Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-19366-01-02 according to DIN EN ISO/IEC 17025:2018

Valid from: 26.07.2019

Date of issue: 15.10.2020

Holder of certificate:

E & C Testlab GmbH (Engineering & Certification Testlab GmbH)
Industriestraße 8, 78647 Trossingen

Scope:	Medical devices complying with the requirements of Directives 93/42/EEC[1] and 98/79/EC[2] on independence
Testing fields/Test items:	Compatibility with electromagnetic interference (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.

Department	Standard / date of issue In-house method/ version	Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item / Inspection item
EMC	Medical devices, active	Testing for verification of compliance - Emission - Immunity	DIN EN 60601-1-2 IEC 60601-1-2
	Information provided by the manufacturer - inscription - description - Instructions / accompanying documents	Check for agreement	
	Devices for stimulation or inhibition - defibrillators - Devices for the stimulation of nerves and muscles	Verification of compliance with general and specific specifications	DIN EN 60601-2-4 IEC 60601-2-4 DIN EN 60601-2-10 IEC 60601-2-10
	Surgery equipment and surgical equipment - Endoscopy Equipment - HF surgical equipment and accessories	Verification of compliance with general and specific specifications	DIN EN 60601-2-18 IEC 60601-2-18 DIN EN 60601-2-2 IEC 60601-2-2
	Active rehabilitation aids and prostheses - Technical aids for disabled persons	Testing for verification of compliance	DIN EN 12182
EMC	Equipment for non-ionizing radiation imaging - Ultrasound equipment for	Verification of compliance with general and specific specifications	DIN EN 60601-2-37 IEC 60601-2-37

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Department	Standard / date of issue In-house method/ version	Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item / Inspection item
	diagnosis and monitoring		
	Devices for monitoring Devices for monitoring non-vital physiological parameters - Electroencephalo-graph - Devices for transcutaneous partial pressure monitoring	Verification of compliance with general and specific specifications	DIN EN 60601-2-26 IEC 60601-2-26 DIN EN 60601-2-23 IEC 60601-2-23
	Equipment for radiation and thermotherapy Devices with non-ionizing radiation - microwave therapy devices - ultrasonic physiotherapy devices	Verification of compliance with general and specific specifications	DIN EN 60601-2-6 IEC 60601-2-6 DIN EN 60601-2-5 IEC 60601-2-5
EMC	In vitro diagnostic (IVD) medical devices	Testing for verification of compliance - Emission - Immunity	DIN EN 61326-2-6 IEC 61326-2-6
	Information provided by the manufacturer - inscription - description - Instructions / accompanying documents	Check for agreement	DIN EN 61326-2-6 IEC 61326-2-6

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Any existing exclusions from partial tests of a test are not included in the scope of the accreditation and must be communicated to the client by the laboratory when the contract is examined.

The accreditation assessment took place in consideration of the normative references of the European regulations (DIN EN). The normative references of the international regulations (IEC, ISO) were not taken into account, as long as the referenced international versions of the standards are not explicitly stated in the annex to the decision.

Regulations[3]

DIN EN 12182 : 2012-07	Assistive products for persons with disability - General requirements and test methods; German version EN 12182:2012
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 VDE 0750-1-2:2016-05
	DIN EN 60601-1-2:2007-12⊗ - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007, modified); German version EN 60601-1-2:2007 VDE 0750-1-2:2007-12
DIN EN 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 and high frequency surgical accessories (IEC 60601-2-2:2017); German version EN IEC 60601-2-2:2018 VDE 0750-2-2:2018-12
	DIN EN 60601-2-2:2010-01⊗ - Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009); German version EN 60601-2-2:2009 VDE 0750-2-2:2010-01
DIN EN 60601-2-4 : 2012-05	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4:2010); German version EN 60601-2-

	4:2011 VDE 0750-2-4:2012-05
DIN EN 60601-2-5 : 2016-08	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment (IEC 60601-2-5:2009); German version EN 60601-2-5:2015 VDE 0750-2-5:2016-08
DIN EN 60601-2-6 : 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 VDE 0750-2-6:2017-10
	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 VDE 0750-2-6:2016-03
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 VDE 0750-2-10:2017-09
	DIN EN 60601-2-10:2015-11⊗ - Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10:2012); German version EN 60601-2-10:2015 VDE 0750-2-10:2015-11
DIN EN 60601-2-18 : 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 VDE 0750-2-18:2016-10
DIN EN 60601-2-23 : 2016-08	Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment (IEC 60601-2-23:2011); German version EN 60601-2-23:2015 VDE 0750-2-23:2016-08
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

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	EN 60601-2-26:2015 VDE 0750-2-26:2016-02
DIN EN 60601-2-37 : 2016-11	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007 + A1:2015); German version EN 60601-2-37:2008 + A11:2011 + A1:2015 VDE 0750-2-37:2016-11
	DIN EN 60601-2-37:2012-05⊗ - Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007); German version EN 60601-2-37:2008 + A11:2011 VDE 0750-2-37:2012-05
DIN EN 61326-2-6 : 2013-09	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2012); German version EN 61326-2-6:2013
IEC 60601-1-2 : 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
	IEC 60601-1-2 : 2007-03⊗ - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-2 : 2017-03	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
	IEC 60601-2-2 : 2009-02⊗ - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-2-4 : 2010-12	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators
IEC 60601-2-5 : 2009-07	Medical electrical equipment - Part 2-5: Particular requirements for basic safety and essential performance of ultrasonic physiotherapy equipment

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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 60601-2-10 : 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 60601-2-18 : 2009-08	Medical electrical equipment - Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment
IEC 60601-2-23 : 2011-02	Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
IEC 60601-2-26 : 2012-05	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 60601-2-37 : 2007-08	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment + Amendment 1 : 2015-06
IEC 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

Used abbreviations:

CENELEC	European Committee for Electrotechnical Standardization
DIN	Deutsches Institut für Normung (German institute for standardization)
EN	Europäische Norm (European Standard)
IEC	International Electrotechnical Commission
Medical devices, active	Medical electrical equipment, medical electrical systems and components
⊗	Standards withdrawn from standardization

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1 Guideline 93/42 / EEC of 14 June 1993 about medical devices

2 Guideline 98/79 / EC of the European Parliament and of the Council of 27 October 1998 about in vitro diagnostic medical devices

3 For the transitional periods see the list of harmonized standards on the homepage of the EU.

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