

THE DEPARTMENT OF HEALTH AND SOCIAL CARE
NOTICE OF PUBLICATION
0129/26
of 17 January 2026

**of references to standards for medical devices in support of the Medical
Devices Regulations 2002 (S.I. 2002/618)**

This notice confirms that:

- a) The references to standards listed in Annex I to this notice are published for the purposes of regulation 3A of S.I. 2002/618 and accordingly are designated pursuant to that regulation in relation to England and Wales and Scotland. The list of published standards set out in Annex I to notice 0034/21 is amended in accordance with Annex I to this notice from the date of this notice. For clarity, Part 2 of Annex I to this notice sets out the complete list of references to standards which have been published and accordingly are designated for the purposes of S.I. 2002/618 as at the date of this notice.
- b) The list of references to standards to be removed from publication, set out in Annex II to notice 0034/21, is amended in accordance with Annex II to this notice from the date of this notice.

ANNEX I

Part 1

The list of published standards as set out in Annex I to notice 0034/21 is to be amended as follows:

- (1) rows 1, 2, 3, 4, 6, 7, 25, 72, 78, 81, 83, 84, 85, 88, 94, 95, 97, 98, 115, 117, 123, 126, 159, 163, 178, 196, 200, 208 and 271 are replaced by the following:

1.	EN 285:2015+A1:2021 Sterilization - Steam sterilizers - Large sterilizers
2.	EN 455-1:2020+A2:2024 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
3.	EN 455-2:2024 Medical gloves for single use - Part 2: Requirements and testing for physical properties
4.	EN 455-3:2023 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
6.	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
7.	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
25.	EN 1865-2:2024 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher
72.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity EN ISO 10993-5:2009+A11:2025
78.	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials EN ISO 10993-12:2021+A1:2025
81.	EN ISO 10993-15:2023 Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
83.	EN ISO 10993-17:2023 Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents

84.	EN ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process EN ISO 10993-18:2020/A1:2023
85.	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 EN ISO 11135:2014/A1:2019
88.	EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose EN ISO 11137-2:2015/A1:2023
94.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-1:2020/A1:2023
95.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes EN ISO 11607-2:2020/A1:2023
97.	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products EN ISO 11737-1:2018/A1:2021
98.	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
115.	EN ISO 12870:2025 Ophthalmic optics - Spectacle frames - Requirements and test methods
117.	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements
123.	EN ISO 13408-6:2021 Aseptic processing of health care products – Part 6: Isolator systems
126.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/AC:2018 EN ISO 13485:2016+A11:2021

159.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices EN ISO 14971:2019/A11:2021
163.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
178.	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
196.	EN ISO 22675:2025 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods
200.	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 EN ISO 25424:2019/A1:2022
208.	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 EN 60601-1:2006/A13:2024
271.	EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices EN 62366-1:2015/A1:2020 Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.

(2) the following rows are inserted in sequential order:

28a.	EN 1865-6:2024 Patient handling equipment used in ambulances – Part 6: Powered chairs
76a.	EN ISO 10993-10:2023 Biological evaluation of medical devices – Part 10: Tests for skin sensitisation

84a.	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation EN ISO 10993-23:2021/A1:2025
144a.	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
178a.	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

(3) rows 76, 86, 103, 104, 118, 125, 140, 154, 164, 170, 177 and 190 are deleted.

ANNEX I

Part 2

No	Reference of standard
1.	EN 285:2015+A1:2021 Sterilization - Steam sterilizers - Large sterilizers
2.	EN 455-1:2020+A2:2024 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
3.	EN 455-2:2024 Medical gloves for single use - Part 2: Requirements and testing for physical properties
4.	EN 455-3:2023 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
5.	EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination
6.	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
7.	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
8.	EN 794-3:1998+A2:2009 Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators
9.	EN 1041:2008 Information supplied by the manufacturer of medical devices
10.	EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
11.	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
12.	EN ISO 1135-4:2011 Transfusion equipment for medical use - Part 4: Transfusion sets for single use

