Deutsche Akkreditierungsstelle

Annex to the Partial Accreditation Certificate D-PL-15110-01-01 according DIN EN ISO/IEC 17025:2018

Valid from: **03.05.2024**

Date of issue: 09.05.2025

This annex is a part of the accreditation certificate D-PL-15110-01-00.

Holder of partial accreditation certificate:

SLG Prüf- und Zertifizierungs GmbH
Burgstädter Straße 20, 09232 Hartmannsdorf

with the location

SLG Prüf- und Zertifizierungs GmbH
Burgstädter Straße 20, 09232 Hartmannsdorf

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

Safety testing of active medical devices and electromagnetic compatibility (EMC) testing of active medical devices and IVD devices

outside of approval under Section 18 of the Medical Devices Implementation Act.

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at https://www.dakks.de.

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

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
Safety checks	Medical devices, active	Check for compliance Components and ME systems electrical testing and protection against electrical hazards mechanical strength and protection against mechanical hazards Protection against hazards caused by unwanted/excessive radiation Protection against excessive temperatures including fire prevention Environmental simulation tests	DIN EN 60601-1 IEC 60601-1 DIN EN 60601-1-1⊗ IEC 60601-1-1⊗
	information provided by the manufacturer - to components and assemblies - on biocom-patibility - Instructions for use/accompanying documents - Usability file	Check for compliance	
Safety checks	- to programmable electrical medical systems (PEMS) - Risk management files		DIN EN 60601-1-4⊗ IEC 60601-1-4⊗

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	- to radiation, ionizing / non-ionizing		
	Diagnostic X-ray equipment	Check for compliance - Transmitting radiation (only in the charged state) - Filtering - Interference radiation	DIN EN 60601-1-3 IEC 60601-1-3
	information provided by the manufacturer - Instructions for use/accompanying documents - Risk management files	Check for compliance	
	Medical devices, active	Check for compliance - visual alarms - audible alarms	DIN EN 60601-1-8 IEC 60601-1-8
	information provided by the manufacturer - Instructions for use / Accompanying documents / Technical description - Risk management files		
Safety checks	Information provided by the manufacturer on physiological, closed-loop control	Check for compliance	DIN EN 60601-1-10 IEC 60601-1-10

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Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	- Instructions for use/accompanying documents - Usability file - Risk management files - to programmable electrical medical systems (PEMS)		
	Active medical devices for use in the home	Check for compliance Mechanical strength and protection against mechanical hazards Environmental simulation tests	DIN EN 60601-1-11 IEC 60601-1-11
	information provided by the manufacturer - Instructions for use/accompanying documents - Usability file - Risk management files		
Safety checks	Medical devices, active, for use in the emergency environment	Check for compliance Environmental simulation tests	DIN EN 60601-1-12 IEC 60601-1-12
	information provided by the manufacturer - Instructions for use/accompanying documents	Check for compliance	

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	- Usability file - Risk management files		
	- Devices for extracorporeal circuits, infusions and hemopheresis	Checking compliance with general and specific requirements	
	- Infusion pumps and control devices		DIN EN 60601-2-24 IEC 60601-2-24
	- Ventilation, oxygen therapy (including hyperbaric therapy chambers) and inhalation anesthesia devices	Checking compliance with general and specific requirements	
	- Ventilators		DIN EN 80601-2-12 ISO 80601-2-12
	- Oxygen concentrators		DIN EN ISO 80601-2-69
Safety checks	- Devices for stimulation or inhibition	Checking compliance with general and specific requirements	
	- Defibrillators	- without testing ECG signal via defibrillator electrodes and separate monitoring electrodes	DIN EN 60601-2-4 IEC 60601-2-4
	- Devices for stimulating nerves and muscles		DIN EN 60601-2-10 IEC 60601-2-10

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	Surgical devices and surgical aids	Checking compliance with general and specific requirements	
	- Endoscopy devices		DIN EN 60601-2-18 IEC 60601-2-18
	- HF surgical devices and accessories		DIN EN 60601-2-2 IEC 60601-2-2
	- Operating lights and examination lights		DIN EN 60601-2-41⊗ IEC 60601-2-41⊗
	Ophthalmic devices	Checking compliance with general and specific requirements	DIN EN ISO 15004-1 DIN EN ISO 15004-2
	- Endoilluminatore		DIN EN ISO 15752
	- Dental equipment	Checking compliance with general and specific requirements	DIN EN IEC 80601-2-60
Safety checks	- Patient positioning and transport facilities	Checking compliance with general and specific requirements	-
	- Blankets, mats and mattresses		DIN EN 80601-2-3 IEC 80601-2-35 DIN EN 60601-2-35⊗ IEC 60601-2-35⊗
	- electrically operated hospital beds		DIN EN 60601-2-38⊗ IEC 60601-2-38⊗
	- medical beds		DIN EN 60601-2-52 IEC 60601-2-52
	- Operating tables		DIN EN 60601-2-46 IEC 60601-2-46

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	- Infant incubators - Transport incubators		DIN EN 60601-2-19 IEC 60601-2-19 DIN EN 60601-2-20 IEC 60601-2-20
	Devices for imaging procedures using ionizing radiation - Radiography and radioscopy equipment - X-ray equipment for interventional procedures	Checking compliance with general and specific requirements	DIN EN 60601-2-54 IEC 60601-2-54 DIN EN 60601-2-7⊗ IEC 60601-2-7⊗ DIN EN 60601-2-43 IEC 60601-2-43
Safety checks	Non-ionizing radiation imaging devices - Ultrasound devices for diagnosis and monitoring	Checking compliance with general and specific requirements	DIN EN 60601-2-37 IEC 60601-2-37
	Monitoring devices - multifunctional patient monitoring devices	Checking compliance with general and specific requirements	DIN EN IEC 80601-2-49 DIN EN 60601-2-49⊗ IEC 60601-2-49⊗
	- Devices for monitoring non-vital physiological parameters - Electroencephalographs	Checking compliance with general and specific requirements	DIN EN IEC 80601-2-26 DIN EN 60601-2-26⊗ IEC 60601-2-26⊗

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	- Electromyographs and evoked potential devices		DIN EN 60601-2-40 IEC 60601-2-40
	- Devices for monitoring vital parameters	Checking compliance with general and specific requirements	
	- ambulatory electrocardiographic systems		DIN EN 60601-2-47 IEC 60601-2-47
Safety checks	- recording and interpreting single-channel and multi-channel electrocardiographs	Checking compliance with general and specific requirements	DIN EN 60601-2-51⊗ IEC 60601-2-51⊗
	- automatic, cyclic, non-invasive blood pressure monitoring devices		DIN EN IEC 80601-2-30
	- Blood pressure monitoring devices		DIN EN 60601-2-34 IEC 60601-2-34
	- Electrocardiographs		DIN EN 60601-2-25 IEC 60601-2-25
	- ECG monitoring		DIN EN 60601-2-27 IEC 60601-2-27
	- non-invasive blood pressure monitors	- without testing for measurement accuracy	DIN EN ISO 81060-1 DIN EN 1060-1⊗ DIN EN 1060-3⊗
	- Pulse oximetry devices		DIN EN ISO 80601-2-61
	- Medical thermometers		DIN EN ISO 80601-2-56

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	Devices for radiation and thermotherapy	Checking compliance with general and specific requirements	
	- Devices with ionizing radiation		
	- X-ray equipment from 10 kV to 1 MV		DIN EN 60601-2-8 IEC 60601-2-8
	- Devices with non-ionizing radiation		
	- medical lasers		DIN EN 60601-2-22 IEC 60601-2-22
Safety checks	Devices with non-ionizing radiation	Checking compliance with general and specific requirements	
	- Devices with non-laser light sources for use in therapy, diagnosis, monitoring and cosmetic/aesthetic purposes		DIN EN 60601-2-57 IEC 60601-2-57
	- Home light therapy devices		DIN EN IEC 60601-2-83
	- Devices for photodynamic therapy and photodynamic diagnostic devices		IEC 60601-2-75
	- Microwave therapy devices		DIN EN 60601-2-6 IEC 60601-2-6
	- Infant phototherapy devices		DIN EN 60601-2-50 IEC 60601-2-50
	- Infant warmer		DIN EN 60601-2-21 IEC 60601-2-21

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	- Ultrasound physiotherapy devices - Devices for extracorporeally induced lithotripsy		DIN EN 60601-2-5 IEC 60601-2-5 DIN EN 60601-2-36 IEC 60601-2-36

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
EMC	- Medical devices, active	Testing to demonstrate compliance - Emitted interference - Interference immunity up to 5.785 GHz	DIN EN 60601-1-2 IEC 60601-1-2
	- Information provided by the manufacturer - inscriptions - Designations - Instructions for use/accompanying documents	Check for compliance	
	- Ventilation, oxygen therapy (including hyperbaric therapy chambers) and inhalation anesthesia devices - Ventilators	Checking compliance with general and specific requirements	DIN EN ISO 80601-2-12
	- Devices for stimulation or inhibition - Defibrillators - Devices for stimulating nerves and muscles	Checking compliance with general and specific requirements	DIN EN 60601-2-4 IEC 60601-2-4 DIN EN 60601-2-10 IEC 60601-2-10

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
EMC	Surgical devices and surgical aids	Checking compliance with general and specific requirements	
	- Endoscopy devices		DIN EN 60601-2-18 IEC 60601-2-18
	- HF surgical devices and accessories		DIN EN 60601-2-2 IEC 60601-2-2
	Ophthalmic devices	Checking compliance with general and specific requirements	
	- Devices for lens and vitreous removal		DIN EN 80601-2-58 IEC 80601-2-58
	- Endoilluminators		DIN EN ISO 15752
	Active rehabilitation aids and prostheses	Testing to demonstrate compliance	
	- Wheelchairs		ISO 7176-21
	- Patient positioning and transport facilities	Checking compliance with general and specific requirements	
	- Blankets, mats and mattresses		DIN EN 80601-2-35 IEC 80601-2-35⊗ DIN EN 60601-2-35⊗ IEC 60601-2-35⊗
	- electrically operated hospital beds		DIN EN 60601-2-38⊗ IEC 60601-2-38⊗
	- Operating tables		DIN EN 60601-2-46 IEC 60601-2-46
EMC	- Infant incubators		DIN EN 60601-2-19⊗ IEC 60601-2-19⊗
	- Transport incubators		DIN EN 60601-2-20 IEC 60601-2-20

