Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-11020-03-02 according to 93/42/EWG[1], 90/385/EWG[2], 98/79/EG[3] and DIN EN ISO/IEC 17025:2005[4]

Period of validity: 2018-08-30 to 2023-07-29 Date of issue: 2018-08-30

Holder of certificate:

SGS Germany GmbH
Rödingsmarkt 16, 20459 Hamburg

At the location:

SGS Germany GmbH
Hofmannstr. 50, 81379 München

Testing field:	**Medical devices**
Test area:	**safety tests on active medical devices and testing on compatibility with electromagnetic disturbances (EMC) of active medical devices and IVD-devices**

Scope:

1) Safety testing

Test area	Test item Product (category)	Kind of test	Test standard Test method
Safety tests	Active medical devices	Compliance testing Components and ME systems Electrical testing and protection against electrical hazards - Without resistance to environmental stress (natural latex) - Without annex L Mechanical stability and protection against mechanical hazards - without hand vibrations Protection against unwanted / excessive radiation hazards Protection against excessive temperatures including fire prevention - Without tests according to annex G Climatic environmental simulation tests	DIN EN 60601-1 IEC 60601-1 DIN EN 60601-1-1⊗ IEC 60601-1-1⊗
	Information provided by the manufacturer - about components and assemblies - About Biocompatibility - instructions for use / accompanying documents	Compliance testing	
Safety tests	- usability engineering file		

Test area	Test item Product (category)	Kind of test	Test standard Test method
	- about programmable electrical medical systems (PEMS) - risk management file - about radiation, ionizing / not ionizing		DIN EN 60601-1-4⊗ IEC 60601-1-4⊗
	Diagnostic X-ray equipment	Testing to proof the compliance - leakage radiation - filtration - stray radiation	DIN EN 60601-1-3 IEC 60601-1-3
	Information provided by the manufacturer - instructions for use / accompanying documents - risk management file	Compliance testing	
	Medical devices, active Information provided by the manufacturer - usability engineering file	Compliance testing	DIN EN 60601-1-6 IEC 60601-1-6
	Medical devices, active	Compliance testing - visual alarms - acoustic alarms	DIN EN 60601-1-8 IEC 60601-1-8
	Information provided by the manufacturer - instructions for use / accompanying documents / technical description - risk management file		
Safety tests	Information provided by the manufacturer about physiologic closed-loop	Compliance testing	DIN EN 60601-1-10 IEC 60601-1-10

Test area	Test item Product (category)	Kind of test	Test standard Test method
	controllers - instructions for use / accompanying documents - usability engineering file - risk management file - about programmable electrical medical systems (PEMS)		
	Medical devices, active, used in the home healthcare environment	Compliance testing Mechanical strength and protection against mechanical hazards Climatic environmental simulation tests	DIN EN 60601-1-11 IEC 60601-1-11
	Information provided by the manufacturer - instructions for use / accompanying documents - usability engineering file - risk management file		
	Medical devices, active, intended for use in the emergency medical services environment	Compliance testing Mechanical strength and protection against mechanical hazards Climatic environmental simulation tests	DIN EN 60601-1-12 IEC 60601-1-12
Safety tests	Information provided by the manufacturer - instructions for use /		

Test area	Test item Product (category)	Kind of test	Test standard Test method
	accompanying documents - usability engineering file - risk management file		
	Medical devices, active, used in road ambulances	Compliance testing	DIN EN 1789
	Equipment for extracorporeal circuits, infusions and haemophoresis - infusion pumps and controllers	Verification of compliance with general and special specifications	DIN EN 60601-2-24 IEC 60601-2-24
	Ventilators, oxygen therapy apparatus (including devices for hyperbaric therapy) and devices for inhalation anaesthesia - anaesthesia workplaces - respiratory humidifier - Ventilators	Verification of compliance with general and special specifications	DIN EN ISO 80601-2-13 ISO 80601-2-13 ISO 80601-2-74 DIN EN ISO 80601-2-12 ISO 80601-2-12 DIN EN 60601-2-12⊗ IEC 60601-2-12⊗
Safety tests	- Home care ventilators		DIN EN ISO 80601-2-72 ISO 80601-2-72

