THE DEPARTMENT OF HEALTH AND SOCIAL CARE
NOTICE OF PUBLICATION
0034/21
of 1 January 2021

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.

b) The references to standards listed in Annex II to this notice are published for the purposes of regulation 3A of S.I. 2002/618 but will be removed from publication from the dates set out in that Annex. Accordingly, each of these standards will not be designated, or give rise to any presumption of conformity, on or after the date set out in respect of it.

ANNEX I

No	Reference of standard
1.	EN 285:2006+A2:2009 Sterilization - Steam sterilizers - Large sterilizers
2.	EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
3.	EN 455-2:2009+A2:2013 Medical gloves for single use - Part 2: Requirements and testing for physical properties
4.	EN 455-3:2006 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 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices EN 556-1:2001/AC:2006
7.	EN 556-2:2015 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 1865-2:2010+A1:2015 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
29.	EN 1985:1998 Walking aids - General requirements and test methods *Notice*: This standard still needs to be amended to take into amendments made to 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 (ISO 8185:2007)
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 (ISO 10535:2006) *Notice*: This standard still needs to be amended to take into account the amendments made to 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 of the amended directive 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
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.	EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
77.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
78.	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
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 10993-15:2009 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 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
84.	EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials
85.	EN ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
86.	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
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 (ISO 11137-2:2013)
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 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
95.	EN ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
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 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products EN ISO 11737-1:2006/AC:2009
98.	EN ISO 11737-2:2009 Sterilization of medical devices - 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.	EN ISO 11990-1:2014 Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 1: Tracheal tube shaft
104.	EN ISO 11990-2:2014 Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 2: Tracheal tube cuffs
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) *Notice*: This standard still needs to be amended to take into account the amendments made to 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.
115.	EN ISO 12870:2009 Ophthalmic optics - Spectacle frames - Requirements and test methods
116.	EN 13060:2014 Small steam sterilizers
117.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements
118.	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration
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 13408-6:2011 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.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/AC:2016
126.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/AC:2018
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.	EN 13976-2:2011 Rescue systems - Transportation of incubators - Part 2: System requirements
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
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.	EN 14683:2005 Surgical masks - Requirements and test methods
155.	EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
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 14971:2012 Medical devices - Application of risk management to medical devices
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 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
164.	EN ISO 15747:2011 Plastic containers for intravenous injections
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.	EN ISO 15883-4:2009 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
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.	EN ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
178.	EN ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of 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.	EN ISO 21987:2009 Ophthalmic optics - Mounted spectacle lenses
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 (ISO 22523:2006) *Notice*: This standard still needs to be amended to take into account the amendments made to 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 of the amended directive are appropriately covered.
196.	EN ISO 22675:2016 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
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.	EN 27740:1992 Instruments for surgery, scalpels with detachable blades, fitting dimensions EN 27740:1992/A1:1997 EN 27740:1992/AC:1996
205.	EN 60118-13:2005 Electroacoustics - Hearing aids - Part 13: Electromagnetic compatibility (EMC) *Notice*: 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)
206.	EN 60522:1999 Determination of the permanent filtration of X- ray tube assemblies *Notice*: 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)
207.	EN 60580:2000 Medical electrical equipment - Dose area product meters *Notice*: 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).
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
209.	EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems *Notice*: 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).
210.	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
211.	EN 60601-1-3:2008 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment EN 60601-1-3:2008/AC:2010 EN 60601-1-3:2008/A11:2016 *Notice*: 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)
212.	EN 60601-1-4:1996 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems EN 60601-1-4:1996/A1:1999 (IEC 60601-1-4:1996/A1:1999) *Notice*: 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).
213.	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability *Notice*: 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).

214.	EN 60601-1-8:2007 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 EN 60601-1-8:2007/AC:2010 EN 60601-1-8:2007/A11:2017 *Notice*: 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).
215.	EN 60601-1-10:2008 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 *Notice*: 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).
216.	EN 60601-1-11:2010 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 *Notice*: 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).
217.	EN 60601-2-1:1998 Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV EN 60601-2-1:1998/A1:2002 *Notice*: 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).
218.	EN 60601-2-2:2009 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 *Notice*: 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).
219.	EN 60601-2-3:1993 Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment EN 60601-2-3:1993/A1:1998 *Notice*: 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).
220.	EN 60601-2-4:2003 Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators *Notice*: 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).
221.	EN 60601-2-5:2000 Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment *Notice*: 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).

222.	EN 60601-2-8:1997 Medical electrical equipment - Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV EN 60601-2-8:1997/A1:1997 *Notice*: 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).
223.	EN 60601-2-10:2000 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators EN 60601-2-10:2000/A1:2001 *Notice*: 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)
224.	EN 60601-2-11:1997 Medical electrical equipment - Part 2-11: Particular requirements for the safety of gamma beam therapy equipment EN 60601-2-11:1997/A1:2004 *Notice*: 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)
225.	EN 60601-2-12:2006 Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators *Notice*: 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).
226.	EN 60601-2-13:2006 Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems EN 60601-2-13:2006/A1:2007 *Notice*: 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).
227.	EN 60601-2-16:1998 Medical electrical equipment - Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment EN 60601-2-16:1998/AC:1999 *Notice*: 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)
228.	EN 60601-2-17:2004 Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment *Notice*: 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).
229.	EN 60601-2-18:1996 Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment EN 60601-2-18:1996/A1:2000 *Notice*: 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).
230.	EN 60601-2-19:2009 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators *Notice*: 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).