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	Devices for imaging procedures using ionizing radiation - Radiography and radioscopy equipment	Checking compliance with general and specific requirements	DIN EN 60601-2-54 IEC 60601-2-54
	Non-ionizing radiation imaging devices - Ultrasound devices for diagnosis and monitoring	Checking compliance with general and specific requirements	DIN EN 60601-2-37 IEC 60601-2-37
	Monitoring devices - multifunctional patient monitoring devices	Checking compliance with general and specific requirements	DIN EN IEC 80601-2-49 DIN EN 60601-2-49⊗ IEC 60601-2-49⊗
	- Devices for monitoring non-vital physiological parameters		
	- Electroencephalographs		DIN EN IEC 80601-2-26 DIN EN 60601-2-26⊗ IEC 60601-2-26⊗
EMC	- Electromyographs and evoked potential devices		DIN EN 60601-2-40 IEC 60601-2-40
	- Devices for monitoring vital parameters	Checking compliance with general and specific requirements	
	- ambulatory electrocardiographic systems		DIN EN 60601-2-47 IEC 60601-2-47

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	- recording and interpreting single-channel and multi-channel electrocardiographs		DIN EN 60601-2-51⊗ IEC 60601-2-51⊗
	- automatic, cyclic, non-invasive blood pressure monitoring devices		DIN EN IEC 80601-2-30
	- Blood pressure monitoring devices		DIN EN 60601-2-34 IEC 60601-2-34
	- Electrocardiographs		DIN EN 60601-2-25 IEC 60601-2-25
	- ECG monitoring		DIN EN 60601-2-27 IEC 60601-2-27
	- Pulse oximetry devices		DIN EN ISO 80601-2-61
	- Medical thermometers		DIN EN ISO 80601-2-56
EMC	Devices for radiation and thermotherapy - Devices with non-ionizing radiation	Checking compliance with general and specific requirements	
	- Microwave therapy devices		DIN EN 60601-2-6 IEC 60601-2-6
	- Shortwave therapy devices		DIN EN 60601-2-3 IEC 60601-2-3
	- Infant phototherapy devices		DIN EN 60601-2-50⊗ IEC 60601-2-50⊗
	- Infant warmer		DIN EN 60601-2-21 IEC 60601-2-21

Test area	Test object Product (category)	Examination type Examination	Rules and regulations Test procedures
	- Ultrasound physiotherapy devices - Devices for extracorporeally induced lithotripsy		DIN EN 60601-2-5 IEC 60601-2-5 DIN EN 60601-2-36 IEC 60601-2-36
	- In vitro diagnostic (IVD) medical devices	Testing to demonstrate compliance - Emitted interference - Interference immunity	DIN EN 61326-2-6 IEC 61326-2-6
	Information provided by the manufacturer - inscriptions - Designations - Instructions for use/accompanying documents	Check for compliance	

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Test area	Test object Product (category)	Examination Type Examination	Rules and regulation Test procedures
EMC	Medical devices, active	Testing to demonstrate compliance - Emitted interference - Interference immunity up to 5.785 GHz	DIN EN 60601-1-2 IEC 60601-1-2
	Information provided by the manufacturer - inscriptions - Designations - Instructions for use/accompanying documents	Check for compliance	
	- Ventilation, oxygen therapy (including hyperbaric therapy chambers) and inhalation anesthesia devices - Ventilators	Checking compliance with general and specific requirements	DIN EN ISO 80601-2-12
	- Devices for stimulation or inhibition - Defibrillators - Devices for stimulating nerves and muscles	Checking compliance with general and specific requirements	DIN EN 60601-2-4 IEC 60601-2-4 DIN EN 60601-2-10 IEC 60601-2-10
EMC	Surgical devices and surgical aids - Endoscopy devices	Checking compliance with general and specific requirements	DIN EN 60601-2-18 IEC 60601-2-18

Test area	Test object Product (category)	Examination Type Examination	Rules and regulation Test procedures
EMC	- HF surgical devices and accessories		DIN EN 60601-2-2 IEC 60601-2-2
	Ophthalmic devices - Devices for lens and vitreous removal - Endoilluminators	Checking compliance with general and specific requirements	 DIN EN 80601-2-58 IEC 80601-2-58 DIN EN ISO 15752
	Active rehabilitation aids and prostheses - Wheelchairs	Testing to demonstrate compliance	 ISO 7176-21
	- Patient positioning and transport facilities - Blankets, mats and mattresses - electrically operated hospital beds - Operating tables - incubators - Transport incubators	Checking compliance with general and specific requirements	 DIN EN 80601-2-35 IEC 80601-2-35 DIN EN 60601-2-35⊗ IEC 60601-2-35⊗ DIN EN 60601-2-38⊗ IEC 60601-2-38⊗ DIN EN 60601-2-46 IEC 60601-2-46 DIN EN 60601-2-19 IEC 60601-2-19 DIN EN 60601-2-20 IEC 60601-2-20
	Devices for imaging procedures using ionizing radiation - Radiography and radioscopy equipment	Checking compliance with general and specific requirements	 DIN EN 60601-2-54 IEC 60601-2-54

Test area	Test object Product (category)	Examination Type Examination	Rules and regulation Test procedures
	Non-ionizing radiation imaging devices	Checking compliance with general and specific requirements	
	- Ultrasound devices for diagnosis and monitoring		DIN EN 60601-2-37 IEC 60601-2-37
	Monitoring devices	Checking compliance with general and specific requirements	
	- multifunctional patient monitoring devices		DIN EN IEC 80601-2-49 DIN EN 60601-2-49⊗ IEC 60601-2-49⊗
	- Devices for monitoring non-vital physiological parameters		
	- Electroencephalographs		DIN EN IEC 80601-2-26 DIN EN 60601-2-26⊗ IEC 60601-2-26⊗
	- Electromyographs and evoked potential devices		DIN EN 60601-2-40 IEC 60601-2-40
EMC	- Devices for monitoring vital parameters	Checking compliance with general and specific requirements	
	- ambulatory electrocardiographic systems		DIN EN 60601-2-47 IEC 60601-2-47
	- recording and interpreting single-channel and multi-channel electrocardiographs		DIN EN 60601-2-51⊗ IEC 60601-2-51⊗

Test area	Test object Product (category)	Examination Type Examination	Rules and regulation Test procedures
EMC	- automatic, cyclic, non-invasive blood pressure monitoring devices		DIN EN IEC 80601-2-30
	- Blood pressure monitoring devices		DIN EN 60601-2-34 IEC 60601-2-34
	- Electrocardiographs		DIN EN 60601-2-25 IEC 60601-2-25
	- ECG monitoring		DIN EN 60601-2-27 IEC 60601-2-27
	- Pulse oximetry devices		DIN EN ISO 80601-2-61
	- Medical thermometers		DIN EN ISO 80601-2-56
	Devices for radiation and thermotherapy - Devices with non-ionizing radiation	Checking compliance with general and specific requirements	
	- Microwave therapy devices		DIN EN 60601-2-6 IEC 60601-2-6
	- Shortwave therapy devices		DIN EN 60601-2-3 IEC 60601-2-3
	- Infant phototherapy devices		DIN EN 60601-2-50 IEC 60601-2-50
	- Infant warmer		DIN EN 60601-2-21 IEC 60601-2-21
	- Ultrasound physiotherapy devices		DIN EN 60601-2-5 IEC 60601-2-5
	- Devices for extracorporeally induced lithotripsy		DIN EN 60601-2-36 IEC 60601-2-36

Test area	Test object Product (category)	Examination Type Examination	Rules and regulation Test procedures
	- In vitro diagnostic (IVD) medical devices	Testing to demonstrate compliance - Emitted interference - Interference immunity	DIN EN 61326-2-6 IEC 61326-2-6
	Information provided by the manufacturer - inscriptions - Designations - Instructions for use/accompanying documents	Check for compliance	

Any existing exclusions from partial tests are not listed in the scope of the accreditation and must be communicated to the client by the laboratory during the contract review.

The accreditation assessment was conducted taking into account the normative references of the European standards (DIN EN). The normative references of the international standards (IEC, ISO) were not considered unless the referenced international editions of the standards are explicitly stated in the appendix to the certificate.

List of sources for regulations/test procedures:

DIN EN 1060-1 : 2010-03⊗	Non-invasive blood pressure measuring devices - Part 1: General requirements; German version EN 1060-1: 1995+A2: 2009
DIN EN 1060-3 : 2010-03⊗	Non-invasive blood pressure measuring devices - Part 3: Supplementary requirements for electromechanical blood pressure measuring systems; German version EN 1060-3: 1997 + A2:2009
DIN EN ISO 15004-1 : 2021-05	Ophthalmic instruments - Basic requirements and test methods - Part 1: General requirements for ophthalmic instruments (ISO 15004-1:2020); German version EN ISO 15004-1:2020 DIN EN ISO 15004-1:2009-07⊗ - Ophthalmic instruments - Basic requirements and test methods - Part 1: General requirements for ophthalmic instruments (ISO 15004-1:2006); German version EN ISO 15004-1:2009
DIN EN ISO 15004-2 : 2007-06	Ophthalmic instruments - Basic requirements and test methods - Part 2: Protection against hazards due to light (ISO 15004-2:2007); German version EN ISO 15004-2:2007 DIN EN ISO 15004 : 1998-04⊗ - Ophthalmic instruments - Basic requirements and test methods (ISO 15004:1997); German version EN ISO 15004:1997
DIN EN ISO 15752 : 2010-05	Ophthalmic instruments - Endoluminators - Basic requirements and test methods related to optical radiation safety (ISO 15752:2010); German version EN ISO 15752:2010