13.	EN 1282-2:2005+A1:2009 Tracheostomy tubes - Part 2: Paediatric tubes
14.	EN 1422:1997+A1:2009 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
15.	EN 1618:1997 Catheters other than intravascular catheters - Test methods for common properties
16.	EN 1639:2009 Dentistry - Medical devices for dentistry - Instruments
17.	EN 1640:2009 Dentistry - Medical devices for dentistry - Equipment
18.	EN 1641:2009 Dentistry - Medical devices for dentistry - Materials
19.	EN 1642:2011 Dentistry - Medical devices for dentistry - Dental implants
20.	EN 1707:1996 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
21.	EN 1782:1998+A1:2009 Tracheal tubes and connectors
22.	EN 1789:2007+A1:2010 Medical vehicles and their equipment - Road ambulances
23.	EN 1820:2005+A1:2009 Anaesthetic reservoir bags
24.	EN 1865-1:2010+A1:2015 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment
25.	EN 1865-2:2024 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher
26.	EN 1865-3:2012 Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher
27.	EN 1865-4:2012 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair

28.	EN 1865-5:2012 Patient handling equipment used in road ambulances - Part 5: Stretcher support
28a.	EN 1865-6:2024 Patient handling equipment used in ambulances – Part 6: Powered chairs
29.	EN 1985:1998 Walking aids - General requirements and test methods Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.
30.	EN ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components - Part 2: Graphical symbols for use on labels and instruction leaflets
31.	EN ISO 3826-3:2007 Plastics collapsible containers for human blood and blood components - Part 3: Blood bag systems with integrated features
32.	EN ISO 3826-4:2015 Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features
33.	EN ISO 4074:2002 Natural latex rubber condoms - Requirements and test methods
34.	EN ISO 4135:2001 Anaesthetic and respiratory equipment - Vocabulary
35.	EN ISO 5359:2008 Low-pressure hose assemblies for use with medical gases EN ISO 5359:2008/A1:2011
36.	EN ISO 5360:2009 Anaesthetic vaporizers - Agent-specific filling systems
37.	EN ISO 5366-1:2009 Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults
38.	EN ISO 5840:2009 Cardiovascular implants - Cardiac valve prostheses
39.	EN ISO 7197:2009 Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components

40.	EN ISO 7376:2009 Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation
41.	EN ISO 7396-1:2007 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum EN ISO 7396-1:2007/A1:2010 EN ISO 7396-1:2007/A2:2010
42.	EN ISO 7396-2:2007 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems
43.	EN ISO 7886-3:2009 Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization
44.	EN ISO 7886-4:2009 Sterile hypodermic syringes for single use - Part 4: Syringes with reuse prevention feature
45.	EN ISO 8185:2009 Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems
46.	EN ISO 8359:2009 Oxygen concentrators for medical use - Safety requirements EN ISO 8359:2009/A1:2012
47.	EN ISO 8835-2:2009 Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems
48.	EN ISO 8835-3:2009 Inhalational anaesthesia systems - Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems EN ISO 8835-3:2009/A1:2010
49.	EN ISO 8835-4:2009 Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices
50.	EN ISO 8835-5:2009 Inhalational anaesthesia systems - Part 5: Anaesthetic ventilators
51.	EN ISO 9170-1:2008 Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum
52.	EN ISO 9170-2:2008 Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems

53.	EN ISO 9360-1:2009 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml
54.	EN ISO 9360-2:2009 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml
55.	EN ISO 9713:2009 Neurosurgical implants - Self-closing intracranial aneurysm clips
56.	EN ISO 10079-1:2009 Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements
57.	EN ISO 10079-2:2009 Medical suction equipment - Part 2: Manually powered suction equipment
58.	EN ISO 10079-3:2009 Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source
59.	EN ISO 10328:2016 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods
60.	EN ISO 10524-1:2006 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow- metering devices
61.	EN ISO 10524-2:2006 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators
62.	EN ISO 10524-3:2006 Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves
63.	EN ISO 10524-4:2008 Pressure regulators for use with medical gases - Part 4: Low-pressure regulators
64.	EN ISO 10535:2006 Hoists for the transfer of disabled persons - Requirements and test methods Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.
65.	EN ISO 10555-1:2009 Sterile, single-use intravascular catheters - Part 1: General requirements

66.	EN ISO 10651-2:2009 Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients
67.	EN ISO 10651-4:2009 Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators
68.	EN ISO 10651-6:2009 Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices
69.	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process EN ISO 10993-1:2009/AC:2010
70.	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
71.	EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
72.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity EN ISO 10993-5:2009+A11:2025
73.	EN ISO 10993-6:2009 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
74.	EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals EN ISO 10993-7:2008/AC:2009
75.	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
76.	
76a.	EN ISO 10993-10:2023 Biological evaluation of medical devices – Part 10: Tests for skin sensitisation
77.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

78.	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials EN ISO 10993-12:2021+A1:2025
79.	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
80.	EN ISO 10993-14:2009 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics
81.	EN ISO 10993-15:2023 Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
82.	EN ISO 10993-16:2010 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
83.	EN ISO 10993-17:2023 Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents
84.	EN ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process EN ISO 10993-18:2020/A1:2023
84a.	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation EN ISO 10993-23:2021/A1:2025
85.	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 EN ISO 11135:2014/A1:2019
86.	
87.	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 EN ISO 11137-1:2015/A2:2019

88.	EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose EN ISO 11137-2:2015/A1:2023
89.	EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
90.	EN ISO 11138-3:2009 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
91.	EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements
92.	EN ISO 11140-3:2009 Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
93.	EN ISO 11197:2009 Medical supply units
94.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-1:2020/A1:2023
95.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes EN ISO 11607-2:2020/A1:2023
96.	EN ISO 11608-7:2017 Needle-based injection systems for medical use - Requirements and test methods - Part 7: Accessibility for persons with visual impairment
97.	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products EN ISO 11737-1:2018/A1:2021
98.	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

99.	EN ISO 11810-1:2009 Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers - Part 1: Primary ignition and penetration
100.	EN ISO 11810-2:2009 Lasers and laser-related equipment - Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers - Part 2: Secondary ignition
101.	EN ISO 11979-8:2009 Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements
102.	EN ISO 11990:2018 Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs
103.	
104.	
105.	EN 12006-2:1998+A1:2009 Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2: Vascular prostheses including cardiac valve conduits
106.	EN 12006-3:1998+A1:2009 Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices
107.	EN 12183:2009 Manual wheelchairs - Requirements and test methods
108.	EN 12184:2009 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
109.	EN 12342:1998+A1:2009 Breathing tubes intended for use with anaesthetic apparatus and ventilators
110.	EN 12470-1:2000+A1:2009 Clinical thermometers - Part 1: Metallic liquid- in-glass thermometers with maximum device
111.	EN 12470-2:2000+A1:2009 Clinical thermometers - Part 2: Phase change type (dot matrix) thermometers
112.	EN 12470-3:2000+A1:2009 Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device

113.	EN 12470-4:2000+A1:2009 Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement
114.	EN 12470-5:2003 Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device)
115.	EN ISO 12870:2025 Ophthalmic optics - Spectacle frames - Requirements and test methods
116.	EN 13060:2014 Small steam sterilizers
117.	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements
118.	
119.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Sterilizing filtration
120.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization
121.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies
122.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place
123.	EN ISO 13408-6:2021 Aseptic processing of health care products – Part 6: Isolator systems
124.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
125.	
126.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/AC:2018 EN ISO 13485:2016+A11:2021
127.	EN 13544-1:2007+A1:2009 Respiratory therapy equipment - Part 1: Nebulizing systems and their component

128.	EN 13544-2:2002+A1:2009 Respiratory therapy equipment - Part 2: Tubing and connectors
129.	EN 13544-3:2001+A1:2009 Respiratory therapy equipment - Part 3: Air entrainment devices
130.	EN 13624:2003 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase 2, step 1)
131.	EN 13718-1:2008 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
132.	EN 13718-2:2015 Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements for air ambulances
133.	EN 13726-1:2002 Test methods for primary wound dressings - Part 1: Aspects of absorbency EN 13726-1:2002/AC:2003
134.	EN 13726-2:2002 Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings
135.	EN 13727:2012 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)
136.	EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
137.	EN 13795-2:2019 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits
138.	EN 13867:2002+A1:2009 Concentrates for haemodialysis and related therapies
139.	EN 13976-1:2011 Rescue systems - Transportation of incubators - Part 1: Interface conditions
140.	
141.	EN 13976-2:2018 Rescue systems - Transportation of incubators - Part 2: System requirements

142.	EN 14079:2003 Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze
143.	EN 14139:2010 Ophthalmic optics - Specifications for ready-to- wear spectacles
144.	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice EN ISO 14155:2011/AC:2011
144a.	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
145.	EN 14180:2003+A2:2009 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing
146.	EN 14348:2005 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)
147.	EN ISO 14408:2009 Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information
148.	EN 14561:2006 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)
149.	EN 14562:2006 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)
150.	EN 14563:2008 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)
151.	EN ISO 14602:2011 Non-active surgical implants - Implants for osteosynthesis - Particular requirements
152.	EN ISO 14607:2009 Non-active surgical implants - Mammary implants - Particular requirements

153.	EN ISO 14630:2009 Non-active surgical implants - General requirements
154.	
155.	EN 14683:2019 Medical face masks - Requirements and test methods EN 14683:2019+AC:2019
156.	EN ISO 14889:2009 Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses
157.	EN 14931:2006 Pressure vessels for human occupancy (PVHO) - Multi-place pressure chamber systems for hyperbaric therapy - Performance, safety requirements and testing
158.	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
159.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices EN ISO 14971:2019/A11:2021
160.	EN ISO 15001:2011 Anaesthetic and respiratory equipment - Compatibility with oxygen
161.	EN ISO 15002:2008 Flow-metering devices for connection to terminal units of medical gas pipeline systems
162.	EN ISO 15004-1:2009 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
163.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
164.	
165.	EN ISO 15747:2019 Plastic containers for intravenous injections
166.	EN ISO 15798:2010 Ophthalmic implants - Ophthalmic viscosurgical devices

167.	EN ISO 15883-1:2009 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
168.	EN ISO 15883-2:2009 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
169.	EN ISO 15883-3:2009 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
170.	
171.	EN ISO 15883-4:2018 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
172.	EN 15986:2011 Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalate
173.	EN ISO 16061:2009 Instrumentation for use in association with non- active surgical implants - General requirements
174.	EN ISO 16201:2006 Technical aids for disabled persons - Environmental control systems for daily living
175.	EN ISO 17510-1:2009 Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment
176.	EN ISO 17510-2:2009 Sleep apnoea breathing therapy - Part 2: Masks and application accessories
177.	
178.	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
178a.	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
179.	EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

180.	EN ISO 18777:2009 Transportable liquid oxygen systems for medical use - Particular requirements
181.	EN ISO 18778:2009 Respiratory equipment - Infant monitors - Particular requirements
182.	EN ISO 18779:2005 Medical devices for conserving oxygen and oxygen mixtures - Particular requirements
183.	EN ISO 19054:2006 Rail systems for supporting medical equipment
184.	EN 20594-1:1993 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements EN 20594-1:1993/A1:1997 EN 20594-1:1993/AC:1996
185.	EN ISO 21534:2009 Non-active surgical implants - Joint replacement implants - Particular requirements
186.	EN ISO 21535:2009 Non-active surgical implants - Joint replacement implants - Specific requirements for hip- joint replacement implants
187.	EN ISO 21536:2009 Non-active surgical implants - Joint replacement implants - Specific requirements for knee- joint replacement implants
188.	EN ISO 21649:2009 Needle-free injectors for medical use - Requirements and test methods
189.	EN ISO 21969:2009 High-pressure flexible connections for use with medical gas systems
190.	
191.	EN ISO 21987:2017 Ophthalmic optics - Mounted spectacle lenses
192.	EN ISO 22442-1:2007 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
193.	EN ISO 22442-2:2007 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling

194.	EN ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
195.	EN ISO 22523:2006 External limb prostheses and external orthoses - Requirements and test methods Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered
196.	EN ISO 22675:2025 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods
197.	EN ISO 23328-1:2008 Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance
198.	EN ISO 23328-2:2009 Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects
199.	EN ISO 23747:2009 Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
200.	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 EN ISO 25424:2019/A1:2022
201.	EN ISO 25539-1:2009 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses EN ISO 25539-1:2009/AC:2011
202.	EN ISO 25539-2:2009 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents EN ISO 25539-2:2009/AC:2011
203.	EN ISO 26782:2009 Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans EN ISO 26782:2009/AC:2009

204.	<p>EN 27740:1992 Instruments for surgery, scalpels with detachable blades, fitting dimensions</p> <p>EN 27740:1992/A1:1997 EN 27740:1992/AC:1996</p>
205.	<p>EN 60118-13:2005 Electroacoustics - Hearing aids - Part 13: Electromagnetic compatibility (EMC)</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered</p>
206.	<p>EN 60522:1999 Determination of the permanent filtration of X- ray tube assemblies</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
207.	<p>EN 60580:2000 Medical electrical equipment - Dose area product meters</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered</p>
208.	<p>EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</p> <p>EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 EN 60601-1:2006/A13:2024</p>
209.	<p>EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered</p>
210.	<p>EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests</p>

211.	<p>EN 60601-1-3:2008</p> <p>Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment</p> <p>EN 60601-1-3:2008/AC:2010</p> <p>EN 60601-1-3:2008/A11:2016</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered</p>
212.	<p>EN 60601-1-4:1996</p> <p>Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems</p> <p>EN 60601-1-4:1996/A1:1999</p>
213.	<p>EN 60601-1-6:2010</p> <p>Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered</p>
214.	<p>EN 60601-1-8:2007</p> <p>Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems</p> <p>EN 60601-1-8:2007/AC:2010</p> <p>EN 60601-1-8:2007/A11:2017</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered</p>
215.	<p>EN 60601-1-10:2008</p> <p>Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>

216.	<p>EN 60601-1-11:2010</p> <p>Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
217.	<p>EN 60601-2-1:1998</p> <p>Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV</p> <p>EN 60601-2-1:1998/A1:2002</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
218.	<p>EN 60601-2-2:2009</p> <p>Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
219.	<p>EN 60601-2-3:1993</p> <p>Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment</p> <p>EN 60601-2-3:1993/A1:1998</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
220.	<p>EN 60601-2-4:2003</p> <p>Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>

221.	<p>EN 60601-2-5:2000</p> <p>Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
222.	<p>EN 60601-2-8:1997</p> <p>Medical electrical equipment - Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV</p> <p>EN 60601-2-8:1997/A1:1997</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
223.	<p>EN 60601-2-10:2000</p> <p>Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators</p> <p>EN 60601-2-10:2000/A1:2001</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
224.	<p>EN 60601-2-11:1997</p> <p>Medical electrical equipment - Part 2-11: Particular requirements for the safety of gamma beam therapy equipment</p> <p>EN 60601-2-11:1997/A1:2004</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
225.	<p>EN 60601-2-12:2006</p> <p>Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators</p>
226.	<p>EN 60601-2-13:2006</p> <p>Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems</p> <p>EN 60601-2-13:2006/A1:2007</p>

227.	<p>EN 60601-2-16:1998</p> <p>Medical electrical equipment - Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment</p> <p>EN 60601-2-16:1998/AC:1999</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
228.	<p>EN 60601-2-17:2004</p> <p>Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
229.	<p>EN 60601-2-18:1996</p> <p>Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment</p> <p>EN 60601-2-18:1996/A1:2000</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
230.	<p>EN 60601-2-19:2009</p> <p>Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
231.	<p>EN 60601-2-20:2009</p> <p>Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>

