Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-14169-03-04 according to according to DIN EN ISO/IEC 17025:2005[1] and the Directives 93/42/EEC[2], 90/385/EEC[3] and 98/79/EC[4]

Valid from: 19.03.2019

Date of issue: 19.03.2019

Holder of certificate:

TÜV Rheinland LGA Products GmbH

at the locations

Alboinstraße 56, 12103 Berlin
Am Grauen Stein 29, 51105 Köln
Tillystraße 2, 90431 Nürnberg

Field:	Medical devices
Testing fields/test items:	Biological testing of medical devices as well as safety tests and compatibility tests with regard to electromagnetic disturbances (EMC) of active medical devices and IVD devices

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

Locations

Tillystr. 2
90431 Nürnberg

Alboinstraße 56
12103 Berlin

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
Safety tests	Medical devices, active	Verification of compliance	DIN EN 60601-1 IEC 60601-1
		Components and ME Systems	DIN EN 60601-1-1⊗ IEC 60601-1-1⊗
		Electrical tests and protection against electrical hazards	
		Mechanical strength and protection against mechanical hazards	
		Protection against hazards due to unwanted/excessive radiation	
		Protection against excessive temperatures including fire prevention	
		- Without tests in accordance with Annex G (flammability)	
		Climatic environmental simulation tests	
	Information provided by the manufacturer - On components and assemblies - On biocompatibility		

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	**Test item** **Device (category)**	**Type of testing** **Test**	**Reagulation** **Testing method**
Safety tests	Information provided by the manufacturer - On electromagnetic compatibility - Instructions for use/accompanying documents - Fitness for purpose file - On programmable electrical medical systems (PEMS) - Risk management file - For radiation, ionizing/non-ionizing		DIN EN 60601-1 IEC 60601-1 DIN EN 60601-1-4⊗ IEC 60601-1-4⊗
	Diagnostic X-ray equipment	Test for verification of compliance - Leakage radiation - Filtering - Interference radiation	DIN EN 60601-1-3 IEC 60601-1-3
	Information provided by the manufacturer - Instructions for use/accompanying documents - Risk management file	Verification of compliance	

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	**Test item** **Device (category)**	**Type of testing** **Test**	**Reagulation** **Testing method**
Safety tests	Medical devices, active Information provided by the manufacturer - Fitness for purpose file	Verification of compliance	DIN EN 60601-1-6 IEC 60601-1-6
	Medical devices, active, alarm systems Information provided by the manufacturer - Instructions for use/accompanying documents - Risk management file	Verification of compliance	DIN EN 60601-1-8 IEC 60601-1-8
	Medical devices, active, for use in the home healthcare environment	Verification of 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 - Fitness for purpose file - Risk management file		

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
Safety tests	Medical devices, active, in the environment for emergency use	Verification of compliance	DIN EN 60601-1-12 IEC 60601-1-12
	Medical devices, active, general - In vitro diagnostics (IVD) medical equipment - Luminaires	Test for verification of compliance	DIN EN 61010-2-101 IEC 61010-2-101 DIN EN 60601-2-41 IEC 60601-2-41
	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - Anaesthesia workplaces	Verification of compliance with general and particular requirements	DIN EN ISO 80601-2-13
	Devices for stimulation or inhibition - Defibrillators - Nerve and muscle stimulators	Verification of compliance with general and particular requirements	DIN EN 60601-2-4 IEC 60601-2-4 DIN EN 60601-2-10 IEC 60601-2-10
	Surgical devices and surgical aids - Endoscopic equipment - High frequency surgical equipment and accessories	Verification of compliance with general and particular requirements	DIN EN 60601-2-18 IEC 60601-2-18 DIN EN 60601-2-2 IEC 60601-2-2