DIN EN 60601-1 : 2022-11	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014 + A2:2020); German version EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021
	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
	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
	+ Corrigendum 1:2008-08
	+ Corrigendum 2:2010-05
DIN EN 60601-1-1 : 2002-08⊗	Medical electrical equipment - Part 1-1: General requirements for safety; Collateral standard: Requirements for the safety of medical electrical systems (IEC 60601-1-1:2000); German version EN 60601-1-1:2001
DIN EN 60601-1-2 : 2022-01	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 + A1:2020); German version EN 60601-1-2:2015 + A1:2021
	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

DIN EN 60601-1-3 : 2021-10	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection of diagnostic X-ray equipment (IEC 60601-1-3:2008 + A1:2013 + A2:2021); German version EN 60601-1-3:2008 + Cor.:2010 + A1:2013 + A1:2013/AC:2014 + A11:2016 + A2:2021 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 of diagnostic X-ray equipment (IEC 60601-1-3:2008 + A1:2013); German version EN 60601-1-3:2008 + Cor.:2010 + A1:2013
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
DIN EN 60601-1-8 : 2021-12	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: Alarm systems - General requirements, tests, and guidelines for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006 + A1:2012 + A2:2020); German version EN 60601-1-8:2007 + Cor.:2010 + A1:2013 + A1:2013/AC:2014 + A11:2017 + A2:2021 DIN EN 60601-1-8 : 2014-04⊗ - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: Alarm systems - General requirements, tests, and guidelines 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 DIN EN 60601-1-8 : 2008-02⊗ - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: Alarm systems - General requirements, tests, and guidelines for alarm systems in medical electrical equipment and medical systems (IEC 60601-1-8:2006); German version EN 60601-1-8:2007 + CENELEC-Cor.:2010 to EN 60601-1-8:2007 + Cor.1 : 2010-05

DIN EN 60601-1-10 : 2021-11	04 Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral standard: Requirements for the design of physiological closed-loop control systems (IEC 60601-1-10:2007 + A1:2013 + A2:2020); German version EN 60601-1-10:2008 + A1:2015 + A2:2021
	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 design of physiological closed-loop control systems (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 design of physiological closed-loop control systems (IEC 60601-1-10:2007); German version EN 60601-1-10:2008
DIN EN 60601-1-11 : 2021-12	Medical electrical equipment - Part 1-11: Particular requirements for essential 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 + A1:2020); German version EN 60601-1-11:2015 + A1:2021
	DIN EN 60601-1-11 : 2016-04⊗ - Medical electrical equipment - Part 1-11: Particular 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 60601-1-12 : 2022-02	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 in the emergency response environment (IEC 60601-1-12:2014 + A1:2020); German version EN 60601-1-12:2015 + A1:2020
	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 in the emergency response environment (IEC 60601-1-12:2014); German version EN 60601-1-12:2015

DIN EN IEC 60601-2-2 : 2018-12	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high-frequency surgical equipment (IEC 60601-2-2:2017); German version EN IEC 60601-2-2:2018
	DIN EN 60601-2-2: 2010-01- Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high-frequency surgical equipment and accessories (IEC 60601-2-2:2009); German version EN 60601-2-2:2009
DIN EN 60601-2-3 : 2017-10	Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of shortwave therapy equipment (IEC 60601-2-3:2012 + A1:2016); German version EN 60601-2-3:2015 + A1:2016
	DIN EN 60601-2-3 : 2016-02⊗ - Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of shortwave therapy equipment (IEC 60601-2-3:2012); German version EN 60601-2-3:2015
DIN EN 60601-2-4 : 2021-09	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of defibrillators (IEC 60601-2-4:2010 + A1:2018); German version EN 60601-2-4:2011 + A1:2019
	DIN EN 60601-2-4 : 2012-05⊗ Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of defibrillators (IEC 60601-2-4:2010); German version EN 60601-2-4:2011
	DIN EN 60601-2-4 : 2003-07⊗ - Medical devices - Part 2-4: Particular requirements for the safety of defibrillators (IEC 60601-2-4:2002); German version EN 60601-2-4:2003
DIN EN 60601-2-5 : 2016-08	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasound physiotherapy equipment (IEC 60601-2-5:2009); German version EN 60601-2-5:2015
	DIN EN 60601-2-5 : 2001-12⊗ - Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasound physiotherapy equipment (IEC 60601-2-5:2000); German version EN 60601-2-5:2000

DIN EN 60601-2-6 : 2017-10	Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment (IEC 60601-2-6:2012 + A1:2016); German version EN 60601-2-6:2015 + A1:2016 DIN EN 60601-2-6 : 2016-03⊗ - Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment (IEC 60601-2-6:2012); German version EN 60601-2-6:2015
DIN EN 60601-2-7 : 2000-03⊗	Medical electrical equipment - Part 2-7: Particular requirements for the safety of X-ray generators of diagnostic X-ray generators (IEC 60601-2-7:1998); German version EN 60601-2-7:1998
DIN EN 60601-2-8 : 2016-08	Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment in the range 10 kV to 1 MV (IEC 60601-2-8:2010 + A1:2015); German version EN 60601-2-8:2015 + A1:2016
DIN EN 60601-2-10 : 2017-09	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulation devices (IEC 60601-2-10:2012 + A1:2016); German version EN 60601-2-10:2015 + A1:2016 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 stimulation devices (IEC 60601-2-10:2012); German version EN 60601-2-10:2015
DIN EN 60601-2-18 : 2016-10	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (IEC 60601-2-18:2009); German version EN 60601-2-18:2015 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

