**Generated on 17.6.2026**

| Legislation | ESO | Reference and title Provision | Start of legal effect | Publication OJ reference | Publication Decision reference | Publication OJ date | End of legal effect | Withdrawal OJ reference | Withdrawal Decision reference | Withdrawal OJ date |
|---|---|---|---|---|---|---|---|---|---|---|
| 2017/745 - Medical Devices | CEN | EN 285:2015+A1:2021<br>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<br>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<br>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<br>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<br>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<br>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 | | | | |

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| 2017/745 - Medical Devices | CEN | EN 1865-2:2024<br>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<br>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<br>Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing | 07.04.2026 | OJ L | 2026/760 | 07.04.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN 13795-1:2025<br>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<br>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<br>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<br>Stainless steel steam boilers | 07.04.2026 | OJ L | 2026/760 | 07.04.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN 14683:2025<br>Medical face masks - Requirements and test methods | 20.10.2025 | OJ L | 2025/2078 | 20.10.2025 | | | | |
| 2017/745 - Medical Devices | Cenelec | EN 60601-1:2006<br>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance<br>EN 60601-1:2006/A13:2024 | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |

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| 2017/745 - Medical Devices | Cenelec | EN IEC 60118-0:2024<br>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<br>Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment<br>EN IEC 60601-2-83:2020/A11:2021 | 05.01.2022 | OJ L 1 | 2022/6 | 05.01.2022 | 15.12.2027 | OJ L | 2021/1182 | 17.06.2026 |
| 2017/745 - Medical Devices | Cenelec | EN IEC 60601-2-83:2020<br>Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment<br>EN IEC 60601-2-83:2020/A11:2021<br>EN IEC 60601-2-83:2020/A1:2025 | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 1135-4:2025<br>Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed (ISO 1135-4:2025) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 1135-5:2025<br>Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus (ISO 1135-5:2025) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 7197:2024<br>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 10993-1:2025<br>Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process (ISO 10993-1:2025) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |

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| 2017/745 - Medical Devices | CEN | EN ISO 10993-4:2017<br>Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)<br>EN ISO 10993-4:2017/A1:2025 | 30.01.2026 | OJ L | 2026/193 | 30.01.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 10993-5:2009<br>Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)<br>EN ISO 10993-5:2009/A11:2025 | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 10993-9:2021<br>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 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 10993-10:2023<br>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<br>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 | 15.12.2027 | OJ L | 2021/1182 | 17.06.2026 |
| 2017/745 - Medical Devices | CEN | EN ISO 10993-12:2021<br>Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)<br>EN ISO 10993-12:2021/A1:2025 | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 10993-15:2023<br>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 | | | | |

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| 2017/745 - Medical Devices | CEN | EN ISO 10993-17:2023<br>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 | 15.12.2027 | OJ L | 2021/1182 | 17.06.2026 |
| 2017/745 - Medical Devices | CEN | EN ISO 10993-17:2023<br>Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)<br>EN ISO 10993-17:2023/A1:2025 | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 10993-18:2020<br>Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)<br>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<br>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 | 15.12.2027 | OJ L | 2021/1182 | 17.06.2026 |
| 2017/745 - Medical Devices | CEN | EN ISO 10993-23:2021<br>Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)<br>EN ISO 10993-23:2021/A1:2025 | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 11135:2014<br>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)<br>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<br>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)<br>EN ISO 11137-1:2015/A2:2019 | 19.07.2021 | OJ L 256 | 2021/1182 | 19.07.2021 | | | | |

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| 2017/745 - Medical Devices | CEN | EN ISO 11137-2:2015<br>Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)<br>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<br>Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)<br>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<br>Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)<br>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<br>Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)<br>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<br>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 12870:2025<br>Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2024) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 13408-1:2024<br>Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2023) | 09.10.2024 | OJ L | 2024/2631 | 09.10.2024 | | | | |

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| 2017/745 - Medical Devices | CEN | EN ISO 13408-6:2021<br>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<br>Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)<br>EN ISO 13485:2016/AC:2018<br>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<br>Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)<br>EN ISO 14155:2020/A11:2024 | 30.01.2026 | OJ L | 2026/193 | 30.01.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 14160:2021<br>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 14607:2025<br>Non-active surgical implants - Mammary implants - Specific requirements (ISO 14607:2024) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 14630:2024<br>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 14889:2025<br>Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses (ISO 14889:2025) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |

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| 2017/745 - Medical Devices | CEN | EN ISO 14971:2019<br>Medical devices - Application of risk management to medical devices (ISO 14971:2019)<br>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<br>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 | 15.06.2031 | OJ L | 2021/1182 | 17.06.2026 |
| 2017/745 - Medical Devices | CEN | EN ISO 15223-1:2021<br>Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)<br>EN ISO 15223-1:2021/A1:2025 | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 15883-1:2025<br>Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2024) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 15883-2:2025<br>Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices (ISO 15883-2:2024) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 15883-3:2025<br>Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2024) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 15883-7:2025<br>Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment (ISO 15883-7:2025) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |

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| 2017/745 - Medical Devices | CEN | EN ISO 17664-1:2021<br>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<br>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<br>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 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 18562-1:2024<br>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<br>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<br>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 | | | | |

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| 2017/745 - Medical Devices | CEN | EN ISO 18562-4:2024<br>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<br>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<br>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 22675:2025<br>Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2024) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 23908:2025<br>Sharps injury protection - Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration - Requirements and test methods (ISO 23908:2024) | 17.06.2026 | OJ L | 2021/1182 | 17.06.2026 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 25424:2019<br>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 |

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| 2017/745 - Medical Devices | CEN | EN ISO 25424:2019<br>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)<br>EN ISO 25424:2019/A1:2022 | 05.07.2023 | OJ L 170 | 2023/1410 | 05.07.2023 | | | | |
| 2017/745 - Medical Devices | CEN | EN ISO 80369-2:2024<br>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 | | | | |

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