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
Safety tests	Ophthalmologic devices - Vitrectomy devices and lens removal devices	Verification of compliance with general and particular requirements	DIN EN 80601-2-58 IEC 80601-2-58
	Sterilisers, washers, disinfectors	Verification of compliance with general and particular requirements	DIN EN 61010-2-040 IEC 61010-2-040
	Equipment for imaging processes with ionising radiation - Associated equipment of X-ray equipment	Verification of compliance with general and particular requirements	DIN EN 60601-2-32⊗ IEC 60601-2-32⊗
	Equipment for imaging processes with ionising radiation - X-ray equipment for computed tomography - X-ray equipment for interventional procedures - Mammographic X-ray equipment and mammographic stereotactic devices - Equipment for radiography and radioscopy	Verification of compliance with general and particular requirements	DIN EN 60601-2-44 IEC 60601-2-44 DIN EN 60601-2-43 IEC 60601-2-43 DIN EN 60601-2-45 IEC 60601-2-45 DIN EN 60601-2-54 IEC 60601-2-54 DIN EN 60601-2-7⊗ IEC 60601-2-7⊗

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
Safety tests	Equipment for imaging processes with ionising radiation - X-ray tube assemblies for medical diagnosis	Verification of compliance with general and particular requirements	DIN EN 60601-2-28 IEC 60601-2-28
	Equipment for imaging processes with non-ionising radiation - Magnetic resonance equipment - Infant radiant warmers	Verification of compliance with general and particular requirements	DIN EN 60601-2-33 IEC 60601-2-33 DIN EN 60601-2-21 IEC 60601-2-21
	Equipment for extracorporeally induced lithotripsy Monitoring devices - Multifunctional patient monitoring devices	Verification of compliance with general and particular requirements Verification of compliance with general and particular requirements	DIN EN 60601-2-36 IEC 60601-2-36 DIN EN 60601-2-49 IEC 60601-2-49
	Monitoring devices of non-vital physiological parameters - Electroencephalographs	Verification of compliance with general and particular requirements	DIN EN 60601-2-26 IEC 60601-2-26
	Monitoring devices of vital parameters - Ambulatory electrocardiographic systems	Verification of compliance with general and particular requirements	DIN IEC 60601-2-47 IEC 60601-2-47

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
Safety tests	Monitoring devices of vital parameters - Automatic, cyclic, non-invasive blood pressure monitors - Electrocardiographs - External pacemakers with internal power supply	Verification of compliance with general and particular requirements	DIN EN 80601-2-30 IEC 80601-2-30 DIN EN 60601-2-25 IEC 60601-2-25 DIN EN 60601-2-27 IEC 60601-2-27 DIN EN 60601-2-31 IEC 60601-2-31
	Devices for radiation therapy and thermo therapy Devices utilising non-ionising radiation - Therapeutic and diagnostic lasers - Short-wave therapy equipment - Ultrasound physiotherapy devices	Verification of compliance with general and particular requirements	DIN EN 60601-2-22 IEC 60601-2-22 DIN EN 60601-2-3 IEC 60601-2-3 DIN EN 60601-2-5 IEC 60601-2-5

Any exclusions of partial tests for a test are not specified within the scope of accreditation and must be reported to the client by the laboratory during order verification.

The accreditation assessment was conducted with reference to the normative references of European regulations (DIN EN). Where the referenced International versions of the standards are not explicitly listed in the appendix to the notice, the normative references of international regulations (IEC, ISO) were not taken into account.

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

For the Nuremberg location, the following also apply:

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
EMC	Medical devices, active Information provided by the manufacturer - Inscriptions - Designations - Instructions for use/accompanying documents	Test for verification of compliance in the measuring range 9 kHz to 90 GHz - Interference emission - Interference immunity Verification of compliance	DIN EN 60601-1-2 IEC 60601-1-2
	Medical devices, active, in the emergency medical services environment	Verification of compliance	DIN EN 60601-1-12 IEC 60601-1-12
	Devices for stimulation or inhibition - Defibrillators - Nerve and muscle stimulators - External pacemakers with internal power supply	Verification of compliance with general and particular requirements	DIN EN 60601-2-4 IEC 60601-2-4 DIN EN 60601-2-10 IEC 60601-2-10 DIN EN 60601-2-31 IEC 60601-2-31
	Surgical devices and surgical aids - Endoscopic equipment	Verification of compliance with general and particular requirements	DIN EN 60601-2-18 IEC 60601-2-18

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
EMC	Surgical devices and surgical aids - High frequency surgical equipment and accessories	Verification of compliance with general and particular requirements	DIN EN 60601-2-2 IEC 60601-2-2
	Ophthalmologic devices - Vitrectomy devices and lens removal devices	Verification of compliance with general and particular requirements	DIN EN 80601-2-58 IEC 80601-2-58
	Devices for patient positioning and transport - Electrically operated hospital beds - Operating tables - Infant incubators - Transport incubators	Verification of compliance with general and particular requirements	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
	Equipment for extracorporeally induced lithotripsy	Verification of compliance with general and particular requirements	DIN EN 60601-2-36 IEC 60601-2-36
	Equipment for imaging processes with ionising radiation - Radiography and radioscopy devices - X-ray equipment for computed tomography	Verification of compliance with general and particular requirements	DIN EN 60601-2-54 IEC 60601-2-54 DIN EN 60601-2-44 IEC 60601-2-44

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
EMC	Equipment for imaging processes with ionising radiation - X-ray equipment for interventional procedures - Mammographic X-ray equipment and mammographic stereotactic devices	Verification of compliance with general and particular requirements	DIN EN 60601-2-43 IEC 60601-2-43 DIN EN 60601-2-45 IEC 60601-2-45
	Equipment for imaging processes with non-ionising radiation - Magnetic resonance equipment		DIN EN 60601-2-33 IEC 60601-2-33
	Monitoring devices - Multifunctional patient monitoring devices	Verification of compliance with general and particular requirements	DIN EN 60601-2-49 IEC 60601-2-49
	Monitoring devices of non-vital physiological parameters - Electroencephalographs	Verification of compliance with general and particular requirements	DIN EN 60601-2-26 IEC 60601-2-26
	Monitoring devices of vital parameters - Ambulatory electrocardio-graphic systems	Verification of compliance with general and particular requirements	DIN IEC 60601-2-47 IEC 60601-2-47

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
EMC	Monitoring devices of vital parameters - Electrocardio-graphs		DIN EN 60601-2-25 IEC 60601-2-25 DIN EN 60601-2-27 IEC 60601-2-27
	Devices for radiation therapy and thermo therapy - Devices utilising ionising radiation - Infant radiant warmers	Verification of compliance with general and particular requirements	DIN EN 60601-2-21 IEC 60601-2-21
	Devices utilising non-ionising radiation - Microwave therapy equipment - Ultrasound physiotherapy devices	Verification of compliance with general and particular requirements	DIN EN 60601-2-6 IEC 60601-2-6 DIN EN 60601-2-5 IEC 60601-2-5
	In vitro diagnostics (IVD) medical equipment	Test for verification of compliance in the measuring range 9 kHz to 40 GHz - Interference emission - Interference immunity	DIN EN 61326-2-6 IEC 61326-2-6
	Information provided by the manufacturer - Inscriptions - Designations	Verification of compliance	DIN EN 61326-2-6 IEC 61326-2-6
	- Instructions for use/accompanying documents		

Any exclusions of partial tests for a test are not specified within the scope of accreditation and must be reported to the client by the laboratory during order verification.

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

The accreditation assessment was conducted with reference to the normative references of European regulations (DIN EN). Where the referenced International versions of the standards are not explicitly listed in the appendix to the notice, the normative references of international regulations (IEC, ISO) were not taken into account.

For the Cologne location, the following also apply:

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
Biological tests	Medical devices	Test for cytotoxicity	DIN EN ISO 10993-5
		- Cell proliferation assay after contact with extracts and in direct contact (colorimetric measurement of DNA synthesis using BrdU)	QAA_Biokomp_PA_10 QAA_Biokomp_PA_11
		- Morphology test after contact with extracts and in direct contact (microscopic assessment of cell morphology after haemalm staining)	QAA_Biokomp_PA_12 QAA_Biokomp_PA_13
		- Cell proliferation assay after contact with extracts and in direct contact (colorimetric determination of protein synthesis)	QAA_Biokomp_PA_14 QAA_Biokomp_PA_15
		- Test for membrane integrity after contact with extracts and in direct contact (vital staining with FDA/EB)	QAA_Biokomp_PA_16 QAA_Biokomp_PA_17
		- Determination of metabolic activity after contact with extracts and in direct contact (XTT test)	QAA_Biokomp_PA_18 QAA_Biokomp_PA_19
			Also applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Haemocompatibility	DIN EN ISO 10993-4

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
Biological tests	Medical devices	Thrombosis	QAA_Biokomp_PA_01
		Coagulation	QAA_Biokomp_PA_04 QAA_Biokomp_PA_05 QAA_Biokomp_PA_06 QAA_Biokomp_PA_08 QAA_Biokomp_PA_21 QAA_Biokomp_PA_22
		Thrombocytes	QAA_Biokomp_PA_03 QAA_Biokomp_PA_07 QAA_Biokomp_PA_20 QAA_Biokomp_PA_44
		Haematology	QAA_Biokomp_PA_02 QAA_Biokomp_PA_03 QAA_Biokomp_PA_23
		Complement system	QAA_Biokomp_PA_09
			Also applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Testing field	Test item Device (category)	Type of testing Test	Reagulation Testing method
Biological tests	Medical devices	Test as part of the assessment of local effects after implantation	DIN EN ISO 10993-6
		- Microscopy	QAA_Biokomp_PA_24 QAA_Biokomp_PA_25 QAA_Biokomp_PA_26 QAA_Biokomp_PA_27 QAA_Biokomp_PA_28 QAA_Biokomp_PA_29 QAA_Biokomp_PA_30 QAA_Biokomp_PA_31 QAA_Biokomp_PA_32 QAA_Biokomp_PA_33 QAA_Biokomp_PA_34 QAA_Biokomp_PA_35 QAA_Biokomp_PA_36 QAA_Biokomp_PA_37 QAA_Biokomp_PA_38
		Test as part of the assessment of local effects after implantation	DIN EN ISO 10993-6
		- Microscopy	QAA_Biokomp_PA_39 QAA_Biokomp_PA_40 QAA_Biokomp_PA_41 QAA_Biokomp_PA_42 QAA_Biokomp_PA_43 Also applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-2 DIN EN ISO 10993-12

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

Rules/standards[5]

DIN EN ISO 10993-1 : 2010-04	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system (ISO 10993-1:2009); German version EN ISO 10993-1:2009
DIN EN ISO 10993-2 : 2006-10	Biological evaluation of medical devices – Part 2: Animal welfare requirements (ISO 10993-2:2006); German version EN ISO 10993-2:2006
DIN EN ISO 10993-4: 2017-12	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017); German version EN ISO 10993-4:2017
DIN EN ISO 10993-5 : 2009-10	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009); German version EN ISO 10993-5:2009
DIN EN ISO 10993-6 : 2017-09	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation (ISO 10993-6:2016); German version EN ISO 10993-6:2016
DIN EN ISO 10993-12 : 2012-10	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials (ISO 10993-12:2012); German version EN ISO 10993-12:2012
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 DIN EN 60601-1: 2002-09⊗ – 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
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
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 –

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

	Requirements and tests (IEC 60601-1-2:2014, modified); 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 : 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
	DIN EN 60601-1-3:2008-12⊗ – 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); German version EN60601-1-3:2008
	DIN EN 60601-1-3:1995-02⊗ – Medical electrical equipment – Part 1: General requirements for safety, 3rd collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:1994); German version EN 60601-1-3:1994
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 60601-1-6 : 2016-02	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Fitness for purpose (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
	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

-Translation-

Abbreviations used: see last page

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 guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006 + A1:2012); German version EN 60601-1-8:2007 + Cor.:2010 + A1:2013
	DIN EN 60601-1-8 : 2010-05⊗ – Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: Alarm systems – General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8: 2006); German version EN 60601-1-8: 2007 + CENELEC-Cor. :2010 to EN 60601-1-8: 2007
	DIN EN 60601-1-8 : 2004-09⊗ – Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: Alarm systems – General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2003); German version EN 60601-1-8:2004
DIN EN 60601-1-11 : 2016-04	Medical electrical equipment – Part 1-11: Particular requirements for basic safety and essential performance – Collateral standard: Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015); German version EN 60601-1-11:2015
	DIN EN 60601-1-11 : 2011-03⊗ – Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2010); German version EN 60601-1-11:2010
DIN EN 60601-1-12 : 2016-01	Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral standard: Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment (IEC 60601-1-12:2014); German version EN 60601-1-12:2015
DIN EN 60601-2-2 : 2010-01	Medical electrical equipment – Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009); German version EN 60601-2-2:2009
	DIN EN 60601-2-2: 2001-08⊗ – Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency

-Translation-

	surgical equipment (IEC 60601-2-2:1998); German version EN 60601-2-2:2000
DIN EN 60601-2-3 : 2016-02	Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment (IEC 60601-2-3:2012); German version EN 60601-2-3:2015
	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
DIN EN 60601-2-5 : 2016-08	Medical electrical equipment – Part 2-5: Particular requirements for the safety of ultrasonic 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 ultrasonic physiotherapy equipment (IEC 60601-2-5:2000); German version EN 60601-2-5:2000
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 high-voltage generators of diagnostic X-ray generators (IEC 60601-2-7:1998); German version EN 60601-2-7:1998
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 stimulators (IEC 60601-2-10:2012 + A1:2016); German version EN 60601-2-10:2015 + A1:2016
	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
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 : 2017-09	Medical electrical equipment – Part 2-19: Particular requirements for 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 basic safety and essential performance of infant incubators (IEC 60601-2-19:2009); German version EN 60601-2-19:2009
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
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 : 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 60601-2-25 : 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 60601-2-27 : 2007-05⊗ – Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (IEC 60601-2-27:2005); German version EN 60601-2-27:2006 + Cor. 1
	DIN EN 60601-2-27 : 1996-02⊗ – Medical electrical equipment – Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment (IEC 60601-2-27:1994); German version EN 60601-2-27:1994
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
	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
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
	DIN EN 60601-2-31:2009-01⊗ – 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); German version EN 60601-2-31:2008
	DIN EN 60601-2-31/A1:1999-05⊗ - Medical electrical equipment – Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source; Amendment A1 (IEC 60601-2-31/A1:1998); German version EN 60601-2-31:1996/A1:1998

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

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
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
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
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 60601-2-41 : 2016-02	Medical electrical equipment – Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009 + A1:2013); German version EN 60601-2-41:2009 + A1:2015 DIN EN 60601-2-41 : 2010-05⊗ – Medical electrical equipment – Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009); German version EN 60601-2-41:2009
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 DIN EN 60601-2-43:2002-11⊗ – Medical electrical equipment – Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures (IEC 60601-2-43:2000); German version EN 60601-2-43:2000
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

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

	DIN EN 60601-2-44 : 2010-02⊗ – Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (IEC 60601-2-44:2009); German version EN 60601-2-44:2009, Corrigendum to DIN EN 60601-2-44 (VDE 0750-2-44):2010-02; (IEC Cor. 1.:2010 to IEC 60601-2-44:2009)
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
	DIN EN 60601-2-45 : 2003-02⊗ – Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices (IEC 60601-2-45:2001-05); German version EN 60601-2-45:2001
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 60601-2-46 : 1999-02⊗ – Medical electrical equipment – Part 2-46: Particular requirements for the safety of operating tables (IEC 60601-2-46:1998); German version EN 60601-2-46:1998
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
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 60601-2-49 : 2002-12⊗ – Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunction

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

	patient monitoring equipment (IEC 60601-2-49:2001); German version EN 60601-2-49:2001
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 + Cor. 1 (2010-07) + Cor. 2 (2011-12) + Cor. 3 (2012-04)
DIN EN 61010-2-040 : 2016-06	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilisers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015); German version EN 61010-2-040:2015
	(in conjunction with DIN EN 61010-1: 2011-07, as long as there is a valid accreditation for this)
	DIN EN 61010-2-040 : 2006-02⊗ – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilisers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2005); German version EN 61010-2-040:2005
	(in conjunction with DIN EN 61010-1: 2002-08, as long as there is a valid accreditation for this)
DIN EN 61010-2-101 : 2017-10	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2015); German version EN 61010-2-101:2017
	(in conjunction with DIN EN 61010-1: 2011-07, as long as there is a valid accreditation for this)
	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 DIN EN 61010-1: 2002-08, as long as there is a valid accreditation for this)
DIN EN 61326-2-6 : 2013-09	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements - In

