Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-12122-01-02 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **01.12.2020**

Date of issue: 05.08.2021

Holder of certificate:

EMCE GmbH Ingenieurbüro für EMV-Prüfungen und Schaltungsentwicklung
Wichernweg 1, 89233 Neu-Ulm

At location:
EMCE GmbH Ingenieurbüro für EMV-Prüfungen und Schaltungsentwicklung
Untere Wiesen 1, 88483 Burgrieden

Field:	Medical devices and the Directive 93/42/EEC[2] and 98/79/EEC[3]
Testing fields/test items:	Compatibility tests for electromagnetic interference (EMC) of Active medical devices and IVD devices

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.

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

Abbreviations used: see last page

Testing field	**Test item** **Device (category)**	**Type of testing** **Test**	**Regulation** **Testing method**
EMC	Medical devices, active	Compliance Tests - Emissions - Immunity	DIN EN 60601-1-2 IEC 60601-1-2
	Information provided by the manufacturer - Markings - Designations - User manual/ accompanying documents	Compliance Tests	
	Equipment for extracorporeal circular flow, Infusions and haemopheresis - Infusion pumps und controllers	Compliance Test for basic safety and essential performance	DIN EN 60601-2-24⊗ IEC 60601-2-24⊗
	Equipment for stimulation or inhibition - Equipment for stimulation for nerves and muscles	Compliance Test for basic safety and essential performance	DIN EN 60601-2-10⊗ IEC 60601-2-10⊗
	Surgical equipment and surgical auxiliary equipment - High frequency surgical equipment and assessories	Compliance Test for basic safety and essential performance	DIN EN 60601-2-2⊗ IEC 60601-2-12⊗

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
	Patient positioning- and Transport facilities - blankets, pads and mattressess	Compliance Test for basic safety and essential performance	DIN EN 60601-2-35⊗ IEC 60601-2-35⊗
EMC	Equipment for monitoring Equipment for monitoring of vital parameters - Electrocardio-graphs - ECG monitoring equipment - automated, cyclic, non-invasale blood pressure monitoring equipment - recording and analysing single and multichannel electrocardio-graphs	Compliance Test for basic safety and essential performance	DIN EN 60601-2-2 IEC 60601-2-25 DIN EN 60601-2-2 IEC 60601-2-27 DIN EN 60601-2-30⊗ IEC 60601-2-30⊗ DIN EN 60601-2-51⊗ IEC 60601-2-51⊗
	Devices for Radiation- and thermotherapy Equipment with non-ionizing radiation - Short-wave therapy equipment - Ultrasonic physiotherapy equipment	Compliance Test for basic safety and essential performance	DIN EN 60601-2-3⊗ IEC 60601-2-3⊗ DIN EN 60601-2-5⊗ IEC 60601-2-5⊗

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
	In-vitro-Diagnostik-(IVD-)Medical equipment	Compliance Tests - Emissions - Immunity	DIN EN 61326-2-6 IEC 61326-2-6
EMC	Information provided by manufacturer - Markings - Designations - User manual / accompanying documents	Compliance Tests	DIN EN 61326-2-6 IEC 61326-2-6

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

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

Regulations[4]

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 60601-2-2 : 2010-01⊗	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009); German Version EN 60601-2-2:2009
DIN EN 60601-2-3 : 1999-10⊗	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 + A1:2016); German version EN 60601-2-3:2015 + A1:2016
DIN EN 60601-2-5 : 2001-12⊗	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
DIN EN 60601-2-10 : 2003-04⊗	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 60601-2-24 : 1999-02⊗	Medical electrical equipment - Part 2-24: Particular requirements for basic safety and essential performance of infusion pumps and controllers (IEC 60601-2-24:2012); German version EN 60601-2-24:2015
DIN EN 60601-2-25 : 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 60601-2-27 : 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

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DIN EN 60601-2-30 : 2000-12⊗	Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999); German version EN 60601-2-30:2000
DIN EN 60601-2-35 : 1997-12⊗	Medical electrical equipment - Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use (IEC 60601-2-35:1996); German version EN 60601-2-35:1996
DIN EN 60601-2-51 : 2004-02⊗	Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs (IEC 60601-2-51:2003); German version EN 60601-2-51:2003
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	IEC 60601-1-2 : 2001-09⊗ - Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility; Requirements and tests
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 60601-2-2 : 2006-07⊗ - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-2-3 : 1991-06⊗	Medical electrical equipment; part 2: particular requirements for the safety of short-wave therapy equipment + Amendment 1 : 1998-09
IEC 60601-2-5 : 2000-07⊗	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
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 60601-2-24 : 1998-02⊗	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers

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IEC 60601-2-25 : 2011-10	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electro-cardiographs IEC 60601-2-25 : 1993-03⊗ - Medical electrical equipment - Part 2-25: Particular requirements for the safety of electro-cardiographs + A1:1999
IEC 60601-2-27 : 2011-03	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardio-graphic monitoring equipment + Cor.:2012 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 60601-2-30 : 1999-12⊗	Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cyclic non-invasive blood pressure monitoring equipment
IEC 60601-2-35 : 1996-10⊗	Medical electrical equipment - Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use
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 61326-2-6 : 2012-07	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

Abbreviations used:

CENELEC	European Committee for Electrotechnical Standardization
DIN	German Institute for Standardization (Deutsches Institut für Normung)
EN	European standard
IEC	International Electrotechnical Commission
Medical devices, active	Medical electrical equipment, medical electrical systems and components
⊗	Withdrawn standards

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[1] DIN EN ISO/IEC 17025:2018: 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 98/78/EWG of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices