of the European Union* (OJEU) under the Directives:

- on Medical Devices Regulation **(EU) 2017/745**
- on In Vitro Diagnostic Regulation **(EU) 2017/426**

This snapshot identifies work items for which:

- drafts have been received in CCMC for Formal Vote or UAP (Unique Acceptance Procedure);
- the Formal Vote or UAP has been launched;
- the Formal Vote or UAP is closed;
- DAV (date of publication) has been reached within the last 6 months.

For information on work items under development, please use the search engine available on the CEN website or on the CENELEC website.

For standards whose references have been published in the OJEU under one of the relevant Directives, please refer to the European Commission DG GROW's website, in the section 'Legislation and standards' (http://ec.europa.eu/growth/index_en.htm).

2017/745 - Regulation (EU) 2017/745 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

EN 285:2015+A1:2021

Sterilization - Steam sterilizers - Large sterilizers

DAV: 2021-10-06
DOW: 2022-04-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes		

CEN/TC 102 - Sterilizers and associated equipment for processing of medical devices
Chairman: Dr.-Ing. A. Berthe ( ); Secretary: Dr S. Minkwitz (DIN)

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)

DAV: 2021-09-29
DOW: 2022-03-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 1	2022-01-05

CEN/TC 206 - Biological and clinical evaluation of medical devices
Chairman: Dr H. Hofman-Hüther ( ); Secretary: Dipl.-Ing. K. Wenzelewski (DIN)

EN ISO 10993-12:2021

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

DAV: 2021-06-16
DOW: 2021-12-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 1	2022-01-05

CEN/TC 206 - Biological and clinical evaluation of medical devices
Chairman: Dr H. Hofman-Hüther ( ); Secretary: Dipl.-Ing. K. Wenzelewski (DIN)

EN ISO 10993-23:2021

Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)

DAV: 2021-03-31
DOW: 2021-09-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 256	2021-07-19

2017/745 - Regulation (EU) 2017/745 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

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/BC/CEN/89/9	Yes		2021-07-19
M/575			2021-07-19
M/BC/CEN/89/9		L 256	2021-07-19

CEN/TC 206 - Biological and clinical evaluation of medical devices
Chairman: Dr H. Hofman-Hüther ( ); Secretary: Dipl.-Ing. K. Wenzelewski (DIN)

EN ISO 11737-1:2018/A1:2021

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1 (ISO 11737-1:2018/Amd 1:2021)

DAV: 2021-06-16
DOW: 2021-12-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 4	2022-01-05
M/575		L 1	2022-01-05

CEN/TC 204 - Sterilization of medical devices
Chairman: Dr E. Hoxey (GB); Secretary: Mr A. Patel (BSI)

EN ISO 13408-6:2021

Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)

DAV: 2021-05-19
DOW: 2021-11-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 4	2022-01-05
M/575		L 1	2022-01-05
M/565		L 4	2022-01-05
M/565		L 1	2022-01-05

CEN/TC 204 - Sterilization of medical devices
Chairman: Dr E. Hoxey (GB); Secretary: Mr A. Patel (BSI)

EN ISO 13485:2016/A11:2021

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

DAV: 2021-09-08
DOW: 2022-03-31

2017/745 - Regulation (EU) 2017/745 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

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 1	2022-01-05
M/575		L 4	2022-01-05

CEN/CLC/JTC 3 - Quality management and corresponding general aspects for medical devices
Chairman: Mr R. Geertsma ( ); Secretary: Mrs S. Golyardi (NEN)

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)

DAV: 2021-06-30
DOW: 2021-12-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 1	2022-01-05

CEN/TC 204 - Sterilization of medical devices
Chairman: Dr E. Hoxey (GB); Secretary: Mr A. Patel (BSI)

EN ISO 14971:2019/A11:2021

Medical devices - Application of risk management to medical devices (ISO 14971:2019)

DAV: 2021-12-08
DOW: 2022-06-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes		

CEN/CLC/JTC 3 - Quality management and corresponding general aspects for medical devices
Chairman: Mr R. Geertsma ( ); Secretary: Mrs S. Golyardi (NEN)

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)

DAV: 2021-09-29
DOW: 2022-03-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 4	2022-01-05
M/575		L 1	2022-01-05

2017/745 - Regulation (EU) 2017/745 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

CEN/CLC/JTC 3 - Quality management and corresponding general aspects for medical devices
Chairman: Mr R. Geertsma ( ); Secretary: Mrs S. Golyardi (NEN)

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)

DAV: 2021-09-01
DOW: 2022-03-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 1	2022-01-05

CEN/TC 204 - Sterilization of medical devices
Chairman: Dr E. Hoxey (GB); Secretary: Mr A. Patel (BSI)

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

DAV: 2021-04-02
DOW: 2023-11-03

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/565	Yes	L 1	2022-01-05
M/023		L 1	2022-01-05

CLC/TC 62 - Electrical equipment in medical practice
Chairman: Dr P.W.J. Linders ( ); Secretary: Mr P. Luzajic (BSI)

2017/746 - Regulation (EU) 2017/746 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

EN ISO 11737-1:2018/A1:2021

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1 (ISO 11737-1:2018/Amd 1:2021)

DAV: 2021-06-16
DOW: 2021-12-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 1	2022-01-07
M/575		L 4	2022-01-07

CEN/TC 204 - Sterilization of medical devices
Chairman: Dr E. Hoxey (GB); Secretary: Mr A. Patel (BSI)

EN ISO 13408-6:2021

Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)

DAV: 2021-05-19
DOW: 2021-11-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/565	Yes	L 1	2022-01-07
M/565		L 4	2022-01-07
M/575		L 4	2022-01-07
M/575		L 1	2022-01-07

CEN/TC 204 - Sterilization of medical devices
Chairman: Dr E. Hoxey (GB); Secretary: Mr A. Patel (BSI)

EN ISO 13485:2016/A11:2021

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

DAV: 2021-09-08
DOW: 2022-03-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 1	2022-01-07
M/575		L 4	2022-01-07

CEN/CLC/JTC 3 - Quality management and corresponding general aspects for medical devices
Chairman: Mr R. Geertsma ( ); Secretary: Mrs S. Golyardi (NEN)

2017/746 - Regulation (EU) 2017/746 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

EN ISO 14971:2019/A11:2021

Medical devices - Application of risk management to medical devices (ISO 14971:2019)

DAV: 2021-12-08
DOW: 2022-06-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes		

CEN/CLC/JTC 3 - Quality management and corresponding general aspects for medical devices
Chairman: Mr R. Geertsma ( ); Secretary: Mrs S. Golyardi (NEN)

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)

DAV: 2021-09-29
DOW: 2022-03-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 1	2021-01-07
M/575		L 4	2021-01-07

CEN/CLC/JTC 3 - Quality management and corresponding general aspects for medical devices
Chairman: Mr R. Geertsma ( ); Secretary: Mrs S. Golyardi (NEN)

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)

DAV: 2021-06-02
DOW: 2024-06-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/537	Yes	L 4	2022-01-07
M/575		L 4	2022-01-07

CEN/TC 140 - In vitro diagnostic medical devices
Chairman: Mr R. Zielenski (DE); Secretary: Dipl.-Ing. B. Hermes (DIN)

90/385/EEC - Active implantable medical devices

EN ISO 10993-23:2021

Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)

DAV: 2021-03-31
DOW: 2021-09-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 256	
M/575			
M/BC/CEN/89/9		L 256	
M/BC/CEN/89/9			

CEN/TC 206 - Biological and clinical evaluation of medical devices
Chairman: Dr H. Hofman-Hüther ( ); Secretary: Dipl.-Ing. K. Wenzelewski (DIN)

EN ISO 14155:2020

Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)

DAV: 2020-08-19
DOW: 2021-02-28

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/295	Yes		

CEN/TC 206 - Biological and clinical evaluation of medical devices
Chairman: Dr H. Hofman-Hüther ( ); Secretary: Dipl.-Ing. K. Wenzelewski (DIN)

93/42/EEC - Medical devices

EN 1789:2020
Medical vehicles and their equipment - Road ambulances

DAV: 2020-09-02
DOW: 2022-03-31

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/023	Yes	L 129	2021-04-15

CEN/TC 239 - Rescue systems
Chairman: Mr A. Schulte ( ); Secretary: Dipl.-Ing. S. Mann (DIN)

EN ISO 10993-23:2021
Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)

DAV: 2021-03-31
DOW: 2021-09-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/575	Yes	L 256	
M/BC/CEN/89/9			
M/BC/CEN/89/9		L 256	
M/575			

CEN/TC 206 - Biological and clinical evaluation of medical devices
Chairman: Dr H. Hofman-Hüther ( ); Secretary: Dipl.-Ing. K. Wenzelewski (DIN)

EN ISO 14155:2020
Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)

DAV: 2020-08-19
DOW: 2021-02-28

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/295	Yes		

CEN/TC 206 - Biological and clinical evaluation of medical devices
Chairman: Dr H. Hofman-Hüther ( ); Secretary: Dipl.-Ing. K. Wenzelewski (DIN)

EN 14222:2021
Stainless steel steam boilers

DAV: 2021-01-20
DOW: 2021-07-31

93/42/EEC - Medical devices

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/023	Yes	L 361	
M/071			
M/071		L 361	
M/023			

CEN/TC 102 - Sterilizers and associated equipment for processing of medical devices
Chairman: Dr.-Ing. A. Berthe ( ); Secretary: Dr S. Minkwitz (DIN)

EN ISO 22442-1:2020

Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2020)

DAV: 2020-12-09
DOW: 2021-06-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/023	Yes	L 129	2021-04-15

CEN/TC 206 - Biological and clinical evaluation of medical devices
Chairman: Dr H. Hofman-Hüther ( ); Secretary: Dipl.-Ing. K. Wenzelewski (DIN)

EN ISO 22442-2:2020

Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2020)

DAV: 2020-12-09
DOW: 2021-06-30

Mandate(s):	To be cited in OJ:	OJ reference:	OJ date:
M/023	Yes	L 129	2021-04-15

CEN/TC 206 - Biological and clinical evaluation of medical devices
Chairman: Dr H. Hofman-Hüther ( ); Secretary: Dipl.-Ing. K. Wenzelewski (DIN)

Work Programme ABHS N 636

Directive 2017/745 - Regulation (EU) 2017/745 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

00204084 EN ISO 11137-2:2015/prA1

Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose - Amendment 1 (ISO 11137-2:2013/DAmd 1:2021)

Vienna Agreement: VA/ISO Lead — Track: EN/ENQ+FV/VA ISO
Last Realized milestone: Dispatch //FV draft to CMC (2021-12-08) — To be cited in OJ: Yes

Planning:			Mandate(s):
FCST	Submission to // Formal Vote	2022-03-16	
FCST	Closure of // Formal Vote	2022-05-11	M/575
FCST	DOR/Ratification	2022-06-13	
FCST	DAV/Definitive text available	2022-08-16	

00206086 FprEN ISO 10993-10

Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO/FDIS 10993-10:2021)

Vienna Agreement: VA/ISO Lead — Track: EN/ENQ+FV/VA ISO
Last Realized milestone: DOR/Ratification (2021-09-13) — To be cited in OJ: Yes

Planning:			Mandate(s):
FCST	DAV/Definitive text available	2021-11-15	M/575

00215281 FprEN ISO 80601-2-13

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO/FDIS 80601-2-13:2021)

Vienna Agreement: VA/ISO Lead — Track: EN/ENQ+FV/VA ISO
Last Realized milestone: Submission to // Formal Vote (2021-12-16) — To be cited in OJ: Yes

Planning:			Mandate(s):
FCST	Closure of // Formal Vote	2022-02-04	M/575
FCST	DOR/Ratification	2022-03-04	
FCST	DAV/Definitive text available	2022-05-04	

CEN/TC 215/WG 1 - Anaesthetic machines, medical breathing systems and anaesthetic gas scavenging systems
Convenor: Mr R. Heesch ( ); Secretary: Dr K. Stehfest (DIN)

00216133 FprEN 14885

Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

Vienna Agreement: No — Track: EN/ENQ+FV
Last Realized milestone: Acceptance of FV draft (2021-10-20) — To be cited in OJ: Yes

Planning:			Mandate(s):
FCST	Submission to Formal Vote	2021-12-29	
FCST	Closure of Formal Vote	2022-02-23	M/575
FCST	DOR/Ratification	2022-03-23	
FCST	DAV/Definitive text available	2022-05-23	

CEN/TC 216/WG 5 - Strategy Group
Convenor: Dr F. Brill ( ); Secretary: Ms H. Moser (DIN)

JT003057 EN ISO 15223-1:2016/FprA11
Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, including corrected version 2017-03)

Vienna Agreement: No — Track: EN/ENQ+FV
Last Realized milestone: DOR/Ratification (2021-03-19) — To be cited in OJ: Yes

Planning:

FCST	DAV/Definitive text available	2021-05-19

JT016003 FprEN ISO 14708-4
Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pump systems (ISO/FDIS 14708-4:2021)

Vienna Agreement: VA/ISO Lead — Track: EN/ENQ+FV/VA ISO
Last Realized milestone: Closure of // Formal Vote (2022-01-10) — To be cited in OJ: Yes

Planning:			Mandate(s):
FCST	DOR/Ratification	2022-02-11	
FCST	DAV/Definitive text available	2022-04-11	

Directive 2017/746 - Regulation (EU) 2017/746 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

00204084 EN ISO 11137-2:2015/prA1
Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose - Amendment 1 (ISO 11137-2:2013/DAmd 1:2021)

Vienna Agreement: VA/ISO Lead — Track: EN/ENQ+FV/VA ISO
Last Realized milestone: Dispatch //FV draft to CMC (2021-12-08) — To be cited in OJ: Yes

Planning:			Mandate(s):
FCST	Submission to // Formal Vote	2022-03-16	
FCST	Closure of // Formal Vote	2022-05-11	M/575
FCST	DOR/Ratification	2022-06-13	
FCST	DAV/Definitive text available	2022-08-16	

JT003057 EN ISO 15223-1:2016/FprA11
Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, including corrected version 2017-03)

Vienna Agreement: No — Track: EN/ENQ+FV
Last Realized milestone: DOR/Ratification (2021-03-19) — To be cited in OJ: Yes

Planning:		
FCST	DAV/Definitive text available	2021-05-19