Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-20201-01-01 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: 18.07.2019

Date of issue: 19.07.2019

Holder of certificate:

Siemens Healthcare GmbH
Corporate Testing Laboratory

At the following locations:

Allee am Röthelheimpark 2, 91052 Erlangen
Guenther-Scharowsky-Straße 21, 91058 Erlangen

Tests in the fields:

Safety tests and compatibility tests with regard to electromagnetic disturbances (EMC) of active medical devices and IVD devices

Scope:

On-site assessment in the field safety tests

1) Safety tests

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Safety tests	Medical devices, active	Compliance tests Components and ME-Systems	DIN EN 60601-1 IEC 60601-1 DIN EN 60601-1-1⊗ IEC 60601-1-1⊗

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH. https://www.dakks.de/en/content/accredited-bodies-dakks

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
		Electrical tests and protection against electrical hazards	
Safety tests		Mechanical strength and protection against mechanical hazards Protection against hazards by unwanted/excessive radiation Protection against excessive temperatures incl. prevention of fire Environmental simulation tests	
	Information provided by the manufacturer - for components and assemblies - for biocompatibility - user manual / accompanying documents - usability file - on programmable electrical medical systems (PEMS) - risk management file - on radiation, ionizing / non-ionizing	Compliance tests	
Safety tests	Diagnostic X-ray equipment	Compliance tests - Leakage radiation - Filtering - Stray radiation	DIN EN 60601-1-3 IEC 60601-1-3
	Information provided by the manufacturer	Compliance tests	

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Safety tests	- user manual / accompanying documents - risk management file		
	Medical devices, active Information provided by the manufacturer - Usability file	Compliance Tests	DIN EN 60601-1-6 IEC 60601-1-6
	Patient positioning and transport - Operating tables	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-46 IEC 60601-2-46
	Imaging equipment with ionizing radiation	Compliance Tests for Basic Safety and Essential Performance	
	- Radiographic- and Radioscopic equipment		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 source assemblies and X-ray tube assemblies for medical diagnosis		DIN EN 60601-2-28 IEC 60601-2-28

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
	Imaging equipment with non-ionizing radiation		
	- Magnetic resonance equipment for medical diagnosis		DIN EN 60601-2-33 IEC 60601-2-33
Safety tests	Devices for Radiation- and Thermo-therapy Devices for extracorporeally induced lithotripsy	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-36 IEC 60601-2-36
	In-vitro Diagnostic-(IVD-) Medical Equipment	Compliance Tests for Basic Safety and Essential Performance	DIN EN 61010-2-101 IEC 61010-2-101

If exclusions of partial tests exist they are not listed in the scope of the accreditation. The test lab has to notify the client of those exclusions while clarifying an order.

The assessment for accreditation was performed taking into account the normative references of the European standards (DIN EN). The normative references of the international standards (IEC, ISO) have not been taken into account unless the referenced international versions of the standards are explicitly listed in the annex to the notice.

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2) EMC

Testing Area	Test Object Product(category)	Test type Test	Standard Test method
EMC	Medical devices, active	Compliance Tests - Emissions - Immunity	DIN EN 60601-1-2 IEC 60601-1-2
	Information provided by the manufacturer - Markings - Designations - user manual / accompanying documents	Compliance Tests	Further applicable: IEC TR 60601-4-2
	Equipment for extracorporeal circular flow, Infusions and haemopheresis - Infusion pumps and controllers - Pertonealdialysis equipment	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-24 IEC 60601-2-24 DIN EN 60601-2-39 IEC 60601-2-39
	Equipment for stimulation or inhibition - Defibrillators - External cardiac pacemakers with internal power source - Nerve and muscle stimulators	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-4 IEC 60601-2-4 DIN EN 60601-2-31 IEC 60601-2-31 DIN EN 60601-2-10 IEC 60601-2-10
	Surgical equipment and surgical auxiliary equipment - Endoscopic equipment - High frequency surgical equipment and accessories	Compliance Tests for Basic Safety and Essential Performance	IEC 60601-2-18 DIN EN 60601-2-2 IEC 60601-2-2

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Testing Area	Test Object Product(category)	Test type Test	Standard Test method
EMC	Patient positioning and transport	Compliance Tests for Basic Safety and Essential Performance	
	- Operating tables		DIN EN 60601-2-46 IEC 60601-2-46
	- Infant incubators		DIN EN 60601-2-19 IEC 60601-2-19
	- Infant transport incubators		DIN EN 60601-2-20 IEC 60601-2-20
	Imaging equipment with ionizing radiation	Compliance Tests for Basic Safety and Essential Performance	
	- Radiographic- and Radioscopic equipment		DIN EN 60601-2-54 IEC 60601-2-54
	- 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
	Imaging equipment with non-ionizing radiation		
	- Magnetic resonance equipment for medical diagnosis		DIN EN 60601-2-33 IEC 60601-2-33
	- Ultrasonic medical diagnostic and monitoring equipment		DIN EN 60601-2-37 IEC 60601-2-37
	Equipment for monitoring	Compliance Tests for Basic Safety and Essential Performance	
	- Multifunction patient monitoring equipment		DIN EN 60601-2-49 IEC 60601-2-49

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Testing Area	Test Object Product(category)	Test type Test	Standard Test method
EMC	Equipment for monitoring of non-vital physiological parameters	Compliance Tests for Basic Safety and Essential Performance	
	- Electroencephalographs		DIN EN 60601-2-26 IEC 60601-2-26
	- Transcutaneous partial pressure monitoring equipment		IEC 60601-2-23
	Equipment for monitoring of vital parameters		
	- Ambulatory electrocardiographic systems		DIN IEC 60601-2-47 IEC 60601-2-47
	- blood pressure monitoring equipment		IEC 60601-2-34
	- Electrocardiographs		IEC 60601-2-25 IEC 60601-2-27
	Devices for Radiation- and Thermo-therapy	Compliance Tests for Basic Safety and Essential Performance	
	Equipment with ionizing radiation		
	- Therapeutic X-ray equipment operating in the range of 10 kV to 1 MV		IEC 60601-2-8
	- Radiotherapy simulators		DIN EN 60601-2-29 IEC 60601-2-29
	Equipment with non-ionizing radiation		
	- Short wave therapy equipment		DIN EN 60601-2-3 IEC 60601-2-3
	- Microwave therapy equipment		IEC 60601-2-6
	- Infant radiant warmers		DIN EN 60601-2-21 IEC 60601-2-21

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Testing Area	Test Object Product(category)	Test type Test	Standard Test method
EMC	- Ultrasonic physiotherapy equipment Equipment for extracorporeally induced lithotripsy	Compliance Tests for Basic Safety and Essential Performance	DIN EN 60601-2-5 IEC 60601-2-5 DIN EN 60601-2-36 IEC 60601-2-36
	In-vitro Diagnostik-(IVD-) Medical equipment	Compliance Tests - Emissions - Immunity	DIN EN 61326-2-6 IEC 61326-2-6
	Information provided by the manufacturer - Markings - Designations - user manual / accompanying documents	Compliance Tests	

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Standards[2]

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 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 German version of 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 disturbances - 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 60601-1-2:2006-10⊗ - Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2001 + A1:2004); German version EN 60601-1-2:2001 + A1:2006-

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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 60601-1-6:2016-02	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 60601-1-6:2008-02⊗ - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability (IEC 60601-1-6:2006); German version EN 60601-1-6:2007 DIN EN 60601-1-6:2005-06⊗ - Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability (IEC 60601-1-6:2004); German version EN 60601-1-6:2004 VDE 0750-1-6:2005-06⊗
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 60601-2-3:1999-10	Medical electrical equipment - Part 2-3: Particular requirements for the safety of short-wave therapy equipment (IEC 60601-2-3:1991 + A1:1998); German version EN 60601-2-3:1993 + A1:1998
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

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DIN EN 60601-2-5:2016-08	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment (IEC 60601-2-5:2009); German version EN 60601-2-5:2015 VDE 0750-2-5:2016-08 DIN EN 60601-2-5:2001-12⊗ - Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment (IEC 60601-2-5:2000); German version EN 60601-2-5:2000 VDE 0750-2-5:2001-12
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 basic safety and essential performance 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 60601-2-19:2010-01	Medical electrical equipment - Part 2-19: Particular requirements for basic safety and essential performance of infant incubators (IEC 60601-2-19:2009); German version EN 60601-2-19:2009 VDE 0750-2-19:2010-01
DIN EN 60601-2-20:2010-06	Medical electrical equipment - Part 2-20: Particular requirements for basic safety and essential performance of infant transport incubators (IEC 60601-2-20:2009); German version EN 60601-2-20:2009 VDE 0750-2-20:2010-06

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DIN EN 60601-2-21:2010-01	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers (IEC 60601-2-21:2009); German version EN 60601-2-21:2009 VDE 0750-2-21:2010-01
DIN EN 60601-2-24:2016-04	Medical electrical equipment - Part 2-24: Particular requirements for basic safety and essential performance 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 60601-2-26:2016-02	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance 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 60601-2-28:2010-11	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 60601-2-28:1995-12⊗ - Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis (IEC 60601-2-28:1993); German version EN 60601-2-28:1993 VDE 0750-2-28:1995-12
DIN EN 60601-2-29:2009-06	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators (IEC 60601-2-29:2008); German version EN 60601-2-29:2008 VDE 0750-2-29:2009-06