DIN EN 60601-2-19 : 2022-08	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC 60601-2-19:2020); German version EN IEC 60601-2-19:2021
	DIN EN 60601-2-19 : 2017-09⊗ - Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC 60601-2-19:2009 + Cor.:2012 + A1:2016); German version EN 60601-2-19:2009 + A11:2011 + A1:2016
	DIN EN 60601-2-19 : 2010-01⊗ - Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC 60601-2-19:2009); German version EN 60601-2-19:2009
DIN EN IEC 60601-2-20 : 2021-08	Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators (IEC 60601-2-20:2020); German version EN IEC 60601-2-20:2020
	DIN EN 60601-2-20 : 2017-09⊗ Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of transport incubators (IEC 60601-2-20:2009 + Cor.:2012 + Cor.:2013 + A1:2016); German version EN 60601-2-20:2009 + A11:2011 + A1:2016
	DIN EN 60601-2-20 : 2010-06⊗ - Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of transport incubators (IEC 60601-2-20:2009); German version EN 60601-2-20:2009
DIN EN 60601-2-21 : 2017-09	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers (IEC 60601-2-21:2009 + Cor.:2013 + A1:2016); German version EN 60601-2-21:2009 + A11:2011 + A1:2016
	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

DIN EN 60601-2-22 : 2022-10	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment (IEC 60601-2-22:2019); German version EN IEC 60601-2-22:2020
	DIN EN 60601-2-22 : 2015-08⊗ - Medical electrical equipment - Part 2-22: 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
	DIN EN 60601-2-22 : 1996-12⊗ - Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment (IEC 60601-2-22:1995; German version EN 60601-2-22:1996
DIN EN 60601-2-24 : 2016-04	Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and infusion controllers (IEC 60601-2-24:2012); German version EN 60601-2-24:2015
DIN EN 60601-2-25 : 2016-08	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs (IEC 60601-2-25:2011); German version EN 60601-2-25:2015
	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
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
DIN EN 60601-2-27 : 2015-04	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (IEC 60601-2-27:2011 + Cor.:2012); German version EN 60601-2-27:2014

DIN EN 60601-2-34 : 2015-01	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and 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 basic safety and essential performance of invasive blood pressure monitoring equipment (IEC 60601-2-34:2000); German version EN 60601-2-34:2000
DIN EN IEC 60601-2-35 : 2022-10	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of patient warming blankets, mats, and mattresses for medical use (IEC 60601-2-35:2020); German version EN IEC 60601-2-35:2021 DIN EN 60601-2-35 : 1997-12⊗ - Medical electrical equipment - Part 2: Particular requirements for the safety of mats, supports, and mattresses for patient warming in medical applications (IEC 60601-2-35:1996); German version EN 60601-2-35:1996
DIN EN 60601-2-36 : 2015-11	Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of extracorporeally induced lithotripsy equipment (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 extracorporeally induced lithotripsy equipment (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 ultrasound equipment for medical diagnosis and monitoring (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 ultrasound equipment for medical diagnosis and monitoring (IEC 60601-2-37:2007); German version EN 60601-2-37:2008 + A11:2011

DIN EN 60601-2-38 : 2001-07⊗	Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds (IEC 60601-2-38:1996 + A1:1999); German version EN 60601-2-38:1996 + A1:2000
DIN EN 60601-2-40 : 2019-04	Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked potential devices (IEC 60601-2-40:2016); German version EN 60601-2-40:2019
	DIN EN 60601-2-40 : 1998-12⊗ - Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked potential devices (IEC 60601-2-40:1998); German version EN 60601-2-40:1998
DIN EN 60601-2-41 : 2016-02	Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of operating room and examination lights (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 the basic safety and essential performance of operating room and examination lights (IEC 60601-2-41:2009); German version EN 60601-2-41:2009
DIN EN 60601-2-43 : 2020-12	Medical electrical equipment - Part 2-43: Particular requirements for the essential safety and essential performance of X-ray equipment used in interventional procedures (IEC 60601-2-43:2010 + A1:2017 + A2:2019); German version EN 60601-2-43:2010 + AC:2014 + A1:2018 + A2:2020
	DIN EN 60601-2-43 : 2019-04⊗ - Medical electrical equipment - Part 2-43: Particular requirements for the essential safety and essential performance of X-ray equipment used in interventional procedures (IEC 60601-2-43:2010 + A1:2017); German version EN 60601-2-43:2010 + A1:2018
	DIN EN 60601-2-43 : 2011-03⊗ - Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment used in interventional procedures (IEC 60601-2-43:2010); German version EN 60601-2-43:2010

DIN EN IEC 60601-2-46 : 2020-04	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables (IEC 60601-2-46:2016); German version EN IEC 60601-2-46:2019
	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
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 basic safety and essential performance of ambulatory electrocardiographic systems (IEC 60601-2-47:2001); German version EN 60601-2-47:2001
DIN EN 60601-2-49 : 2016-10⊗	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment (IEC 60601-2-49:2011); German version EN 60601-2-49:2015
DIN EN 60601-2-50 : 2022-08	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment (IEC 60601-2-50:2020); German version EN IEC 60601-2-50:2021
	DIN EN 60601-2-50 : 2017-09⊗ - Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment (IEC 60601-2-50:2009 + Cor. 1:2010 + A1:2016); German version EN 60601-2-50:2009 + A11:2011 + A1:2016
	DIN EN 60601-2-50 : 2010-02⊗ - Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment (IEC 60601-2-50:2009); German version EN 60601-2-50:2009
DIN EN 60601-2-51 : 2004-02⊗	Medical electrical equipment - Part 2-51: Particular requirements for the safety and essential performance of single-channel and multi-channel recording and interpreting electrocardiographs (IEC 60601-2-51:2003); German version EN 60601-2-51:2003

DIN EN 60601-2-52 : 2016-04	Medical electrical equipment - Part 2-52: Particular requirements for the 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 the basic safety and essential performance of medical beds (IEC 60601-2-52:2009); German version EN 60601-2-52:2010
DIN EN 60601-2-54 : 2020-03	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 + A2:2018); German version EN 60601-2-54:2009 + A1:2015 + A2:2019 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 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
DIN EN 60601-2-57 : 2011-11	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of equipment containing non-laser light sources for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use (IEC 60601-2-57:2011); German version EN 60601-2-57:2011
DIN EN IEC 60601-2-83 : 2021-05	Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy devices (IEC 60601-2-83:2019); German version EN IEC 60601-2-83:2020
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 medical devices (IVD) (IEC 61326-2-6:2012); German version EN 61326-2-6:2013 (in conjunction with DIN EN 61326-1: 2013-07, as long as a valid accreditation exists)

DIN EN ISO 80601-2-12 : 2020-07	Medical electrical equipment - Part 2-12: Particular requirements for the basic safety and essential performance of ventilators for intensive care use (ISO 80601-2-12:2020); German version EN ISO 80601-2-12:2020 DIN EN ISO 80601-2-12 : 2012-02⊗ - Medical electrical equipment - Part 2-12: Particular requirements for the basic safety and essential performance of ventilators for intensive care use (ISO/IEC 80601-2-12:2011 + Cor. :2011); German version EN ISO 80601-2-12:2011 + AC:2011⊗
DIN EN IEC 80601-2-26 : 2022-04	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs (IEC 80601-2-26:2019); German version EN IEC 80601-2-26:2020
DIN EN IEC 80601-2-30 : 2020-03	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive blood pressure measuring devices (IEC 80601-2-30:2018); German version EN IEC 80601-2-30:2019 DIN EN 80601-2-30 : 2016-02⊗ - Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive blood pressure measuring devices (IEC 80601-2-30:2009 + Corrigendum Jan. 2010 + A1:2013); German version EN 80601-2-30:2010 + A1:2015
DIN EN 80601-2-35 : 2017-11	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of blankets, mats, and mattresses for patient warming in medical applications (IEC 80601-2-35:2009 + Cor.:2012 + Cor.:2015 + A1:2016); German version EN 80601-2-35:2009 + A11:2011 + AC:2015 + A1:2016 DIN EN 80601-2-35 : 2010-08⊗ - Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of blankets, mats, and mattresses for patient warming in medical applications (IEC 80601-2-35:2009); German version EN 80601-2-35:2009
DIN EN IEC 80601-2-49 : 2020-10	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment (IEC 80601-2-49:2018); German version EN IEC 80601-2-49:2019