Test area	Test item Product (category)	Kind of test	Test standard Test method
	- respiratory gas monitors		DIN EN ISO 10651-2 DIN EN ISO 80601-2-55 ISO 80601-2-55
	Devices for stimulation or inhibition - Cardiac defibrillators - Nerve and muscle stimulators	Verification of compliance with general and special specifications	DIN EN 60601-2-4 IEC 60601-2-4 DIN EN 60601-2-10 IEC 60601-2-10
	Surgical equipment and surgical accessories - endoscopic equipment - high frequency surgical equipment - luminaires	Verification of compliance with general and special specifications	DIN EN 60601-2-18 IEC 60601-2-18 DIN EN 60601-2-2 IEC 60601-2-2 DIN EN 60601-2-41 IEC 60601-2-41
	Dental equipment	Verification of compliance with general and special specifications	DIN EN 80601-2-60 IEC 80601-2-60
	Sterilizers, washer-disinfectors	Verification of compliance with general and special specifications	DIN EN 61010-2-040 IEC 61010-2-040
Safety tests	Devices for patient positioning and transport - blankets, pads and mattresses - medical beds - operating tables	Verification of compliance with general and special specifications	DIN EN 80601-2-35 IEC 80601-2-35 DIN EN 60601-2-52 IEC 60601-2-52 DIN EN 60601-2-46 IEC 60601-2-46

Test area	Test item Product (category)	Kind of test	Test standard Test method
	Devices for imaging techniques using ionizing radiation	Verification of compliance with general and special specifications	
	- dental extraoral X-ray equipment		DIN EN 60601-2-63 IEC 60601-2-63
	- dental intra-oral X-ray equipment		DIN EN 60601-2-65 IEC 60601-2-65
	- X-ray equipment for radiography and radioscopy		DIN EN 60601-2-54 IEC 60601-2-54 DIN EN 60601-2-7⊗ IEC 60601-2-7⊗
	- associated equipment of X-ray equipment		DIN EN 60601-2-32⊗ IEC 60601-2-32⊗
	- X-ray equipment for computed tomography		DIN EN 60601-2-44 IEC 60601-2-44
	- X-ray equipment for interventional procedures		DIN EN 60601-2-43 IEC 60601-2-43
	- mammographic X-ray equipment and mammographic stereotactic devices		DIN EN 60601-2-45 IEC 60601-2-45
	- X-ray tube assemblies for medical diagnosis		DIN EN 60601-2-28 IEC 60601-2-28
	Devices for imaging techniques using non-ionizing radiation		
	- magnetic resonance equipment		DIN EN 60601-2-33 IEC 60601-2-33
Safety tests	- ultrasonic medical diagnostic and		DIN EN 60601-2-37

Test area	Test item Product (category)	Kind of test	Test standard Test method
	monitoring equipment		IEC 60601-2-37
	Monitoring devices	Verification of compliance with general and special specifications	
	- multifunction patient monitoring equipment		DIN EN 60601-2-49 IEC 60601-2-49
	Monitoring devices of non-vital physiological parameters	Verification of compliance with general and special specifications	
	- electroencephalo-graphs		DIN EN 60601-2-26 IEC 60601-2-26
	- electromygraphs and evoked response equipment		DIN EN 60601-2-40 IEC 60601-2-40
	Monitoring devices of vital parameters	Verification of compliance with general and special specifications	
	- ambulatory electrocardiographic systems		DIN EN 60601-2-47 IEC 60601-2-47
	- recording and analysing single channel and multichannel electrocardiographs		DIN EN 60601-2-51 IEC 60601-2-51
	- automated non-invasive sphygmomanometers		DIN EN 80601-2-30 IEC 80601-2-30
	- blood pressure monitoring equipment		DIN EN 60601-2-34 IEC 60601-2-34
	- electrocardiographs		DIN EN 60601-2-25 IEC 60601-2-25
			DIN EN 60601-2-27 IEC 60601-2-27
Safety tests	- clinical thermometers		DIN EN ISO 80601-2-

Test area	Test item Product (category)	Kind of test	Test standard Test method
	for body temperature measurement - pulse oximeter equipment		56 ISO 80601-2-56 DIN EN ISO 80601-2-61 ISO 80601-2-61
	Devices using non-ionizing radiation - diagnostic and therapeutic laser equipment - non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic / aesthetic use	Verification of compliance with general and special specifications with a maximum output power of 25 W (continuous operation) or 150 W (pulsed operation	DIN EN 60601-2-22 IEC 60601-2-22 DIN EN 60601-2-57 IEC 60601-2-57
	equipment for extracorporeally induced lithotripsy	Verification of compliance with general and special specifications	DIN EN 60601-2-36 IEC 60601-2-36
	in vitro diagnostic medical devices (IVD)	Verification of compliance with general and special specifications	DIN EN 61010-2-101 IEC 61010-2-101

Exclusions of subtests of a test are not listed in this scope of accreditation, and the laboratory must inform the purchaser during contract review.

Only normative references to European standards (DIN EN) were respected during the accreditation assessment. International normative references (IEC ISO) were only respected, if the referenced international editions of the standards are listed explicitly in this annex to the notice of accreditation.

2) EMC

Test area	Test item Product (category)	Kind of test	Test standard Test method
EMC	Medical devices, active	Compliance testing in the frequency range up to 40 GHz - emissions - immunity	DIN EN 60601-1-2 IEC 60601-1-2
	Information provided by the manufacturer - marking - identification - instructions for use / accompanying documents	Test of conformity	
	Medical devices, active, used in the home healthcare environment	Compliance testing	DIN EN 60601-1-11 IEC 60601-1-11
	Medical devices, active, intended for use in the emergency medical services environment	Compliance testing	DIN EN 60601-1-12 IEC 60601-1-12
	Equipment for extracorporeal circuits, infusions and haemophoresis - infusion pumps and controllers	Verification of compliance with general and special specifications	DIN EN 60601-2-24 IEC 60601-2-24
	Ventilators, oxygen therapy apparatus (including devices for hyperbaric therapy) and devices for inhalation anaesthesia - ventilators	Verification of compliance with general and special specifications	DIN EN ISO 80601-2-12 ISO 80601-2-12

Test area	Test item Product (category)	Kind of test	Test standard Test method
EMC	- home care ventilators - respiratory gas monitors		DIN EN ISO 80601-2-72 ISO 80601-2-72 DIN EN ISO 80601-2-55 ISO 80601-2-55
	Devices for stimulation or inhibition - Cardiac defibrillators - Nerve and muscle stimulators	Verification of compliance with general and special specifications	DIN EN 60601-2-4 IEC 60601-2-4 DIN EN 60601-2-10 IEC 60601-2-10
	Surgical equipment and surgical accessories - endoscopic equipment	Verification of compliance with general and special specifications	DIN EN 60601-2-18 IEC 60601-2-18
	Devices for patient positioning and transport - blankets, pads and mattresses - operating tables	Verification of compliance with general and special specifications	DIN EN 80601-2-35 IEC 80601-2-35 DIN EN 60601-2-46 IEC 60601-2-46
	Devices for imaging techniques using ionizing radiation - dental extraoral X-ray equipment - dental intra-oral X-ray equipment	Verification of compliance with general and special specifications	DIN EN 60601-2-63 IEC 60601-2-63 DIN EN 60601-2-65 IEC 60601-2-65

Test area	Test item Product (category)	Kind of test	Test standard Test method
EMC	- X-ray equipment for radiography and radioscopy - X-ray equipment for computed tomography - X-ray equipment for interventional procedures - mammographic X-ray equipment and mammographic stereotactic devices Devices for imaging techniques using non-ionizing radiation - magnetic resonance equipment - ultrasonic medical diagnostic and monitoring equipment		DIN EN 60601-2-54 IEC 60601-2-54 DIN EN 60601-2-44 IEC 60601-2-44 DIN EN 60601-2-43 IEC 60601-2-43 DIN EN 60601-2-45 IEC 60601-2-45 DIN EN 60601-2-33 IEC 60601-2-33 DIN EN 60601-2-37 IEC 60601-2-37
	Equipment for extracorporeally induced lithotripsy		DIN EN 60601-2-36 IEC 60601-2-36
	Monitoring devices - multifunction patient monitoring equipment Monitoring devices of non-vital physiological parameters	Verification of compliance with general and special specifications Verification of compliance with general and special specifications	DIN EN 60601-2-49 IEC 60601-2-49

Test area	Test item Product (category)	Kind of test	Test standard Test method
EMC	- electroencephalo-graphs - electromygraphs and evoked response equipment - clinical thermometers for body temperature measurement Monitoring devices of vital parameters - ambulatory electrocardiographic systems - recording and analysing single channel and multichannel electrocardiographs - automated non-invasive sphygmomanometers - blood pressure monitoring equipment	Verification of compliance with general and special specifications	DIN EN 60601-2-26 IEC 60601-2-26 DIN EN 60601-2-40 IEC 60601-2-40 DIN EN ISO 80601-2-56 ISO 80601-2-56 DIN EN 60601-2-47 IEC 60601-2-47 DIN EN 60601-2-51 IEC 60601-2-51 DIN EN 80601-2-30 IEC 80601-2-30 DIN EN 60601-2-34 IEC 60601-2-34
	- electrocardiographs - pulse oximeter equipment		DIN EN 60601-2-25 IEC 60601-2-25 DIN EN 60601-2-27 IEC 60601-2-27 DIN EN ISO 80601-2-61 ISO 80601-2-61
	In vitro diagnostic (IVD) medical equipment	Compliance testing - emissions - immunity	DIN EN 61326-2-6 IEC 61326-2-6

Test area	Test item Product (category)	Kind of test	Test standard Test method
EMC	Information provided by the manufacturer - marking - identification - instructions for use / accompanying documents	Test of conformity	DIN EN 61326-2-6 IEC 61326-2-6