232.	<p>EN 60601-2-21:2009</p> <p>Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
233.	<p>EN 60601-2-22:1996</p> <p>Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
234.	<p>EN 60601-2-23:2000</p> <p>Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
235.	<p>EN 60601-2-24:1998</p> <p>Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
236.	<p>EN 60601-2-25:1995</p> <p>Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs</p> <p>EN 60601-2-25:1995/A1:1999</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
237.	<p>EN 60601-2-26:2003</p> <p>Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs</p>

238.	<p>EN 60601-2-27:2006</p> <p>Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment</p> <p>EN 60601-2-27:2006/AC:2006</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
239.	<p>EN 60601-2-28:2010</p> <p>Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
240.	<p>EN 60601-2-29:2008</p> <p>Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
241.	<p>EN 60601-2-30:2000</p> <p>Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non- invasive blood pressure monitoring equipment</p>
242.	<p>EN 60601-2-33:2010</p> <p>Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis</p> <p>EN 60601-2-33:2010/A1:2015</p> <p>EN 60601-2-33:2010/A2:2015</p> <p>EN 60601-2-33:2010/AC:2016-03</p> <p>EN 60601-2-33:2010/A12:2016</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>

243.	<p>EN 60601-2-34:2000</p> <p>Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
244.	<p>EN 60601-2-36:1997</p> <p>Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
245.	<p>EN 60601-2-37:2008</p> <p>Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
246.	<p>EN 60601-2-39:2008</p> <p>Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
247.	<p>EN 60601-2-40:1998</p> <p>Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
248.	<p>EN 60601-2-41:2009</p> <p>Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>

249.	<p>EN 60601-2-43:2010</p> <p>Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of X- ray equipment for interventional procedures</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
250.	<p>EN 60601-2-44:2009</p> <p>Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
251.	<p>EN 60601-2-45:2001</p> <p>Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
252.	<p>EN 60601-2-46:1998</p> <p>Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
253.	<p>EN 60601-2-47:2001</p> <p>Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
254.	<p>EN 60601-2-49:2001</p> <p>Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment</p>

255.	<p>EN 60601-2-50:2009</p> <p>Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
256.	<p>EN 60601-2-51:2003</p> <p>Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs</p>
257.	<p>EN 60601-2-52:2010</p> <p>Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds</p> <p>EN 60601-2-52:2010/AC:2011</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
258.	<p>EN 60601-2-54:2009</p> <p>Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
259.	<p>EN 60627:2001</p> <p>Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids</p> <p>EN 60627:2001/AC:2002</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
260.	<p>EN 60645-1:2001</p> <p>Electroacoustics - Audiological equipment - Part 1: Pure-tone audiometers</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>

261.	EN 60645-2:1997 Audiometers - Part 2: Equipment for speech audiometry
262.	EN 60645-3:2007 Electroacoustics - Audiometric equipment - Part 3: Test signals of short duration Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.
263.	EN 60645-4:1995 Audiometers - Part 4: Equipment for extended high-frequency audiometry
264.	EN 61217:2012 Radiotherapy equipment - Coordinates, movements and scales Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.
265.	EN 61676:2002 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology EN 61676:2002/A1:2009 Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.
266.	EN 62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.
267.	EN 62220-1:2004 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.

268.	<p>EN 62220-1-2:2007</p> <p>Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography (IEC 62220-1-2:2007)</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
269.	<p>EN 62220-1-3:2008</p> <p>Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
270.	<p>EN 62304:2006</p> <p>Medical device software - Software life-cycle processes</p> <p>EN 62304:2006/AC:2008</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
271.	<p>EN 62366-1:2015</p> <p>Medical devices - Part 1: Application of usability engineering to medical devices</p> <p>EN 62366-1:2015/A1:2020</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>
272.	<p>EN 80601-2-35:2009</p> <p>Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use</p>
273.	<p>EN 80601-2-58:2009</p> <p>Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery</p> <p>Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.</p>

274.	EN 80601-2-59:2009 Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.
275.	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type
276.	EN ISO 81060-2:2019 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type

ANNEX II

The list of standards for removal from publication, as set out in Annex II to notice 0034/21, is amended as follows:

- (1) rows 1 to 12 inclusive are removed.