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

	vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2012); German version EN 61326-2-6:2013 (in conjunction with DIN EN 61326-1: 2013-07, as long as there is a valid accreditation for this)
DIN EN ISO 80601-2-13 : 2013-03	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2011); German version EN ISO 80601-2-13:2012
DIN EN 80601-2-30 : 2016-02	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (IEC 80601-2-30:2009 + Corrigendum Jan. 2010 + A1:2013); German version EN 80601-2-30:2010 + A1:2015 DIN EN 80601-2-30 : 2011-05⊗ – Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers (IEC 80601-2-30:2009 + Cor. :2010); German version EN 80601-2-30:2010
DIN EN 80601-2-58 : 2015-11	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 (IEC 80601-2-58:2014); German version EN 80601-2-58:2015 DIN EN 80601-2-58 : 2009-10⊗ – 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 (IEC 80601-2-58:2008); German version EN 80601-2-58:2009

IEC 60601-1 : 2005-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance + Corrigendum 1 : 2006-12 + Corrigendum 2 : 2007-12 + Amendment 1 : 2012-07 ANSI/AAMI ES60601-1 : 2005 & C1:2009 + A2:2010 + A1:2012 CAN/CSA-C22.2 No. 60601-1:14 IEC 60601-1 : 2005-12 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance ANSI/AAMI ES60601-1 : 2005 (IEC 60601-1 : 2005, MOD)

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

	CAN/CSA-C22.2 No. 60601-1:08
	KS C IEC 60601-1 : 2011-12
	JIS T 0601-1:2012
	IEC 60601-1 : 1988⊗ – Medical electrical equipment; part 1: general requirements for safety
	+ Amendment 1 : 1991-11
	+ Amendment 2 : 1995-03
	Can/CSA-C22.2 No. 601.1-M90
	UL 60601-1 (2003-04)
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⊗ - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-3 : 2008-01	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
	+ Amendment 1 : 2013-04
	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 60601-1-4 : 1996-05⊗	Medical electrical equipment – Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
	+ Amendment 1 : 1999
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 60601-1-6 : 2006-12⊗ - Medical electrical equipment - Part 1-6:General requirements for basic safety and essential performance - Collateral Standard: Usability
	IEC 60601-1-6 : 2004-06 - Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

IEC 60601-1-8 : 2006-10	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems + Amendment 1 : 2012-11 IEC 60601-1-8 : 2003-08⊗ - Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems + Amendment 1 : 2006-03
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 IEC 60601-1-11 : 2010-04⊗ - Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment + Corrigendum 1 : 2011-04
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
IEC 60601-2-2 : 2017-03	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories IEC 60601-2-2 : 2009-02 – Medical electrical equipment – Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories + Corrigendum 1 : 2014-02 IEC 60601-2-2 : 1998-09⊗ – Medical electrical equipment -Part 2-2: Particular requirements for the safety of high frequency surgical equipment
IEC 60601-2-3 : 2012-04	Medical electrical equipment – Part 2-3: Particular requirements for basic safety and essential performance of short-wave therapy equipment

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

	IEC 60601-2-3 : 1991-06⊗ – Medical electrical equipment – Part 2-3: 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 the basic safety and essential performance of cardiac defibrillators
IEC 60601-2-5 : 2009-07	Medical electrical equipment – Part 2-5: Particular requirements for the 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
	+ Amendment 1 : 2016-04
	IEC 60601-2-6 : 1984-01⊗ - 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 60601-2-10 : 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 : 2002-02⊗ – Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
	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
	+ Corrigendum 1 : 2002-02
IEC 60601-2-18 : 2009-08	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

	IEC 60601-2-18 : 1996-08⊗ – Medical electrical equipment – Part 2-18: Particular requirements for the safety of endoscopic equipment + Amendment 1 : 2000-07
IEC 60601-2-19 : 2009-02	Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators + Corrigendum 1 : 2012-02 + Amendment 1 : 2016-04
IEC 60601-2-20 : 2009-02	Medical electrical equipment – Part 2-20: Particular requirements for basic safety and essential performance of infant transport incubators + Corrigendum 1 : 2012-02 + Corrigendum 2 : 2013-02
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 60601-2-22 : 2007-05	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment + Amendment 1 : 2012-10 IEC 60601-2-22 : 1995-11⊗ - Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
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 : 1993-03⊗ - Medical electrical equipment – Part 2-25: Particular requirements for the safety of electrocardiographs + Amendment 1 : 1999-05
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 : 2002-1⊗ - Medical electrical equipment — Part 2-26: Particular requirements for the safety of electroencephalographs

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

IEC 60601-2-27 : 2011-03	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment + Corrigendum 1 : 2012-05 IEC 60601-2-27 : 2005-08⊗ - Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment IEC 60601-2-27 : 1994-03⊗ - Medical electrical equipment – Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
IEC 60601-2-28 : 2010-03	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 : 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 60601-2-31 : 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 60601-2-31 : 1994-10⊗ - Medical electrical equipment – Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source + Amendment 1 : 1998-01
IEC 60601-2-32 : 1994-03⊗	Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment 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 + Corrigendum 1 : 2012-03 + Amendment 1 : 2013-04 + Amendment 2 : 2015-06 + Corrigendum 2 : 2016-02
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

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

IEC 60601-2-38 : 1996-10⊗	Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds + Amendment 1 : 1999-12
IEC 60601-2-41 : 2009-08	Medical electrical equipment – Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis + Amendment 1 : 2013-10
IEC 60601-2-43 : 2010-03	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 : 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 + Corrigendum 1 : 2010-05 + Amendment 1 : 2012-09 + Amendment 2 : 2016-03
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 60601-2-46 : 1998-06⊗ - Medical electrical equipment - Part 2-46: Particular requirements for the safety 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

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

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 60601-2-49 : 2001-07⊗ - Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
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 + Corrigendum 1 : 2010-03 + Corrigendum 2 : 2011-06 + Amendment 1: 2015-04
IEC 61010-2-040 : 2015-07	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (in conjunction with IEC 61010-1 : 2010-06, as long as a valid accreditation therefor exists) IEC 61010-2-040 : 2005-04⊗ - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (in conjunction with IEC 61010-1 : 2001-02, as long as a valid accreditation therefor exists)
IEC 61010-2-101 : 2015-01	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (in conjunction with IEC 61010-1 : 2010-06, as long as a valid accreditation therefor exists) IEC 61010-2-101 : 2002-01⊗ - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (in conjunction with IEC 61010-1 : 2001-02, as long as a valid accreditation therefor exists)
IEC 61326-2-6 : 2012-07	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (in conjunction with IEC 61326-1 : 2012-07, as long as a valid accreditation therefor exists)

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

IEC 80601-2-30 : 2009-01	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers + Corrigendum 1 : 2010-01 + Amendment 1 : 2013-07
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 IEC 80601-2-58 : 2008-10⊗ - 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

---

QAA_Biokomp_PA_01	Scanning electron microscopy to evaluate the haemocompatibility of surfaces
QAA_Biokomp_PA_02	Determination of haemoglobin in plasma after contact with extracts (haemolysis in indirect contact)
QAA_Biokomp_PA_03	Determination of cell count
QAA_Biokomp_PA_04	Determination of human thrombin/antithrombin III complex
QAA_Biokomp_PA_05	Determination of the partial thromboplastin time (PTT) on the coagulometer
QAA_Biokomp_PA_06	Determination of APTT on coagulometer
QAA_Biokomp_PA_07	Thrombocyte adhesion test using ELISA CD 42b
QAA_Biokomp_PA_08	Fibrinogen adsorption
QAA_Biokomp_PA_09	Complement activation (C5a)
QAA_Biokomp_PA_10	BrdU cell proliferation assay after contact with extracts (colorimetric)
QAA_Biokomp_PA_11	Direct contact BrdU cell proliferation assay (immunofluorescence)
QAA_Biokomp_PA_12	Haemalm staining after contact with extracts
QAA_Biokomp_PA_13	Direct contact haemalm staining
QAA_Biokomp_PA_14	Determination of protein synthesis after contact with extracts
QAA_Biokomp_PA_15	Determination of protein synthesis in direct contact
QAA_Biokomp_PA_16	Vital staining with FDA/EB after contact with extracts

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019

QAA_Biokomp_PA_17	Vital staining with FDA/EB in direct contact
QAA_Biokomp_PA_18	XTT assay after contact with extracts
QAA_Biokomp_PA_19	Direct contact XTT assay
QAA_Biokomp_PA_20	Determination of thrombocyte activation using ELISA CD 62P
QAA_Biokomp_PA_21	Determination of thrombin time
QAA_Biokomp_PA_22	Determination of thrombin binding capacity
QAA_Biokomp_PA_23	Determination of haemoglobin in plasma after contact with extracts (haemolysis in direct contact)
QAA_Biokomp_PA_24	Haematoxylin-eosin (H&E) staining
QAA_Biokomp_PA_25	Elastica van Gieson (EVG) staining
QAA_Biokomp_PA_26	Sirius red staining
QAA_Biokomp_PA_27	Polarisation
QAA_Biokomp_PA_28	Immunohistological staining: antibody CD20c
QAA_Biokomp_PA_29	Immunohistological staining: (a) antibody CD3; (b) antibody CD45RO
QAA_Biokomp_PA_30	Immunohistological staining: (a) antibody CD68 (clone ED1); (b) antibody CD68 (clone KP1)
QAA_Biokomp_PA_31	Immunohistological staining: antibody CD15 (clone P12)
QAA_Biokomp_PA_32	Immunohistological staining: antibody (a) collagen I and (b) collagen III
QAA_Biokomp_PA_33	Immunohistological staining: Antibody FVIII related protein (von Willebrand factor)
QAA_Biokomp_PA_34	Immunohistological staining: (a) antibody CD34 (clone MEC14.7); (b) antibody CD34 (clone B1-3C5)
QAA_Biokomp_PA_35	Immunohistological staining: CD-105 endoglin (mouse/anti-human)
QAA_Biokomp_PA_36	Immunohistological staining: antibody CD61 (integrin β3; clone Y2/51)
QAA_Biokomp_PA_37	Immunohistological staining: antibody fibrinogen
QAA_Biokomp_PA_38	Immunohistological staining: antibody fibrin (clone E8)
QAA_Biokomp_PA_39	Immunohistological staining: antibody HSP70 (clone A0500)
QAA_Biokomp_PA_40	Immunohistological staining: (a) antibody Ki67 (MIB5); (b) antibody Ki67 (MIB1)

-Translation-

Abbreviations used: see last page

QAA_Biokomp_PA_41	Tunel staining: (apoptosis)
QAA_Biokomp_PA_42	Giemsa staining
QAA_Biokomp_PA_43	Iron staining
QAA_Biokomp_PA_44	Determination of platelet factor 4 (PF 4)

Abbreviations used:

APTT	Activated partial thromboplastin time
BrdU	Bromodeoxyuridine
C5a	Complement factor 5a
CD	Cluster of differentiation
CENELEC	European Committee for Electrotechnical Standardization
DIN	Deutsches Institut für Normung (German Institute for Standardization)
EB	Ethidium bromide
EN	European standard
FDA	Fluorescein diacetate
FVIII	Factor VIII
HSP	Heat shock protein
IEC	International Electrical Committee
ISO	International Organization for Standardization
Ki	Clone name of antigen
Medical devices, active	Medical electrical equipment, medical electrical systems and components
QAA	TRLP biocompatibility test instructions
⊗	Withdrawn standards

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

[2] Council Directive 93 / 42 / EEC of 14 June 1993 concerning medical devices

[3] Council Directive 90 / 385 / EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

[4] Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

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

-Translation-

Abbreviations used: see last page

Valid from: 19.03.2019
Date of issue: 19.03.2019