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DIN EN 60601-2-31:2012-04	Medical electrical equipment - Part 2-31: Particular requirements for basic safety and essential performance of external cardiac pacemakers with internal power source (IEC 60601-2-31:2008 + A1:2011); German version EN 60601-2-31:2008 + A1:2011 VDE 0750-2-31:2012-04
DIN EN 60601-2-32:1995-11⊗	Medical electrical equipment - Part 2: 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 60601-2-33:2008-07⊗ - Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2002 + A1:2005 + A2:2007); German version EN 60601-2-33:2002 + A1:2005 + A2:2008 VDE 0750-2-33:2008-07
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 DIN EN 60601-2-36:1997-12⊗ - Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy (IEC 60601-2-36:1997); German version EN 60601-2-36:1997

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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 60601-2-39:2008-09	Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment (IEC 60601-2-39:2007); German version EN 60601-2-39:2008 VDE 0750-2-39:2008-09
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 60601-2-44:2017-03	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); German version EN 60601-2-44:2009 + A11:2011 + A1:2012

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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 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 DIN EN 60601-2-47:2002-11⊗ - Medical electrical equipment - Part 2-47: Particular requirements for the safety, including 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 60601-2-54:2016-07	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 VDE 0750-2-54:2010-05

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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 (in conjunction with valid accreditation acc. to DIN EN 61010-1)
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
IEC 60601-1:2005-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance + Amendment 1:2012-07 ANSI/AAMI ES 60601-1:2005 ANSI/AAMI ES 60601-1:2012 CAN/CSA-C22.2 No. 60601-1:08 CAN/CSA-C22.2 No. 60601-1:14 IEC 60601-1:1988⊗ - Medical electrical equipment; part 1: general requirements for safety + Amendment 1:1991-11;+ Amendment 2:1995-03; CSA-C22.2 No. 601.1-M90, UL 60601-1:2006
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 60601-1-2:2001-09⊗ - Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility; Requirements and tests + Amendment 1:2004-09

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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 IEC 60601-1-3:1994-07⊗ - Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010-01	Medical electrical equipment - General requirements for basic safety and essential performance - Collateral Standard: Usability + Amendment 1:2013-10
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
IEC 60601-2-3:1991-06⊗	Medical electrical equipment; part 2: particular requirements for the safety of short-wave therapy equipment + Amendment 1:1998-09⊗
IEC 60601-2-4:2010-12	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators
IEC 60601-2-5:2009-07	Medical electrical equipment - Part 2-5: Particular requirements for basic safety and essential performance of ultrasonic physiotherapy equipment IEC 60601-2-5:2000-07⊗ - Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
IEC 60601-2-6:2012-04	Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment
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 60601-2-8:2010-11	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

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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 IEC 60601-2-10:1987-12⊗ - Medical electrical equipment; part 2: particular requirements for the safety of nerve and muscle stimulators + Amendment 1:2001-09
IEC 60601-2-18:2009-08	Medical electrical equipment - Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment
IEC 60601-2-19:2009-02	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators + Amendment 1:2016-04
IEC 60601-2-20:2009-02	Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators + Amendment 1:2016-04
IEC 60601-2-21:2009-02	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers + Amendment 1:2016-04
IEC 60601-2-23:2011-02	Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
IEC 60601-2-24:2012-10	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers IEC 60601-2-24:1998-02⊗ - Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers
IEC 60601-2-25:2011-10	Medical electrical equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
IEC 60601-2-26:2012-05	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs IEC 60601-2-26:2002-11⊗ - Medical electrical equipment - Part 2-26: Particular requirements for the safety 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

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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 60601-2-28:2010-03⊗ - Medical electrical equipment - Part 2-28: Particular requirements for basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:1993-03⊗ - Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
IEC 60601-2-29:2008-06	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators
IEC 60601-2-31:2008-03	Medical electrical equipment - Part 2-31: Particular requirements for basic safety and essential performance of external cardiac pacemakers with internal power source + Amendment 1:2011-09
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
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 IEC 60601-2-36:1997-03⊗ - Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy
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
IEC 60601-2-39:2007-11	Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment

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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
IEC 60601-2-43:2010-03	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 IEC 60601-2-43:2000-06⊗ - Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures
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 + Amendment 1:2012-08 + Amendment 2:2016-03 IEC 60601-2-44:2002-11⊗ - Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography
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 IEC 60601-2-45:2001-05⊗ - Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices
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
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 IEC 60601-2-47:2001-07⊗ - Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
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

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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
IEC TR 60601-4-2:2016-05	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
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)
	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

Abbreviations used:

ANSI/AAMI	American National Standards Institute/Association for the Advancement of Medical Instrumentation
ANSI/ISA	American National Standards Institute/International Society of Automation
CAN/CSA	Canadian Standards Association
CENELEC	European Committee for Electrotechnical Standardization
DIN	German Institute for Standardization (Deutsches Institut für Normung)
EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
Medical devices, active	Medical electrical equipment, medical electrical systems and components
UL	Underwriters Laboratories
⊗	Withdrawn standards

[1] DIN EN ISO/IEC 17025:2005-08 General requirements for the competence of testing and calibration laboratories

[2] For transition periods, see list of harmonised standards on the EU website.

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