SFDA Recognized Standards

(Supporting Medical Device Premarket Submissions)

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Introduction

Purpose

The purpose of this guidance is to list the SFDA recognized standards, which will help in premarket submission and satisfy the regulatory needs.

Scope

This guidance applies to following parties and products:

- Medical devices and their manufacturers.
- Research and lab centers.

Background

SFDA/MDS has issued this guidance document in reference to the Article Four of the "Medical Devices Interim Regulation" issued by Saudi Food and Drug Authority Board of Directors decree No. (1-8-1429) dated 29/12/1429 H and amended by Saudi Food and Drug Authority Board of Directors decree No. (4-16-1439) dated 27/12/2017 stating "medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization. The SFDA may exempt any medical device from market authorization, and shall announce the exempt medical devices on its website taking into consideration the public interest. In term of standard, SFDA is the responsible body to regulate and control food and drug through development of mandatory and non-mandatory standards that leads to raising the public's awareness as stipulated in Article Three of SFDA regulation that has been approved by the royal decree No (m/6) dated 25/1/1428H

How to Access Recognized Standards

SFDA publish and update regularly a list of recognized standards (add web-page address). These standards and other prepared or adopted Saudi standards can be accessed and purchased through the SFDA standards store (https://stdstore.sfda.gov.sa). In addition, international standards may be purchased through (https://www.iec.ch) or (https://www.iso.org)

List of Recognized Standards by Category

#	Categories & Standards
Transfusion , infusion and injection , and blood processing equipment for medical and pharmaceutical use Standards	
1	ISO 1135-4:2015 Transfusion equipment for medical use - Part 4: Transfusion sets for single use
2	ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components - Part 2: Graphical symbols for use on labels and instruction leaflets
3	ISO 3826-3:2006 Plastics collapsible containers for human blood and blood components - Part 3: Blood bag systems with integrated features
4	ISO 3826-4:2015 Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features
5	ISO 15747:2018 Plastic containers for intravenous injections
Anesthetic and respiratory equipment Standards	
6	ISO 5362:2006 Anaesthetic reservoir bags
7	ISO 4135:2001 Anaesthetic and respiratory equipment - Vocabulary
8	ISO 7396-2:2007 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems
9	ISO 80601-2-13:2011

	Medical electrical equipment -- part 2-13: particular requirements for basic safety and essential performance of an anaesthetic workstation
10	ISO 9170-2:2008 Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems
11	ISO 9360-1:2000 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
12	ISO 9360-2:2001 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
13	ISO 10079-1:2015 Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements
14	ISO 10079-2:2014 Medical suction equipment - Part 2: Manually powered suction equipment
15	ISO 10079-3:2014 Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source
16	ISO 10524-1:2018 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices
17	ISO 10524-2:2018 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators
18	ISO 10524-3:2019 Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves
19	ISO 10524-4:2008 Pressure regulators for use with medical gases - Part 4: Low-pressure regulators
20	ISO 10651-4:2002 Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators

21	ISO 80601-2-79:2018 Medical electrical equipment -- part 2-79: particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
22	ISO 80601-2-80:2018 Medical electrical equipment -- part 2-80: particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
23	ISO 11197:2016 Medical supply units
24	ISO 15001:2010 Anaesthetic and respiratory equipment - Compatibility with oxygen
25	ISO 18778:2005 Respiratory equipment - Infant monitors - Particular requirements
26	ISO 19054:2005 Rail systems for supporting medical equipment
27	ISO 23328-1:2003 Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance
28	ISO 23328-2:2002 Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects
29	ISO 26782:2009 Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans
30	ISO 81060-1:2007 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type
31	ISO 80601-2-55:2011 Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
32	ISO 5359:2014/Amd 1:2017 Anaesthetic and respiratory equipment – Low-pressure hose assemblies for use with medical gases

33	ISO 27427:2013 Anaesthetic and respiratory equipment -- Nebulizing systems and components
Implants for surgery Standards	
34	ISO 5840-2:2015 Cardiovascular implants - Cardiac valve prostheses
35	ISO 14602:2010 Non-active surgical implants - Implants for osteosynthesis - Particular requirements
36	ISO 14607:2018 Non-active surgical implants - Mammary implants - Particular requirements
37	ISO 14630:2012 Non-active surgical implants - General requirements
38	ISO 16061:2015 Instrumentation for use in association with non-active surgical implants - General requirements
39	ISO 25539-1:2017 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses
40	ISO 25539-2:2008 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents
41	ISO 5840-1:2015 Cardiovascular implants - Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements
42	ISO 14708-6:2010 Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
43	ISO 14708-7:2013 Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems
44	ISO 7198:2016 Cardiovascular implants and extracorporeal systems – Vascular prostheses - Tubular vascular grafts and vascular patches

45	ISO 14708-3:2017 Active implantable medical devices -- Part 3: Implantable neurostimulators
46	ISO 14242-2:2016 Implants for Surgery - Wear of total hip-joint prostheses - Part 2: Methods of measurement
47	ISO 9583:1993 Implants for surgery – Non-destructive testing – Liquid penetrant inspection of metallic surgical implants
48	ISO 7206-4:2010 Implants for surgery partial and total hip joint prostheses – Part 4: Determination of endurance properties and performance of stemmed femoral components
49	ISO 13782:2019 Implants for surgery – Metallic materials – Unalloyed tantalum for surgical implant applications
50	ISO 6474-1:2019 Implants for surgery – Ceramic materials – Part 1: Ceramic materials based on high purity alumina
51	ISO 6474-2:2019 Implants for surgery - Ceramic materials - Part 2: Composite materials based on a high purity alumina matrix with zirconia reinforcement
52	ISO 5834-2:2019 Implants for surgery – Ultra-high molecular weight polyethylene – Part 2: Moulded forms
53	ISO 5832-1:2016 Implants for Surgery – Metallic materials – Part 1: Wrought stainless steel
54	ISO 5832-2:2018 Implants for surgery – Metallic materials – Part 2: Unalloyed titanium
55	ISO 5832-3:2016 Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
56	ISO 5832-4:2014 Implants for surgery – Metallic materials – Part 4: Cobalt-chromiummolybdenum casting alloy
57	ISO 5832-5:2005 Implants for surgery – Metallic materials – Part 5: Wrought cobaltchromium-tungsten-nickel alloy
58	ISO 5832-6:1997 Implants for surgery – Metallic materials – Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy
59	ISO 5832-9:2019 Implants for surgery – Metallic materials – Part 9: Wrought high nitrogen stainless steel
60	ISO 23500-2:2019

	Water treatment equipment for haemodialysis applications and related therapies
61	ISO 7199:2016 Cardiovascular implants and artificial organs – Blood-gas exchangers (oxygenators)
62	ISO 14117:2012 Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices
63	ISO 14708-5:2010 Implants for surgery – Active implantable medical devices – Part 5:Circulatory support devices
64	ISO 23500-4:2019 Preparation and quality management of fluids for haemodialysis and related therapies -- part 4: concentrates for haemodialysis and related therapies
Prosthetics and orthotics Standards	
65	ISO 10328:2016 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods
66	ISO 22523:2006 External limb prostheses and external orthoses - Requirements and test methods
67	ISO 22675:2016 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods
Surgical instruments Standards	
68	ISO 7197:2006, including Cor 1:2007 Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components
69	ISO 9713:2002 Neurosurgical implants - Self-closing intracranial aneurysm clips
70	ISO 7740:1985 Instruments for surgery, scalpels with detachable blades, fitting dimensions
71	IEC 60601-2-2:2017 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

72	IEC 60601-2-18:2009 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment
73	ISO 7153-1:1991/Amd.1:1999 Surgical instruments – Metallic materials – Part 1: Stainless steel
74	ISO 7153-1:2016 Surgical instruments – Materials – Part 1: Metals
Optics and photonics Standards	
75	ISO 11810:2015 Lasers and laser-related equipment -- test method and classification for the laser resistance of surgical drapes and/or patient protective covers -- primary ignition, penetration, flame spread and secondary ignition
76	ISO 11979-8:2017 Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements
77	ISO 11990:2018 Lasers and laser-related equipment -- determination of laser resistance of tracheal tube shaft and tracheal tube cuffs
78	ISO 14889:2013 Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses
79	ISO 15798:2010 Ophthalmic implants - Ophthalmic viscosurgical devices
80	IEC 80601-2-58:2008 Medical electrical equipment -- part 2-58: particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
81	ISO 18369-1:2017 Ophthalmic optics – Contact lenses – Part 1: Vocabulary, classification system and recommendations for labelling specifications
82	ISO 18369-3:2017 Ophthalmic optics – Contact lenses – Part 2: Measurement methods
83	ISO 18369-4:2017 Ophthalmic optics – Contact lenses – Part 4: Physicochemical properties of contact lens materials

84	ISO 11979-1:2018 Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary
85	ISO 11979-2:2014 Ophthalmic implants -- Intraocular lenses -- Part 2: Optical properties and test methods
86	ISO 11979-3:2012 Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods
87	ISO 11979-5:2006 Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility
88	ISO 11979-6:2014 Ophthalmic implants – Intraocular lenses – Part 6: Shelf-life and transport stability testing
89	ISO 11979-7:2018 Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations of intraocular lenses for the correction of aphakia
Assistive Products	
90	ISO 16201:2006 Technical aids for disabled persons - Environmental control systems for daily living
91	ISO 11334-4:1999 Walking aids manipulated by one arm — Requirements and test methods — Part 4: Walking sticks with three or more legs
92	ISO 19894:2019 Walking trolleys — Requirements and test methods
93	ISO 7176-1:2014 Wheelchairs — Part 1: Determination of static stability
94	ISO 7176-5:2008 Wheelchairs — Part 5: Determination of dimensions, mass and manoeuvring space
95	ISO 7176-8:2014 Wheelchairs -- part 8: requirements and test methods for static, impact and fatigue strengths
96	ISO 7176-11:2012 Wheelchairs — Part 11: Test dummies
97	ISO 7176-13:1989 Wheelchairs — Part 13: Determination of coefficient of friction of test surfaces

98	ISO 7176-15:1996 Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling
99	ISO 7176-16:2012 Wheelchairs -- part 16: resistance to ignition of postural support devices
100	ISO 7176-19:2008 Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles
101	ISO 7176-21:2009 Wheelchairs -- part 21: requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
102	ISO 7176-25:2013 Wheelchairs -- part 25: batteries and chargers for powered wheelchairs
Biological evaluation of medical devices Standards	
103	ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
104	ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
105	ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
106	ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
107	ISO 10993-14:2001 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics
108	ISO 10993-15:2000 Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
109	ISO 10993-16:2017

	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
110	ISO 10993-17:2002 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
111	ISO 10993-18:2005 Biological evaluation of medical devices - Part 18: Chemical characterization of materials
112	EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)
Sterilization of health care products Standards	
113	ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
114	ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements
115	ISO 11140-3:2007, including Cor 1:2007 Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
116	ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
117	ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
118	ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
119	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
120	ISO 13408-1:2008, including Amd 1:2013 Aseptic processing of health care products - Part 1: General requirements
121	ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration
122	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
123	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies
124	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place
125	ISO 13408-6:2005 Aseptic processing of health care products - Part 6: Isolator systems
126	ISO 13408-7:2012 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
127	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
128	ISO 15883-1:2006/Amd 1:2014 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
129	ISO 15883-2:2006 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
130	ISO 15883-3:2006

	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)
131	ISO 15883-4:2018 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
132	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
133	ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
134	ISO 11137-1:2006, including Amd 1:2013 & Amd 2:2018 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
135	ISO 11137-2:2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
136	ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements
137	ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
138	ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
139	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
140	ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration

141	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
142	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies
143	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place
144	ISO 13408-7:2012 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
145	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
146	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
147	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
148	ISO 13408-2:2018 Aseptic processing of health care products -- Part 2: Sterilizing filtration
149	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place
150	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
151	ISO 14160:2011 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
152	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
153	ISO/TS 17665-2:2009 Sterilization of health care products -- moist heat -- part 2: guidance on the application of iso 17665-1
154	ISO/TS 17665-3:2013 Sterilization of health care products -- moist heat -- part 3: guidance on the designation of a medical device to a product family and processing category for steam sterilization
155	ISO 25424:2018 Sterilization of health care products -- low temperature steam and formaldehyde -- requirements for development, validation and routine control of a sterilization process for medical devices
Quality management and general corresponding aspects for medical devices Standards	
156	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
157	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies
158	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place
159	ISO 13408-7:2012 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
160	ISO 14971:2007 Medical devices - Application of risk management to medical devices
161	ISO 13408-1:2008, including Amd 1:2013 Aseptic processing of health care products - Part 1: General requirements
162	ISO 13408-2:2018

	Aseptic processing of health care products -- Part 2: Sterilizing filtration
163	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
164	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies
165	ISO 13408-7:2012 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
166	ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications -- part 7: connectors for intravascular or hypodermic applications
167	ISO 13485 :2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
Clinical laboratory testing and in vitro diagnostic test systems Standards	
168	ISO 15197:2013 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
169	ISO 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
170	IEC 61010-2-101:2018 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
171	IEC 61326-2-6:2005 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
Electrical equipment in medical practice	

172	IEC 60118-13:2004 Electroacoustics - Hearing aids -- Part 13: Electromagnetic compatibility (EMC)
173	IEC 60522:1999 Determination of the permanent filtration of X-ray tube assemblies
174	IEC 60580:2000 Medical electrical equipment - Dose area product meters
175	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
176	IEC 60601-2-1:2009 Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV
177	IEC 60601-2-2:2017 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
178	IEC 60601-2-3:2012+AMD1:2016 Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment
179	IEC 60601-2-5:2009 Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
180	IEC 60601-2-8:2010+AMD1:2015 Medical electrical equipment - Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV
181	IEC 60601-2-17:2013 Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy after loading equipment
182	IEC 60601-2-18:2009 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment

183	IEC 60601-2-19:2009+AMD1:2016 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
184	IEC 60601-2-20:2009+AMD1:2016 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
185	IEC 60601-2-21:2009+AMD1:2016 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
186	IEC 60601-2-23:2011 Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment
187	IEC 60601-2-27:2011 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment.
188	IEC 60601-2-28:2017 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
189	IEC 60601-2-29:2008 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators
190	IEC 60601-2-33:2010+AMD1:2013+AMD2:2015 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
191	IEC 60601-2-36:2014 Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy
192	IEC 60601-2-37:2007+AMD1:2015

	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
193	IEC 60601-2-39:2018 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
194	IEC 60601-2-40:2016 Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
195	IEC 60601-2-41:2009+AMD1:2013 Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
196	IEC 60601-2-45:2011+AMD1:2015 Medical electrical equipment -- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices
197	IEC 60601-2-46:2016 Medical electrical equipment -- Part 2-46: Particular requirements for the safety of operating tables
198	IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
199	IEC 60601-2-49:2018 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
200	IEC 60601-2-50:2009+AMD1:2016 Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
201	IEC 60627:2013 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids
202	IEC 60645-1:2017 Electroacoustic - Audiological equipment - Part 1: Pure-tone audiometers

203	IEC 61217:2011 Radiotherapy equipment - Coordinates, movements and scales
204	IEC 61676:2002+AMD1:2008 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology
205	IEC 62220-1:2015 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency
206	IEC 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
207	IEC 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
208	IEC 80601-2-35:2009+AMD1:2016 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
209	IEC 80601-2-58:2014+AMD1:2016 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
210	IEC 80601-2-59:2017 Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening
211	IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
212	IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

213	ISO 80601-2-13:2011-Ed.1.0/Amd.1:2015 Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
214	IEC 60601-2-26:2012-Ed.3.0 Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
215	IEC 60601-2-31:2008-Ed.2.0/Amd.1:2011 Medical electrical equipment – Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
216	IEC 60601-2-57:2011-Ed.1.0 Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
217	ISO 81060-2:2014 Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type
218	ISO 80601-2-56:2017 Medical electrical equipment -- part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
Radiology	
219	IEC 61217:2011 Radiotherapy equipment - Coordinates, movements and scales
220	IEC 61676:2002+AMD1:2008 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology
221	IEC 62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
222	IEC 62220-1:2015 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency

223	IEC 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
224	IEC 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
225	IEC 80601-2-35:2009+AMD1:2016 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
226	IEC 60601-2-45:2011+AMD1:2015 Medical electrical equipment -- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices
227	IEC 60627:2013 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids
228	IEC 60601-2-28:2017 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
229	IEC 60601-2-29:2008 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators
230	IEC 60601-2-33:2010+AMD1:2013+AMD2:2015 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
301	IEC 60601-2-37:2007+AMD1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
302	IEC 60601-2-8:2010+AMD1:2015 Medical electrical equipment - Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

303	IEC 60601-2-17:2013 Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy after loading equipment
304	IEC 60601-2-21:2009+AMD1:2016 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
305	IEC 60522:1999 Determination of the permanent filtration of X-ray tube assemblies
Cardiovascular	
306	ISO 25539-2:2012 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents
307	IEC 60601-2-27:2011 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment.
308	IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
309	ISO 5840-1:2015 Cardiovascular implants - Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements
310	ISO 5840-2:2015 Cardiovascular implants - Cardiac valve prostheses - Part 2: Cardiovascular implants - Surgically implanted heart valve substitutes
311	ISO 5840-3:2013 Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques
312	ISO 7198:2016 Cardiovascular implants and extracorporeal systems – Vascular prostheses - Tubular vascular grafts and vascular patches
313	ISO 11663:2009 Quality of dialysis fluid for haemodialysis and related therapies

314	ISO 13959:2009 Water for haemodialysis and related therapies
315	ISO 7198:2016 Cardiovascular implants and extracorporeal systems -- vascular prostheses -- tubular vascular grafts and vascular patches
316	ISO 25539-1:2017 Cardiovascular implants -- endovascular devices -- part 1: endovascular prostheses
317	ISO 25539-2:2012 Cardiovascular implants -- endovascular devices -- part 2: vascular stents
318	ISO 25539-3:2011 Cardiovascular implants -- endovascular devices -- part 3: vena cava filters
Materials	
319	ISO 5832-11:1994 Implants for surgery – Metallic materials – Part 11: Wrought titanium 6-aluminium 7-niobium alloy
320	ISO 5832-12:2007/Cor.1:2008 Implants for surgery – Metallic materials – Part 12: Wrought cobalt-chromium-molybdenum alloy
Risk Management	
321	ISO 22442-1:2007 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
Clinical Evidence	
322	ISO 22442-1:2007 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
323	ISO 22442-2:2015 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
324	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
325	ISO 14155:2011 Clinical investigation of medical devices for human subjects -- Good clinical practice
Other	
326	ISO 4074:2015 Natural latex rubber condoms - Requirements and test methods
327	EN 60645-4:1995 Audiometers - Part 4: Equipment for extended high-frequency audiometry
328	IEC 62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
329	ISO 13408-1:2008, including Amd 1:2013 Aseptic processing of health care products - Part 1: General requirements
330	IEC 62366:2007 Medical devices - Application of usability engineering to medical devices
331	ISO 14698-1:2003 Cleanrooms and associated controlled environments -- biocontamination control -- part 1: general principles and methods
332	ISO 14698-2:2003 Cleanrooms and associated controlled environments -- biocontamination control -- part 2: evaluation and interpretation of biocontamination data
333	ISO 14644-1:1999 Cleanrooms and associated controlled environments -- part 1: classification of air cleanliness
334	ISO 14644-2:2000 Cleanrooms and associated controlled environments -- part 2: specifications for testing and monitoring to prove continued compliance with ISO 14644-1
335	ISO 14644-3:2005 Cleanrooms and associated controlled environments — Part 3: Test methods

336	ISO 14644-4:2001 Cleanrooms and associated controlled environments -- part 4: design, construction and start-up
337	ISO 14644-5:2004 Cleanrooms and associated controlled environments -- part 5: operations
338	ISO 14644-6:2007 Cleanrooms and associated controlled environments -- part 6: vocabulary
339	ISO 14644-7:2004 Cleanrooms and associated controlled environments -- part 7: separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
340	ISO 14644-8:2013 Cleanrooms and associated controlled environments -- part 8: classification of air cleanliness by chemical concentration (ACC)
341	ISO 14644-9:2012 Cleanrooms and associated controlled environments -- part 9: classification of surface cleanliness by particle concentration
342	ISO 14644-10:2013 Cleanrooms and associated controlled environments -- part 10: classification of surface cleanliness by chemical concentration
343	IEC 60529:1989+AMD1:1999+AMD2:2013 CSV Degrees of protection provided by enclosures (IP Code)
344	IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements
345	IEC 61000-3-2:2018 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase)
346	IEC 61000-3-3:2013+AMD1:2017 CSV Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
347	IEC 61000-4-2:2008 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
348	IEC 61000-4-3:2006+AMD1:2007+AMD2:2010 CSV Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test

349	IEC 61000-4-4:2012 Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
350	IEC 61000-4-5:2014+AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
351	IEC 61000-4-6:2013 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
352	IEC 61000-4-8:2009 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
353	IEC 61000-4-11:2004+AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
354	CISPR 11:2015 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
355	ISO 22609:2004 Clothing for protection against infectious agents -- medical face masks -- test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
356	ISO 386:1977 Liquid-in-glass laboratory thermometers -- principles of design, construction and use

Annexes

Annex (1): Definitions & Abbreviations

1	SFDA	Saudi Food and Drug Authorization
2	MDS	Medical Devices Sector
3	IEC	International Electrotechnical Commission
4	ISO	International Organization for Standardization
5	Standard	document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose
6	Recognized standards	Standards that help applicants in premarket submissions stage to satisfy the SFDA regulatory needs.