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Standards[v]

DIN EN 1789 : 2010-11	Medical vehicles and their equipment –Road ambulances; German version EN 1789:2007+A1:2010
DIN EN ISO 10651-2 : 2011-06⊗	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651-2:2004); German version EN ISO 10651-2:2009
DIN EN 60601-1 : 2013-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012); German version EN 60601-1:2006 + Cor. :2010 + A1:2013 VDE 0750-1:2013-12
	DIN EN 60601-1 : 2007-07⊗ - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1 : 2005); German version EN 60601-1 : 2006; including AC:2010

	DIN EN 60601-1 : 1996-03⊗ - Medical electrical equipment - Part 1: General requirements for basic safety (IEC 60601-1 : 1988 +A1 : 1991 +A2 : 1995); German version EN 60601-1 : 1990 + A1 : 1993 + A2 : 1995 VDE 0750-1:1996-03⊗
DIN EN 60601-1-1 : 2002-08⊗	Medical electrical equipment - Part 1-1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1 : 2000); German version EN 60601-1-1 : 2001 VDE 0750-1-1 : 2002-08⊗
DIN EN 60601-1-2 : 2016-05	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2014); German version EN 60601-1-2:2015 DIN EN 60601-1-2 : 2007-12 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007, modified); German version EN 60601-1-2:2007 VDE 0750-1-2:2007-12 DIN EN 60601-1-2 Correction 1⊗ - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007, modified); German version EN 60601-1-2:2007; Correction to DIN EN 60601-1-2 (VDE 0750-1-2):2007-12; German version CENELEC-Cor.:2010 to EN 60601-1-2:2007
DIN EN 60601-1-3 : 2014-06	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008 + A1:2013); German version EN 60601-1-3:2008 + Cor.:2010 + A1:2013 VDE 0750-1-3:2014-06
DIN EN 60601-1-4 : 2001-04⊗	Medical electrical equipment - Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems (IEC 60601-1-4 : 1996 + A1 : 1999); German version EN 60601-1-4 : 1996 + A1 : 1999 VDE 0750-1-4:2001-04⊗

DIN EN 60601-1-6 : 2016-02	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010 + A1:2013); German version EN 60601-1-6:2010 + A1:2015 DIN EN 60601-1-6 : 2010-10⊗ - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6 : 2010); German version EN 60601-1-6 : 2010 VDE 0750-1-6:2010-10⊗
DIN EN 60601-1-8 : 2014-04	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 (IEC 60601-1-8:2006 + A1:2012); German version EN 60601-1-8:2007 + Cor.:2010 + A1:2013 VDE 0750-1-8:2014-04
DIN EN 60601-1-10 : 2016-04	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 (IEC 60601-1-10:2007 + A1:2013); German version EN 60601-1-10:2008 + A1:2015 DIN EN 60601-1-10 : 2008-11⊗ - 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 (IEC 60601-1-10 : 2007); German version EN 60601-1-10 : 2008 VDE 0750-1-10:2008-11
DIN EN 60601-1-11 : 2016-04	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 (IEC 60601-1-11:2015); German version EN 60601-1-11:2015 DIN EN 60601-1-11 : 2011-03⊗ - 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 (IEC 60601-1-11:2010); German version EN 60601-1-11:2010 VDE 0750-1-11:2011-03⊗ DIN EN 60601-1-11 correction 1 : 2011-11: 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 (IEC 60601-1-11:2010); German version EN 60601-1-11:2010, correction to DIN EN 60601-1-11 (VDE 0750-1-11):2011-03; (IEC-Cor.: 2011 to IEC 60601-1-11:2010)
DIN EN 60601-1-12 : 2016-01	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 (IEC 60601-1-12:2014); German version EN 60601-1-12:2015
DIN EN 60601-2-2 : 2010-01	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009); German version EN 60601-2-2:2009 VDE 0750-2-2:2010-01
DIN EN 60601-2-4 : 2012-05	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4:2010); German version EN 60601-2-4:2011 VDE 0750-2-4:2012-05
DIN EN 60601-2-7 : 2000-03⊗	Medical electrical equipment. Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators (IEC 60601-2-7:1998); German version EN 60601-2-7:1998 VDE 0750-2-7:2000-03⊗
DIN EN 60601-2-10 : 2015-11⊗	Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