DIN EN ISO 80601-2-56 : 2020-08	Medical electrical equipment - Part 2-56: Particular requirements for the basic safety and essential performance of medical thermometers for measuring body temperature (ISO 80601-2-56:2017 + A1:2018); German version EN ISO 80601-2-56:2017 + A1:2020
	DIN EN ISO 80601-2-56 : 2018-02⊗ - Medical electrical equipment - Part 2-56: Particular requirements for the basic safety and essential performance of medical thermometers for measuring body temperature (ISO 80601-2-56:2017); German version EN ISO 80601-2-56:2017
	DIN EN ISO 80601-2-56 : 2013-02⊗ - Medical electrical equipment - Part 2-56: Particular requirements for the basic safety and essential performance of medical thermometers for measuring body temperature (ISO 80601-2-56:2009); German version EN ISO 80601-2-56:2012
DIN EN 80601-2-58 : 2020-06	Medical electrical equipment - Part 2-58: Particular requirements for basic safety and essential performance of lens removal and vitrectomy equipment used in ophthalmic surgery (IEC 80601-2-58:2014 + A1:2016); German version EN 80601-2-58:2015 + A1:2019
	DIN EN 80601-2-58 : 2015-11⊗ - Medical electrical equipment - Part 2-58: Particular requirements for basic safety and essential performance of lens removal and vitrectomy equipment used in ophthalmic surgery (IEC 80601-2-58:2014); German version EN 80601-2-58:2015
DIN EN IEC 80601-2-60 : 2021-09	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment (IEC 80601-2-60:2019); German version EN IEC 80601-2-60:2020
	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 : 2019-09	Medical electrical equipment - Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximetry equipment (ISO 80601-2-61:2017, corrected version 2018-02); German version EN ISO 80601-2-61:2019 DIN EN ISO 80601-2-61 : 2012-01⊗ - Medical electrical equipment - Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximetry equipment (ISO 80601-2-61:2011); German version EN ISO 80601-2-61:2011
DIN EN ISO 80601-2-69 : 2021-06	Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrators (ISO 80601-2-69:2020); German version EN ISO 80601-2-69:2020 DIN EN ISO 80601-2-69 : 2014-12⊗ Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrators (ISO 80601-2-69:2014); German version EN ISO 80601-2-69:2014
DIN EN ISO 81060-1 : 2012-08	Non-invasive blood pressure measuring devices - Part 1: Requirements and test methods for non-automated devices (ISO 81060-1:2007); German version EN ISO 81060-1:2012
IEC 60601-1 : 2005-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance + Corrigendum 1 : 2006 + Corrigendum 2 : 2007 + Amendment 1 : 2012 + Amendment 1 : 2012 / Corrigendum 1 : 2014 + Amendment 2 : 2020 IEC 60601-1 : 1988⊗ - Medical electrical equipment; part 1: general requirements for safety + Amendment 1 : 1991 + Amendment 2 : 1995
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 60601-1-1 : 1992⊗ - Medical electrical equipment; part 1: general requirements for safety; 1. collateral standard: safety requirements for medical electrical systems + Amendment 1 : 1995

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 + Amendment 1 : 2020 IEC 60601-1-2 : 2007⊗ - 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 + Amendment 2 : 2021
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
IEC 60601-1-8 : 2006-03	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 + Amendment 2 : 2020 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
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 + Amendment 1 : 2013 + Amendment 2 : 2020

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 + Amendment 1 : 2020 IEC 60601-1-11 : 2010⊗ Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment + Technical Corrigendum 1 : 2011
IEC 60601-1-12 : 2014-06	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 + Amendment 1 : 2020
IEC 60601-2-3 : 2012-04	Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment + Amendment 1 : 2016 IEC 60601-2-3 : 1991⊗ - Medical electrical equipment; part 2: particular requirements for the safety of short-wave therapy equipment + Amendment 1 : 1998
IEC 60601-2-4 : 2010-12	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators + Amendment 1 : 2018 IEC 60601-2-4 : 2005⊗ - Medical electrical equipment - Part 2-4: Particular requirements for the safety 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⊗ - 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 + Amendment 1 : 2016 IEC 60601-2-6:1984⊗ - Medical electrical equipment. Part 2: Particular requirements for the safety 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 basic safety and essential performance of therapeutic X- ray equipment operating in the range 10 kV to 1 MV + Amendment 1 : 2015
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 IEC 60601-2-10 : 1987⊗ - Medical electrical equipment; part 2: particular requirements for the safety of nerve and muscle stimulators + Amendment 1 : 2001 + Corrigendum 1 : 2002
IEC 60601-2-18 : 2009-08	Medical electrical equipment - Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment IEC 60601-2-18 : 1996⊗ - Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment + Amendment 1 : 2000
IEC 60601-2-19 : 2020-09	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19 : 2009⊗ - Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators + Amendment 1 : 2016

IEC 60601-2-21 : 2020-09	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers IEC 60601-2-21 : 2009⊗ - Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers + Amendment 1 : 2016-04
IEC 60601-2-22 : 2019-11	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment IEC 60601-2-22 : 2007⊗ - 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
IEC 60601-2-25 : 2011-10	Medical electrical equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs IEC 60601-2-25 : 1993⊗ - Medical electrical equipment; part 2: particular requirements for the safety of electrocardiographs + Amendment 1 : 1999
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
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 + Technical Corrigendum 1 : 2012 IEC 60601-2-34 : 2000⊗ - Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment

IEC 60601-2-35 : 1996-11⊗	Medical electrical equipment - Part 2-35: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use
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⊗ - 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
IEC 60601-2-38 : 1996-10⊗	Medical electrical equipment - Part 2: Particular requirements for the safety of electrically operated hospital beds + A1 : 1999
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⊗ - 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
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 + Amendment 2 : 2019
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⊗ - 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
IEC 60601-2-50 : 2020-09	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment IEC 60601-2-50 : 2009⊗ - Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment + Amendment 1 : 2016
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 + Corrigendum 1 : 2010 **+** Amendment **1 : 2015**
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 + Amendment 2: 2018
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
IEC 60601-2-75 : 2017-05	Medical Electrical Equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment
IEC 61326-2-6 : 2020-10	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

IEC 80601-2-35 : 2009-10⊗	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
IEC 80601-2-58 : 2014-09	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 + Amendment 1 : 2016
ISO 7176-21 : 2009-04	Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

Abbreviations used:

DIN	Deutsches Institut für Normung e.V. – German institute for standardization
EN	Europäische Norm – European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardisation