مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

Recognized Medical Device Standards in GHC
Central Registration Department
Gulf Health Council

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Contents

Introduction

Purpose

The purpose of this guidance is to highlight the list of standards recognized by Gulf Health Council in the process of registration.

Scope

The guidance document between your hands shed light on all medical device standards that might be used to facilitate the registration process and assist in the technical file submission **if applicable.**

List of recognized standards by category:

Anesthetic and respiratory equipment related Standards	
1	ISO 5362:2006 Anaesthetic reservoir bags
2	ISO 4135:2001 Anaesthetic and respiratory equipment - Vocabulary
3	ISO 7396-2:2007 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems
4	ISO 80601-2-13:2011/AMD 1:2015 Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation — Amendment 1
5	ISO 9170-2:2008 Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems
6	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
7	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
8	ISO 10079-1:2015/AMD 1:2018 Medical suction equipment — Part 1: Electrically powered suction equipment — Amendment 1: Changes to requirements for operating at extremes of temperature

9	ISO 10079-2:2014 Medical suction equipment - Part 2: Manually powered suction equipment
10	ISO 10079-3:2014 Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source
11	ISO 10524-1:2018 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices
12	ISO 10524-2:2018 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators
13	ISO 10524-3:2019 Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves
14	ISO 10524-4:2008 Pressure regulators for use with medical gases - Part 4: Low-pressure regulators
15	ISO 10651-4:2002 Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators
16	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
17	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
18	ISO 11197:2019 Medical supply units
19	ISO 15001:2010 Anaesthetic and respiratory equipment - Compatibility with oxygen
20	ISO 18778:2005 Respiratory equipment - Infant monitors - Particular requirements
21	ISO 19054:2005 /AMD 1:2016 Rail systems for supporting medical equipment — Amendment 1
22	ISO 23328-1:2003 Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance

23	ISO 23328-2:2002 Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects
24	ISO 26782:2009 Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans
25	ISO 81060-1:2007 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type
26	ISO 80601-2-55:2020 Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
27	ISO 5359:2014/AMD 1:2017 Anaesthetic and respiratory equipment – Low-pressure hose assemblies for use with medical gases
28	ISO 27427:2013 Anaesthetic and respiratory equipment -- Nebulizing systems and components
29	ISO 2015: 12-2-80601 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
30	ISO 18250-1:2020 Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods
31	IEC 60601-1-6:2015 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
32	IEC 60601-1-8:2015 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
33	IEC 60601-1-9:2015 Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
34	IEC-60601-1-10:2017 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

35	IEC 60601-1-11:2015 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
36	IEC 60601-1-12:2015 Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
37	ISO 80601-2-12:2015 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
38	ISO 80601-2-70:2017 Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
39	ISO 80601-2-72:2017 Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
40	ISO 80601-2-74:2018 Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
41	ISO 10651-3:1997 Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators
42	ISO 10651-4:2015 Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators
43	ISO 10651-5:2015 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators
44	ISO 17510:2017 Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
45	ISO 18082:2015 Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw threaded (NIST) low-pressure connectors for medical gases
46	ISO 5356-1:2015 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets

47	ISO 5356-2:2015 Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight- bearing connectors
48	ISO 5361:2018 Anaesthetic and respiratory equipment — Tracheal tubes and connectors
49	ISO 5366:2018 Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors
50	ISO 5367:2015 Anaesthetic and respiratory equipment — Breathing sets and connectors

Biological evaluation of medical devices related Standards	
1	ISO 10993-7:2008/AMD 1:2019 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants
2	ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
3	ISO 10993-10:2018 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
4	ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
5	ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
6	ISO 10993-14:2001 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics
7	ISO 10993-15:2019 Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys
8	ISO 10993-16:2017 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachable
9	ISO 10993-17:2002 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
10	ISO 10993-18:2020 Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
11	**BS** EN ISO 10993-18:2020 Biological evaluation of medical devices. Chemical characterization of materials

12	ISO 10993-1:2018 Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process

Surgery implants related Standards	
1	ISO 5840-2:2015 Cardiovascular implants - Cardiac valve prostheses
2	ISO 14602:2010 Non-active surgical implants - Implants for osteosynthesis - Particular requirements
3	ISO 14607:2018 Non-active surgical implants - Mammary implants - Particular requirements
4	ISO 14630:2012 Non-active surgical implants - General requirements
5	ISO 16061:2015 Instrumentation for use in association with non-active surgical implants - General requirements
6	ISO 25539-1:2017 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses
7	ISO 25539-2:2012 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents
8	ISO 5840-1:2015 Cardiovascular implants - Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements
9	ISO 14708-6:2019 Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
10	ISO 14708-7:2019 Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems
11	ISO 7198:2016 Cardiovascular implants and extracorporeal systems – Vascular prostheses - Tubular vascular grafts and vascular patches
12	ISO 14708-3:2017 Active implantable medical devices -- Part 3: Implantable neurostimulators
13	ISO 14242-2:2016 Implants for Surgery - Wear of total hip-joint prostheses - Part 2: Methods of measurement

14	ISO 9583:1993 Implants for surgery – Non-destructive testing – Liquid penetrant inspection of metallic surgical implants
15	ISO 7206-4:2010/AMD 1:2016 Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties and performance of stemmed femoral components — Amendment 1
16	ISO 13782:2019 Implants for surgery – Metallic materials – Unalloyed tantalum for surgical implant applications
17	ISO 6474-1:2019 Implants for surgery – Ceramic materials – Part 1: Ceramic materials based on high purity alumina
18	ISO 6474-2:2019 Implants for surgery - Ceramic materials - Part 2: Composite materials based on a high purity alumina matrix with zirconia reinforcement
19	ISO 5834-2:2019 Implants for surgery – Ultra-high molecular weight polyethylene – Part 2: Moulded forms
20	ISO 5832-1:2016 Implants for Surgery – Metallic materials – Part 1: Wrought stainless steel
21	ISO 5832-2:2018 Implants for surgery – Metallic materials – Part 2: Unalloyed titanium
22	ISO 5832-3:2016 Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
23	ISO 5832-4:2014 Implants for surgery – Metallic materials – Part 4: Cobalt-chromiummolybdenum casting alloy
24	ISO 5832-5:2005 Implants for surgery – Metallic materials – Part 5: Wrought cobaltchromium-tungsten-nickel alloy
25	ISO 5832-6:1997 Implants for surgery – Metallic materials – Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy
26	ISO 5832-9:2019 Implants for surgery – Metallic materials – Part 9: Wrought high nitrogen stainless steel
27	ISO 23500-2:2019 Water treatment equipment for haemodialysis applications and related therapies
28	ISO 7199:2016/AMD 1:2020 Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators) — Amendment 1: Connectors

29	ISO 14117:2019 Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices
30	ISO 14708-5:2020 Implants for surgery – Active implantable medical devices – Part 5: Circulatory support devices
31	ISO 23500-4:2019 Preparation and quality management of fluids for haemodialysis and related therapies -- part 4: concentrates for haemodialysis and related therapies

Medical Device Sterilization Related Standards	
1	ISO 11135:2014/AMD 1:2018 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release
2	ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements
3	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
4	ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
5	ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
6	ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
7	ISO 11737-2:2019 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
8	ISO 13408-1:2008, including Amd 1:2013 Aseptic processing of health care products - Part 1: General requirements
9	ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration
10	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
11	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies

12	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place
13	ISO 13408-6:2005/AMD 1:2013 Aseptic processing of health care products — Part 6: Isolator systems — Amendment 1
14	ISO 13408-7:2012 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
15	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
16	ISO 15883-1:2006/Amd 1:2014 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
17	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.
18	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)
19	ISO 15883-4:2018 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
20	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
21	ISO 10993-7:2008/AMD 1:2019 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants
22	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
23	ISO 11137-2:2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

24	ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements
25	ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
26	ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
27	ISO 11737-2:2019 Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
28	ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration
29	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
30	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies
31	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place
32	ISO 13408-7:2012 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
33	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
34	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
35	ISO 11737-2:2019 Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
36	ISO 13408-2:2018 Aseptic processing of health care products -- Part 2: Sterilizing filtration

37	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place
38	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
39	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
40	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
41	ISO/TS 17665-2:2009 Sterilization of health care products -- moist heat -- part 2: guidance on the application of ISO 17665- 1
42	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
43	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

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 3826-3:2016 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

Quality Management System and other standards used frequently	
1	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
2	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies
3	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place
4	ISO 13408-7:2012 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
5	ISO 14971:2019 Medical devices — Application of risk management to medical devices
6	ISO 13408-1:2008, including Amd 1:2013 Aseptic processing of health care products - Part 1: General requirements
7	ISO 13408-2:2018 Aseptic processing of health care products -- Part 2: Sterilizing filtration
8	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
9	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies
10	ISO 13408-7:2012 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
11	ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications -- part 7: connectors for intravascular or hypodermic applications
12	ISO 13485 :2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
13	ISO 15223-1:2017 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

Electrical Equipment Related Standards	
1	IEC 60118-13:2019 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices
2	IEC 60522:1999 Determination of the permanent filtration of X-ray tube assemblies
3	IEC 60580:2019 Medical electrical equipment - Dose area product meters
4	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
5	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
6	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
7	IEC 60601-2-3:2012+AMD1:2016 CSV Consolidated version Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment
8	IEC 60601-2-5:2009 Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
9	IEC 60601-2-8:2010+AMD1:2015 CSV Consolidated version Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV
10	IEC 60601-2-17:2013 Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically- controlled brachytherapy after loading equipment
11	IEC 60601-2-18:2015 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (IEC 60601-2-18:2009)

12	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
13	IEC 60601-2-20:2009+AMD1:2016 CSV Consolidated version Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
14	IEC 60601-2-21:2009+AMD1:2016 CSV Consolidated version Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
15	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
16	IEC 60601-2-27:2011 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment.
17	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
18	IEC 60601-2-29:2008 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators
19	IEC 60601-2-33:2010+AMD1: 2013+AMD2:2015 CSV Consolidated version Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
20	IEC 60601-2-36:2014 Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy
21	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
22	IEC 60601-2-39:2018 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
23	IEC 60601-2-40:2016 Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment

24	IEC 60601-2-41:2009+AMD1:2013 CSV Consolidated version Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
25	IEC 60601-2-45:2011+AMD1:2015 CSV Consolidated version Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
26	IEC 60601-2-46:2016 Medical electrical equipment -- Part 2-46: Particular requirements for the safety of operating tables
27	IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
28	IEC 60601-2-49:2018 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
29	IEC 60601-2-50:2009+AMD1:2016 CSV Consolidated version Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
30	IEC 60627:2013 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti- scatter grids
31	IEC 60645-1:2017 Electroacoustic - Audiological equipment - Part 1: Pure-tone audiometers
32	IEC 61217:2011 Radiotherapy equipment - Coordinates, movements and scales
33	IEC 61676:2002+AMD1:2008 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology
34	IEC 62220-1-1:2015 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging
35	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
36	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

37	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
38	IEC 80601-2-58:2014+AMD1:2016 CSV Consolidated version 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
39	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
40	IEC 60601-1:2005+AMD1:2012 CSV Consolidated version Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
41	IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 CSV Consolidated version Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
42	ISO 80601-2-13:2011/Amd 2:2018 Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation — Amendment 2
43	IEC 80601-2-26:2019 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph
44	IEC 60601-2-31:2020 Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
45	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
46	ISO 81060-2:2018 Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type
47	ISO 80601-2-56:2017 + AMD 1:2018 Medical electrical equipment -- part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
48	IEC-62281:2016 Safety of primary and secondary lithium cells and batteries during transport
49	IEC-60601-1-10:2015 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

Cardiovascular	
1	ISO 25539-2:2012 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents
2	IEC 60601-2-27:2011 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment.
3	IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
4	ISO 5840-1:2015 Cardiovascular implants - Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements
5	ISO 5840-2:2015 Cardiovascular implants - Cardiac valve prostheses - Part 2: Cardiovascular implants - Surgically implanted heart valve substitutes
6	ISO 5840-3:2013 Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques
7	ISO 7198:2016 Cardiovascular implants and extracorporeal systems – Vascular prostheses - Tubular vascular grafts and vascular patches
8	ISO 11663:2014 Quality of dialysis fluid for haemodialysis and related therapies
9	ISO 13959:2014 Water for haemodialysis and related therapies
10	ISO 7198:2016 Cardiovascular implants and extracorporeal systems -- vascular prostheses -- tubular vascular grafts and vascular patches
11	ISO 25539-1:2017 Cardiovascular implants -- endovascular devices -- part 1: endovascular prostheses
12	ISO 25539-2:2012 Cardiovascular implants -- endovascular devices -- part 2: vascular stents
13	ISO 25539-3:2011 Cardiovascular implants -- endovascular devices -- part 3: vena cava filters

Radiology Related standards	
32	IEC 61217:2011 Radiotherapy equipment - Coordinates, movements and scales
33	IEC 61676:2002+AMD1:2008 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology
34	IEC 62220-1-1:2015 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging
35	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
36	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
37	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
38	IEC 80601-2-58:2014+AMD1:2016 CSV Consolidated version 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
39	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
40	IEC 60601-1:2005+AMD1:2012 CSV Consolidated version Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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48	IEC-62281:2016 Safety of primary and secondary lithium cells and batteries during transport
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1	ISO 22442-1:2015 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
2	ISO 22442-2:2015 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
3	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
4	ISO 14155:2020 Clinical investigation of medical devices for human subjects -- Good clinical practice

Materials	
1	ISO 5832-11:2014 Implants for surgery – Metallic materials – Part 11: Wrought titanium 6- aluminum 7-niobium alloy
2	ISO 5832-12:2019 Implants for surgery – Metallic materials – Part 12: Wrought cobalt-chromium- molybdenum alloy

Optics and photonics Standards	
1	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
2	ISO 11979-8:2017 Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements
3	ISO 11990:2018 Lasers and laser-related equipment -- determination of laser resistance of tracheal tube shaft and tracheal tube cuffs
4	**BS EN** ISO 14889:2013+A1:2017 Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses
5	ISO 15798:2010 Ophthalmic implants - Ophthalmic viscosurgical devices
6	IEC 80601-2-58:2014 Medical electrical equipment -- part 2-58: particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
7	ISO 18369-1:2017 Ophthalmic optics – Contact lenses – Part 1: Vocabulary, classification system and recommendations for labelling specifications
8	ISO 18369-3:2017 Ophthalmic optics – Contact lenses – Part 2: Measurement methods
9	ISO 18369-4:2017 Ophthalmic optics – Contact lenses – Part 4: Physicochemical properties of contact lens materials
10	ISO 11979-1:2018 Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary
11	ISO 11979-2:2014 Ophthalmic implants -- Intraocular lenses -- Part 2: Optical properties and test methods

12	ISO 11979-3:2012 Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods
13	ISO 11979-5:2006 Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility
14	ISO 11979-6:2014 Ophthalmic implants – Intraocular lenses – Part 6: Shelf-life and

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1	ISO 10328:2016 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods
2	ISO 22523:2006 External limb prostheses and external orthoses - Requirements and test methods
3	ISO 22675:2016 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods

Risk Management	
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1	ISO 7197:2006, including Cor 1:2007 Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components
2	ISO 9713:2002 Neurosurgical implants - Self-closing intracranial aneurysm clips
3	ISO 7740:1985 Instruments for surgery, scalpels with detachable blades, fitting dimensions
4	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
5	IEC 60601-2-18:2015 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (IEC 60601-2-18:2009)
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1	ISO 16201:2006 Technical aids for disabled persons - Environmental control systems for daily living
2	ISO 11334-4:1999 Walking aids manipulated by one arm — Requirements and test methods — Part 4: Walking sticks with three or more legs
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4	ISO 7176-1:2014 Wheelchairs — Part 1: Determination of static stability
5	ISO 7176-5:2008 Wheelchairs — Part 5: Determination of dimensions, mass and maneuvering space
6	ISO 7176-8:2014 Wheelchairs -- part 8: requirements and test methods for static, impact and fatigue strengths
7	ISO 7176-11:2012 Wheelchairs — Part 11: Test dummies
8	ISO 7176-13:1989 Wheelchairs — Part 13: Determination of coefficient of friction of test surfaces
9	ISO 7176-15:1996 Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling
10	ISO 7176-16:2012 Wheelchairs -- part 16: resistance to ignition of postural support devices
11	ISO 7176-19:2008/AMD 1:2015 Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles- Amendment 1: Annex G
12	ISO 7176-21:2009 Wheelchairs -- part 21: requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
13	ISO 7176-25:2013 Wheelchairs -- part 25: batteries and chargers for powered wheelchairs

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2	ISO 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
3	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
4	IEC 61326-2-6:2012 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

Other	
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2	EN 60645-4:1995 Audiometers - Part 4: Equipment for extended high-frequency audiometry
3	IEC 62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
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5	IEC 62366-1:2015 + COR 1:2016 + AMD 1:2020 Medical devices — Part 1: Application of usability engineering to medical devices
6	ISO 14698-1:2003 Cleanrooms and associated controlled environments -- biocontamination control -- part 1: general principles and methods

7	ISO 14698-2:2003 + COR 1:2004 Cleanrooms and associated controlled environments -- biocontamination control -- part 2: evaluation and interpretation of biocontamination data
8	ISO 14644-1:1999 Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
9	ISO 14644-2:2015 Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
10	ISO 14644-3:2019 Cleanrooms and associated controlled environments — Part 3: Test methods
11	ISO 14644-4:2001 Cleanrooms and associated controlled environments -- part 4: design, construction and start-up
12	ISO 14644-5:2004 Cleanrooms and associated controlled environments -- part 5: operations
13	ISO 14644-6:2007 Cleanrooms and associated controlled environments -- part 6: vocabulary
14	ISO 14644-7:2004 Cleanrooms and associated controlled environments -- part 7: separative devices (clean air hoods, gloveboxes,
15	ISO 14644-8:2013 Cleanrooms and associated controlled environments -- part 8: classification of air cleanliness by chemical
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24	IEC 61000-4-4:2012 Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst
25	IEC 61000-4-5:2014+AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
26	IEC 61000-4-6:2013 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted
27	IEC 61000-4-8:2009 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field
28	IEC 61000-4-11:2020 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short
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31	ISO 386:1977 Liquid-in-glass laboratory thermometers -- principles of design, construction and use
32	EN 14683:2019 Medical face masks. Requirements and test methods
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34	ASTM F2101 – 14 Standard test method for evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask materials, using a
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40	EN 166:2002 Personal eye protection — Specifications
41	OSHA 1910.133 Eye and face protection

Abbreviations and Acronyms		
1	GHC	Gulf Health Council
2	GSO	GCC Standardization Organization
3	IMDRF	International Medical Device Regulators Forum
4	IEC	International Electrotechnical Commission
5	ISO	International Organization for Standardization
6	WHO	World Health Organization
7	Standard	Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
8	Recognized Standard	Standard deemed to offer the presumption of conformity to specific Essential Principles of Safety and Performance.

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