	(IEC 60601-2-10:2012); German version EN 60601-2-10:2015 VDE 0750-2-10:2015-11 DIN EN 60601-2-10 : 2003-04⊗ - Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators (IEC 60601-2-10:1987 + A1:2001-09 + Corrigendum 1:2002); German version EN 60601-2-10:2000 + A1:2001 VDE 0750-2-10:2003-04⊗
DIN EN 60601-2-12 : 2007-03⊗	Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators (IEC 60601-2-12:2001); German version EN 60601-2-12:2006 VDE 0750-2-12:2007-03⊗
DIN EN 60601-2-18 : 2001-12⊗	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996 + A1:2000); German version EN 60601-2-18:1996 + A1:2000 VDE 0750-2-18:2001-12
DIN EN 60601-2-22 : 2015-08	Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (IEC 60601-2-22:2007 + A1:2012); German version EN 60601-2-22:2013 VDE 0750-2-22:2015-08
DIN EN 60601-2-24 : 2016-04	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:2012); German version EN 60601-2-24:2015 DIN EN 60601-2-24 : 1999-02⊗ - Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998); German version EN 60601-2-24:1998 VDE 0750-2-24:1999-02
DIN EN 60601-2-25 : 2001-04⊗	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993 + A1:1999); German version EN 60601-2-25:1995 + A1:1999 VDE 0750-2-25:2001-04
DIN EN 60601-2-26 : 2016-02	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26:2012); German version EN 60601-2-26:2015 DIN EN 60601-2-26 : 2004-01⊗ - Medical electrical equipment -

	Part 2-26: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26:2002); German version EN 60601-2-26:2003 VDE 0750-2-26:2004-01
DIN EN 60601-2-27 : 2015-04	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment (IEC 60601-2-27:2011 + Cor.:2012); German version EN 60601-2-27:2014 VDE 0750-2-27:2015-04 DIN EN 60601-2-27 : 2006-08⊗ - Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment (IEC 60601-2-27:2005); German version EN 60601-2-27:2006 + Correction 1 : 2007-05⊗ VDE 0750-2-27:2007-05⊗
DIN EN 60601-2-28 : 2010-11	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (IEC 60601-2-28:2010); German version EN 60601-2-28:2010 VDE 0750-2-28:2010-11
DIN EN 60601-2-32 : 1995-11⊗	Medical electrical equipment - Part 2-32: Particular requirements for the safety of associated equipment of X ray equipment (IEC 60601-2-32:1994); German version EN 60601-2-32:1994 VDE 0750-2-32 : 1995-11⊗
DIN EN 60601-2-33 : 2011-07	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2010); German version EN 60601-2-33:2010 + Cor. :2010 VDE 0750-2-33:2011-07
DIN EN 60601-2-34 : 2015-01	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment (IEC 60601-2-34:2011); German version EN 60601-2-34:2014 DIN EN 60601-2-34 : 2001-11⊗ - Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment (IEC 60601-2-34:2000); German version EN 60601-2-34:2000

DIN EN 60601-2-36 : 2015-11	Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy (IEC 60601-2-36:2014); German version EN 60601-2-36:2015 VDE 0750-2-36 : 2015-11 DIN EN 60601-2-36 : 1997-12⊗ - Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy (IEC 60601-2-36:1997); German version EN 60601-2-36:1997
DIN EN 60601-2-37 : 2016-11	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007 + A1:2015); German version EN 60601-2-37:2008 + A11:2011 + A1:2015 DIN EN 60601-2-37 : 2012-05⊗ - Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007); German version EN 60601-2-37:2008 + A11:2011 VDE 0750-2-37:2012-05⊗
DIN EN 60601-2-40 : 1998-12	Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment (IEC 60601-2-40:1998); German version EN 60601-2-40:1998 VDE 0750-2-40:1998-12
DIN EN 60601-2-41 : 2016-02	Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009 + A1:2013); German version EN 60601-2-41:2009 + A1:2015 DIN EN 60601-2-41 : 2010-05⊗ - Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009); German version EN 60601-2-41:2009 VDE 0750-2-41:2010-05⊗

DIN EN 60601-2-43 : 2011-03	Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures (IEC 60601-2-43:2010); German version EN 60601-2-43:2010 VDE 0750-2-43:2011-03
DIN EN 60601-2-44 : 2014-11	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (IEC 60601-2-44:2009 + Cor.:2010 + A1:2012); German version EN 60601-2-44:2009 + A11:2011 + A1:2012 DIN EN 60601-2-44⊗ : 2010-02 - Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (IEC 60601-2-44:2009); German version EN 60601-2-44:2009, Correction to DIN EN 60601-2-44 (VDE 0750-2-44):2010-02; (IEC-Cor. 1.:2010 zu IEC 60601-2-44:2009) VDE 0750-2-44:2010-02⊗
DIN EN 60601-2-44 : 2017-03	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (IEC 60601-2-44:2009 + Cor.:2010 + A1:2012 + A2:2016); German version EN 60601-2-44:2009 + A11:2011 + A1:2012 + A2:2016 DIN EN 60601-2-44 : 2014-11⊗ - Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (IEC 60601-2-44:2009 + Cor.:2010 + A1:2012)
DIN EN 60601-2-45 : 2017-01	Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices (IEC 60601-2-45:2011 + A1:2015); German version EN 60601-2-45:2011 + A1:2015 VDE 0750-2-45:2017-01 DIN EN 60601-2-45 : 2012-03⊗ - Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices (IEC 60601-2-45:2011); German version EN 60601-2-45:2011 VDE 0750-2-45:2012-03⊗

