Zusammenfassung der Fundstellen der im Amtsblatt veröffentlichten harmonisierten Normen – Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates vom 5. April 2017 über Medizinprodukte

Mit der nachstehenden Zusammenfassung werden die Fundstellen harmonisierter Normen, die von der Kommission im *Amtsblatt der Europäischen Union* (ABl.) veröffentlicht wurden, konsolidiert. Sie enthält Angaben, die bereits in der Reihe L oder C des Amtsblatts veröffentlicht wurden, wie in den Spalten (2), (5) und/oder (7) angegeben. Sie enthält alle Fundstellen, bei denen zum Zeitpunkt der Erstellung der Zusammenfassung noch von der Vermutung der Konformität ausgegangen wurde, einschließlich von bereits aus dem Amtsblatt gestrichenen Fundstellen.

Die Dienststellen der Kommission stellen diese Zusammenfassung nur zu Informationszwecken zur Verfügung. Obwohl sie soweit irgend möglich Vorkehrungen treffen, um sicherzustellen, dass die Zusammenfassung regelmäßig aktualisiert wird und korrekt ist, können Fehler auftreten, und die Zusammenfassung kann zu einem bestimmten Zeitpunkt möglicherweise nicht vollständig sein. Die Zusammenfassung selbst entfaltet keine Rechtswirkungen.

Diese Zusammenfassung wurde am 07.04.2026 erstellt.

Erläuterungen zu den Spalten

Legislation / Rechtsvorschrift (A)	ESO (B)	Reference and title Provision / Nummer und Titel der Norm (C)	Start of legal effect / Beginn der Konformitäts-vermutung (1)	Publi-cation OJ reference / Amtsblatt-fundstelle (2)	Publication Decision Reference / Veröffent-lichungs-beschluss (3)	Publication OJ date / Datum der Veröffent-lichung im Amtsblatt (4)	End of legal effect / Ende der Konformitäts-vermutung (5)	Withdrawal OJ reference / Amtsblatt-fundstelle der Streichung aus dem Amtsblatt (6)	Withdrawal Decision Reference / Streichungs-beschluss (7)	With-drawal OJ date / Datum der Streichung aus dem Amtsblatt (8)

Referenzinformationen zu Rechtsvorschriften und Normen

(A) Nummer der einschlägigen Richtlinie oder Verordnung, nach der sie im Amtsblatt veröffentlicht wurde.

(B) Europäische Normungsorganisation, von der die einschlägige Norm angenommen wurde.

(C) Nummer und Titel einer einschlägigen europäischen Norm oder einer europäischen Norm und ihrer Änderung(en).

Datum und Amtsblattfundstelle für die Vermutung der Konformität

(1) Datum, an dem eine Konformitätsvermutung in den Fällen beginnt oder begonnen hat, in denen eine Fundstelle ohne Einschränkung im Amtsblatt veröffentlicht wurde. Dieses Datum entspricht in der Regel nicht immer dem in Spalte (4) angegebenen Datum der Veröffentlichung im Amtsblatt.

(2) Fundstelle einer einschlägigen Veröffentlichung im Amtsblatt.

(3) Referenz des Veröffentlichungsbeschlusses.

(4) Datum einer einschlägigen Veröffentlichung im Amtsblatt.

Datum und Amtsblattfundstelle für das Ende der Vermutung der Konformität

(5) Datum der Beendigung einer Konformitätsvermutung.

(6) Fundstelle einer einschlägigen Veröffentlichung im Amtsblatt, in den Fällen, in denen das Datum der Streichung im Amtsblatt (Datum in Spalte (8)) veröffentlicht wurde.

(7) Referenz des Streichungsbeschlusses.

(8) Datum der Streichung aus dem Amtsblatt.

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Legislation	ESO	Reference and title Provision	Start of legal effect	Publication OJ reference	Publication Decision reference	Publication OJ date	End of legal effect	With-drawal OJ reference	Withdrawal Decision reference	Withdrawal OJ date
2017/745 - Medical Devices	CEN	EN 285:2015+A1:2021 Sterilization - Steam sterilizers - Large sterilizers	17.05.2022	OJ L 138	2022/757	17.05.2022				
2017/745 - Medical Devices	CEN	EN 455-1:2020+A2:2024 Medical gloves for single use - Part 1: Requirements and testing for freedom of holes	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 455-2:2024 Medical gloves for single use - Part 2: Requirements and testing for physical properties	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	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 - Medical Devices	CEN	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 1865-2:2024 Patient handling equipment used in ambulances - Part 2: Power assisted stretcher	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 1865-6:2024 Patient handling equipment used in ambulances - Part 6: Powered chairs	09.04.2025	OJ L	2025/681	09.04.2025				
2017/745 - Medical Devices	CEN	EN 13060:2025 Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing	07.04.2026	OJ L	2026/760	07.04.2026				

Legislation	ESO	Reference and title Provision	Start of legal effect	Publication OJ reference	Publication Decision reference	Publication OJ date	End of legal effect	With-drawal OJ reference	Withdrawal Decision reference	Withdrawal OJ date
2017/745 - Medical Devices	CEN	EN 13795-1:2025 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	20.10.2025	OJ L	2025/2078	20.10.2025				
2017/745 - Medical Devices	CEN	EN 13795-2:2025 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits	20.10.2025	OJ L	2025/2078	20.10.2025				
2017/745 - Medical Devices	CEN	EN 14180:2025 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing	20.10.2025	OJ L	2025/2078	20.10.2025				
2017/745 - Medical Devices	CEN	EN 14222:2021+A1:2025 Stainless steel steam boilers	07.04.2026	OJ L	2026/760	07.04.2026				
2017/745 - Medical Devices	CEN	EN 14683:2025 Medical face masks - Requirements and test methods	20.10.2025	OJ L	2025/2078	20.10.2025				
2017/745 - Medical Devices	Cenelec	EN IEC 60118-0:2024 Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids	07.04.2026	OJ L	2026/760	07.04.2026				
2017/745 - Medical Devices	Cenelec	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	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 7197:2024 Neurosurgical implants - Sterile, single-use hydrocephalus shunts (ISO 7197:2024)	30.01.2026	OJ L	2026/193	30.01.2026				
2017/745 - Medical Devices	CEN	EN ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Amendment 1 (ISO 10993-4:2017/Amd 1:2025, Corrected version 2025-04) EN ISO 10993-4:2017/A1:2025	30.01.2026	OJ L	2026/193	30.01.2026				
2017/745 - Medical Devices	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	2022/6	05.01.2022				

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2017/745 - Medical Devices	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	2023/1410	05.07.2023				
2017/745 - Medical Devices	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	2022/6	05.01.2022				
2017/745 - Medical Devices	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 - Medical Devices	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 - Medical Devices	CEN	EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020) EN ISO 10993-18:2020/A1:2023	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	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	2021/1182	19.07.2021				
2017/745 - Medical Devices	CEN	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	19.07.2021	OJ L 256	2021/1182	19.07.2021				
2017/745 - Medical Devices	CEN	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	19.07.2021	OJ L 256	2021/1182	19.07.2021				

Legislation	ESO	Reference and title Provision	Start of legal effect	Publication OJ reference	Publication Decision reference	Publication OJ date	End of legal effect	With-drawal OJ reference	Withdrawal Decision reference	Withdrawal OJ date
2017/745 - Medical Devices	CEN	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013) EN ISO 11137-2:2015/A1:2023	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	CEN	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019) EN ISO 11607-1:2020/A1:2023	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	CEN	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019) EN ISO 11607-2:2020/A1:2023	08.03.2024	OJ L	2024/815	08.03.2024				
2017/745 - Medical Devices	CEN	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	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	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	2021/1182	19.07.2021				
2017/745 - Medical Devices	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 - Medical Devices	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	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	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	05.01.2022	OJ L 1	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good clinical practice EN ISO 14155:2020/A11:2024	30.01.2026	OJ L	2026/193	30.01.2026				

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2017/745 - Medical Devices	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	2022/6	05.01.2022				
2017/745 - Medical Devices	CEN	EN ISO 14630:2024 Non-active surgical implants - General requirements (ISO 14630:2024)	30.01.2026	OJ L	2026/193	30.01.2026				
2017/745 - Medical Devices	CEN	EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021	17.05.2022	OJ L 138	2022/757	17.05.2022				
2017/745 - Medical Devices	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	2022/6	05.01.2022				
2017/745 - Medical Devices	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	2022/6	05.01.2022				
2017/745 - Medical Devices	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 - Medical Devices	CEN	EN ISO 17665:2024 Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)	30.01.2026	OJ L	2026/193	30.01.2026				

Legislation	ESO	Reference and title Provision	Start of legal effect	Publication OJ reference	Publication Decision reference	Publication OJ date	End of legal effect	With-drawal OJ reference	Withdrawal Decision reference	Withdrawal OJ date
2017/745 - Medical Devices	CEN	EN ISO 18562-1:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process (ISO 18562-1:2024)	30.01.2026	OJ L	2026/193	30.01.2026				
2017/745 - Medical Devices	CEN	EN ISO 18562-2:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter (ISO 18562-2:2024)	30.01.2026	OJ L	2026/193	30.01.2026				
2017/745 - Medical Devices	CEN	EN ISO 18562-3:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic substances (ISO 18562-3:2024)	30.01.2026	OJ L	2026/193	30.01.2026				
2017/745 - Medical Devices	CEN	EN ISO 18562-4:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate (ISO 18562-4:2024)	30.01.2026	OJ L	2026/193	30.01.2026				
2017/745 - Medical Devices	CEN	EN ISO 21535:2024 Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants (ISO 21535:2023)	30.01.2026	OJ L	2026/193	30.01.2026				
2017/745 - Medical Devices	CEN	EN ISO 21536:2024 Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants (ISO 21536:2023)	30.01.2026	OJ L	2026/193	30.01.2026				
2017/745 - Medical Devices	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	2021/1182	19.07.2021	05.07.2023	OJ L 170	2023/1410	05.07.2023
2017/745 - Medical Devices	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) EN ISO 25424:2019/A1:2022	05.07.2023	OJ L 170	2023/1410	05.07.2023				

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2017/745 - Medical Devices	CEN	EN ISO 80369-2:2024 Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for respiratory applications (ISO 80369-2:2024, Corrected version 2025-06)	30.01.2026	OJ L	2026/193	30.01.2026				