231.	EN 60601-2-20:2009 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators *Notice*: 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).
232.	EN 60601-2-21:2009 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers *Notice*: 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).
233.	EN 60601-2-22:1996 Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment *Notice*: 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)
234.	EN 60601-2-23:2000 Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment *Notice*: 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)
235.	EN 60601-2-24:1998 Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers *Notice*: 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)
236.	EN 60601-2-25:1995 Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs EN 60601-2-25:1995/A1:1999 *Notice*: 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)
237.	EN 60601-2-26:2003 Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs *Notice*: 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).
238.	EN 60601-2-27:2006 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment EN 60601-2-27:2006/AC:2006 *Notice*: 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).
239.	EN 60601-2-28:2010 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis *Notice*: 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).
240.	EN 60601-2-29:2008 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators *Notice*: 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).

241.	EN 60601-2-30:2000 Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non- invasive blood pressure monitoring equipment *Notice*: 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).
242.	EN 60601-2-33:2010 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis EN 60601-2-33:2010/A1:2015 EN 60601-2-33:2010/A2:2015 EN 60601-2-33:2010/AC:2016-03 EN 60601-2-33:2010/A12:2016
243.	EN 60601-2-34:2000 Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment *Notice*: 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)
244.	EN 60601-2-36:1997 Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy *Notice*: 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).
245.	EN 60601-2-37:2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment *Notice*: 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).
246.	EN 60601-2-39:2008 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment *Notice*: 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).
247.	EN 60601-2-40:1998 Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment *Notice*: 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).
248.	EN 60601-2-41:2009 Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis *Notice*: 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).
249.	EN 60601-2-43:2010 Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of X- ray equipment for interventional procedures
250.	EN 60601-2-44:2009 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography *Notice*: 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).

251.	EN 60601-2-45:2001 Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices *Notice*: 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).
252.	EN 60601-2-46:1998 Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables *Notice*: 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).
253.	EN 60601-2-47:2001 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems *Notice*: 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).
254.	EN 60601-2-49:2001 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment *Notice*: 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).
255.	EN 60601-2-50:2009 Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment *Notice*: 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).
256.	EN 60601-2-51:2003 Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs *Notice*: 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).
257.	EN 60601-2-52:2010 Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds EN 60601-2-52:2010/AC:2011 *Notice*: 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).
258.	EN 60601-2-54:2009 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy *Notice*: 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)
259.	EN 60627:2001 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids EN 60627:2001/AC:2002 *Notice*: 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).
260.	EN 60645-1:2001 Electroacoustics - Audiological equipment - Part 1: Pure-tone audiometers *Notice*: 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).

261.	EN 60645-2:1997 Audiometers - Part 2: Equipment for speech audiometry Notice: 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)
262.	EN 60645-3:2007 Electroacoustics - Audiometric equipment - Part 3: Test signals of short duration *Notice*: 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)
263.	EN 60645-4:1995 Audiometers - Part 4: Equipment for extended high-frequency audiometry *Notice*: 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)
264.	EN 61217:2012 Radiotherapy equipment - Coordinates, movements and scales
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 *Notice*: 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)
266.	EN 62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems *Notice*: 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).
267.	EN 62220-1:2004 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency *Notice*: 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).
268.	EN 62220-1-2:2007 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography *Notice*: 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)
269.	EN 62220-1-3:2008 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging *Notice*: 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)
270.	EN 62304:2006 Medical device software - Software life-cycle processes EN 62304:2006/AC:2008 *Notice*: 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).
271.	EN 62366:2008 Medical devices - Application of usability engineering to medical devices *Notice*: 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)

272.	EN 80601-2-35:2009 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 *Notice*: This standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
273.	EN 80601-2-58:2009 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 *Notice*: 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).
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 *Notice*: 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).
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

No	Reference of standard	Date of removal from publication
1.	EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	30 September 2021
2.	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	30 September 2021
3.	EN ISO 11990-1:2014 Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 1: Tracheal tube shaft	30 September 2021
4.	EN ISO 11990-2:2014 Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 2: Tracheal tube cuffs	30 September 2021
5.	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration	30 September 2021
6.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/AC:2016	30 September 2021
7.	EN 13976-2:2011 Rescue systems - Transportation of incubators - Part 2: System requirements	30 September 2021
8.	EN 14683:2005 Surgical masks - Requirements and test methods	30 September 2021
9.	EN ISO 15747:2011 Plastic containers for intravenous injections	30 September 2021
10.	EN ISO 15883-4:2009 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes	30 September 2021
11.	EN ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices	30 September 2021
12.	EN ISO 21987:2009 Ophthalmic optics - Mounted spectacle lenses	30 September 2021