DIN EN 60601-2-46 : 2011-12	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables (IEC 60601-2-46:2010); German version EN 60601-2-46:2011 VDE 0750-2-46:2011-12
DIN EN 60601-2-47 : 2016-02	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems (IEC 60601-2-47:2012); German version EN 60601-2-47:2015 VDE 0750-2-47 : 2016-02 DIN EN 60601-2-47 : 2002-11⊗ - Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems (IEC 60601-2-47:2001); German version EN 60601-2-47:2001 VDE 0750-2-47:2002-11⊗
DIN EN 60601-2-49 : 2016-10	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IEC 60601-2-49:2011); German version EN 60601-2-49:2015 VDE 0750-49 : 2016-10 DIN EN 60601-2-49 : 2002-12⊗ - Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IEC 60601-2-49:2001); German version EN 60601-2-49:2001 VDE 0750-2-49:2002-12⊗
DIN EN 60601-2-51 : 2004-02	Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs (IEC 60601-2-51:2003); German version EN 60601-2-51:2003 VDE 0750-2-51:2004-02
DIN EN 60601-2-52 : 2016-04	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009 + Cor.:2010 + A1:2015);

	German version EN 60601-2-52:2010 + AC:2011 + A1:2015 DIN EN 60601-2-52 : 2010-12⊗ - Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009); German version EN 60601-2-52:2010 VDE 0750-2-52:2010-12⊗
DIN EN 60601-2-54 : 2016-07	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (IEC 60601-2-54:2009 + Cor.:2010 + Cor.:2011 + A1:2015); German version EN 60601-2-54:2009 + A1:2015 VDE 0750-2-54:2016-07 DIN EN 60601-2-54 : 2010-05⊗ - Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (IEC 60601-2-54:2009); German version EN 60601-2-54:2009 + Correction 1 : 2010-07 + Correction 2 : 2011-12 + Correction 3 : 2012-04 VDE 0750-2-54:2010-05 + Cor. 1:2010-07 + Cor. 2:2011-12 + Cor. 3:2012-04⊗
DIN EN 60601-2-57 : 2011-11	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 (IEC 60601-2-57:2011); German version EN 60601-2-57:2011 VDE 0750-2-57:2011-11
DIN EN 60601-2-63 : 2016-11	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment (IEC 60601-2-63:2012); German version EN 60601-2-63:2015 VDE 0750-2-63:2016-11
DIN EN 60601-2-65 : 2016-11	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment (IEC 60601-2-65:2012);

	German version EN 60601-2-65:2013 / applies in conjunction with DIN EN 60601-1 (2013-12) VDE 0750-2-65:2016-11
DIN EN 61010-2-040 : 2016-06	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015); German version EN 61010-2-040:2015 (in Verbindung mit DIN EN 61010-1 : 2011-07, solange eine gültige Akkreditierung hierfür besteht) DIN EN 61010-2-040 : 2006-02⊗ : Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2005); German version EN 61010-2-040:2005 (applies in conjunction with DIN EN 61010-1 : 2002-08, as long as a valid accreditation exists)
DIN EN 61010-2-101 : 2003-09⊗	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2002, modified); German version EN 61010-2-101:2002 (applies in conjunction with DIN EN 61010-1, as long as a valid accreditation exists) VDE 0411-2-101:2003-09⊗
DIN EN 61326-2-6 : 2013-09	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2012); German version EN 61326-2-6:2013 (applies in conjunction with DIN EN 61326-1 : 2013-07, as long as a valid accreditation exists)
DIN EN ISO 80601-2-12 : 2012-02	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO/IEC 80601-2-12:2011 + Cor. :2011); German version EN ISO 80601-2-12:2011 + AC:2011 VDE 0750-2-12:2012-02

DIN EN ISO 80601-2-13 : 2013-03	Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2011); German version EN ISO 80601-2-13:2012
DIN EN 80601-2-30 : 2016-02	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers (IEC 80601-2-30:2009 + Corrigendum Jan. 2010 + A1:2013); German version EN 80601-2-30:2010 + A1:2015 DIN EN 80601-2-30 : 2011-05⊗ - Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers (IEC 80601-2-30:2009 + Cor. :2010); German version EN 80601-2-30:2010 VDE 0750-2-30:2011-05
DIN EN 80601-2-35 : 2010-08	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 (IEC 80601-2-35:2009); German version EN 80601-2-35:2009 VDE 0750-2-35:2010-08
DIN EN ISO 80601-2-55 : 2012-03	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011); German version EN ISO 80601-2-55:2011 VDE 0750-2-55:2012-03
DIN EN ISO 80601-2-56 : 2013-02	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009); German version EN ISO 80601-2-56:2012
DIN EN 80601-2-60 : 2016-03	Medical Electrical Equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment (IEC 80601-2-60:2012); German version EN 80601-2-60:2015
DIN EN ISO 80601-2-61 : 2012-01	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2011); German version EN ISO 80601-2-61:2011
DIN EN ISO 80601-2-72 : 2016-04	Medical electrical equipment - Part 2-72: Particular

	requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients (ISO 80601-2-72:2015); German version EN ISO 80601-2-72:2015
IEC 60601-1 : 2005-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance + Corrigendum 1 : 2006-12 + Corrigendum 2 : 2007-12 + Amendment 1 : 2012-07 ANSI/AAMI ES60601-1 : 2005 & C1:2009 & A2:2010 & A1:2012 CAN/CSA-C22.2 NO. 60601-1:14
IEC 60601-1-1 : 2000-12⊗	Medical electrical equipment - Part 1-1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2 : 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests IEC 60601-1-2 : 2007-03⊗ - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-3 : 2008-01	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment + Amendment 1 : 2013-04 CAN/CSA-C22.2 NO. 60601-1-3-09 (R2014)
IEC 60601-1-4 : 1996-05⊗	Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems + Amendment 1 : 1999-10
IEC 60601-1-6 : 2010-01	Medical electrical equipment - General requirements for basic safety and essential performance - Collateral Standard: Usability + Amendment 1 : 2013-10 CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016)
IEC 60601-1-8 : 2006-10	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; + Amendment 1 : 2012-11 CAN/CSA-C22.2 NO. 60601-1-8-08 (R2014)
IEC 60601-1-10 : 2007-11	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
IEC 60601-1-11 : 2015-01	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 ANSI/AAMI HA60601-1-11 : 2015
IEC 60601-1-12 : 2014	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 ANSI/AAMI/IEC 60601-12 : 2016 CAN/CSA-C22.2 NO. 60601-1-12 : 15
IEC 60601-2-2 : 2017-03	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 IEC 60601-2-2 : 2009-02⊗ - 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 ANSI/AAMI/IEC 60601-2-2 : 2009 CAN/CSA-C22.2 NO. 60601-2-2-09 (R2014)
IEC 60601-2-4 : 2010-12	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators
IEC 60601-2-7 : 1998-02⊗	Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators

IEC 60601-2-10 : 2012-06	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators + Amendment 1 : 2016-04 CAN/CSA-C22.2 NO. 60601-2-10:14
IEC 60601-2-12 : 2001-10⊗	Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators; Critical care ventilators
IEC 60601-2-18 : 2009-08	Medical electrical equipment - Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment CAN/CSA-C22.2 NO. 60601-2-18:11
IEC 60601-2-22 : 2007-05	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment + Amendment 1 : 2012-10
IEC 60601-2-24 : 2012-10	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers CAN/CSA-C22.2 NO. 60601-2-24:15
IEC 60601-2-25 : 2011-10	Medical electrical equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs CAN/CSA-C22.2 NO. 60601-2-25:12
IEC 60601-2-26 : 2012-05	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 60601-2-27 : 2011-03	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment + Corrigendum 1 : 2012-05 CAN/CSA-C22.2 NO. 60601-2-27:11
IEC 60601-2-28 : 2010-03	Medical electrical equipment - Part 2-28: Particular requirements for basic safety and essential performance of X-ray tube assemblies for medical diagnosis CAN/CSA-C22.2 NO. 60601-2-28:12
IEC 60601-2-28 : 2017-06	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

IEC 60601-2-32 : 1994-03⊗	Medical electrical equipment; part 2: particular requirements for the safety of X-ray equipment
IEC 60601-2-33 : 2010-03	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis + Amendment 1 : 2013-04 + Amendment 2 : 2015-06
IEC 60601-2-34 : 2011-05	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment CAN/CSA-C22.2 NO. 60601-2-34:12
IEC 60601-2-36 : 2014-04	Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy CAN/CSA-C22.2 NO. 60601-2-36:2016
IEC 60601-2-37 : 2007-08	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment + Amendment 1 : 2015-06 CAN/CSA-C22.2 NO. 60601-2-37:2008
IEC 60601-2-40 : 2016-08	Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment IEC 60601-2-40 : 1998-02⊗ - Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
IEC 60601-2-41 : 2009-08	Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis + Amendment 1 : 2013-10
IEC 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 + Amendment 1 : 2017-05 CAN/CSA-C22.2 NO. 60601-2-43:2011
IEC 60601-2-44 : 2009-02	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography + Corrigendum 1 : 2010-05

	+ Amendment 1 : 2012-08 + Amendment 2 : 2016-03 CAN/CSA-C22.2 NO. 60601-2-44A AMD 1
IEC 60601-2-45 : 2011-02	Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices + Amendment 1 : 2015-06 CAN/CSA-C22.2 NO. 60601-2-45:2011
IEC 60601-2-46 : 2016-08	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables IEC 60601-2-46 : 2010-12⊗ - Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables CAN/CSA-C22.2 NO. 60601-2-46:2012
IEC 60601-2-47 : 2012-02	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems ANSI/AAMI/IEC 60601-2-47:2012 CAN/CSA-C22.2 NO. 60601-2-47:2014
IEC 60601-2-49 : 2011-02	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment CAN/CSA-C22.2 NO. 60601-2-49:11
IEC 60601-2-51 : 2003-02	Medical electrical equipment - Part 2-51: Particular requirements for the safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
IEC 60601-2-52 : 2009-12	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds CAN/CSA-C22.2 NO. 60601-2-52:2011
IEC 60601-2-52 : 2009-12	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds + Corrigendum 1 : 2010-09 + Amendment 1 : 2015-04 CAN/CSA-C22.2 NO. 60601-2-52A:2017

IEC 60601-2-54 : 2009-06	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy + Amendment 1 : 2015-04 CAN/CSA-C22.2 NO. 60601-2-54A:2017
IEC 60601-2-57 : 2011-01	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 CAN/CSA-C22.2 NO. 60601-2-57:2011
IEC 60601-2-63 : 2012-09	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment + Amendment 1 : 2017-07 CAN/CSA-C22.2 NO. 60601-2-63:2015
IEC 60601-2-65 : 2012-09	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment + Amendment 1 : 2017-05 CAN/CSA-C22.2 NO. 60601-2-65:2015
IEC 61010-2-040 : 2015-07	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (in conjunction with IEC 61010-1 : 2010-06⊗, as long as a valid accreditation therefor exists) ANSI/UL 61010-2-040:2016 CAN/CSA-C22.2 NO. 61010-2-040:16 IEC 61010-2-040 : 2005-04⊗ - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (in conjunction with IEC 61010-1 : 2001-02⊗, as long as a valid accreditation therefor exists)
IEC 61010-2-101 : 2015-01	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (in conjunction with IEC 61010-1 : 2010-06 as long as a valid accreditation therefor exists)

	ANSI/UL 61010-2-101:2015 CAN/CSA-C22.2 NO. 61010-2-101:15 IEC 61010-2-101 : 2002-01⊗ - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (in conjunction with IEC 61010-1 : 2001-02⊗, as long as a valid accreditation therefor exists)
IEC 61326-2-6 : 2012-07	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (in conjunction with IEC 61326-1 : 2012-07, as long as a valid accreditation therefor exists)
IEC 80601-2-30 : 2009-01	Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygnomanometers + Corrigendum 1 : 2010-01 + Amendment 1 : 2013-07 CAN/CSA-C22.2 NO. 80601-2-30-10
IEC 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 + Amendment 1 : 2016-04
IEC 80601-2-60 : 2012-02	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment CAN/CSA-C22.2 NO. 80601-2-60:2014
ISO 80601-2-12 : 2011-05	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-13 : 2011	Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation + Amendment 1 : 2015-03
ISO 80601-2-55 : 2011-12	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56 : 2017-03	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of

	clinical thermometers for body temperature measurement ISO 80601-2-13 : 2011-08⊗ - Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation CAN/CSA-C22.2 NO. 80601-2-56:12⊗
ISO 80601-2-61 : 2011-04	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment CAN/CSA-C22.2 NO. 80601-2-61:14
ISO 80601-2-70 : 2015-01	Medical Electrical Equipment -- Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
ISO 80601-2-72 : 2015-09	Medical electrical equipment -- Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
ISO 80601-2-74 : 2017-05	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

Abbreviations

ANSI/AAMI	American National Standards Institute/Association for the Advancement of Medical Instrumentation
CAN/CSA	Canadian Standards Association
DIN	Deutsches Institut für Normung
EN	Europäische Norm
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
Active medical devices	Medical electrical devices, medical electrical systems and components
⊗	Regulations, withdrawn by standardization.

[1] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
[2] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
[3] Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
[4] DIN EN ISO/IEC 17025 : 2005-08 General requirements for the competence of testing and calibration laboratories
[v] For transition periods see list of harmonised standards on the homepage of the EU