Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-12032-01-01 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **2020-08-11**

Date of issue: 2020-08-11

Holder of certificate:

Obering. Berg & Lukowiak GmbH
Löhner Straße 157, 32609 Hüllhorst

Field: Medical devices and the Directive 93/42/EEC[2] and 90/385/EEC[3]

Testing fields/test items: Safety tests and compatibility tests with regard to electromagnetic disturbances (EMC) of active medical devices

1) Safety tests

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Safety tests	Medical devices, active	Compliance tests Components and ME-Systems Electrical tests and protection against electrical hazards Mechanical strength and protection against mechanical hazards	DIN EN 60601-1 IEC 60601-1

The management system requirements in DIN EN ISO/IEC 17025 are written in language relevant to operations of testing laboratories and 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

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Safety tests	Medical devices, active	Protection against excessive temperatures incl. prevention of fire Environmental simulation tests	
	Information provided by the manufacturer - for components and assemblies - user manual / accompanying documents - risk management file	Compliance tests	

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.

2) EMV

Testing Area	Test Object Product(category)	Test type Test	Standard Test method
EMC	Medical devices, active - not life-sustaining only	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	

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.

Standards[4]

DIN EN 60601-1:2013-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012); German version EN 60601-1:2006 + Cor. :2010 + A1:2013 VDE 0750-1:2013-12 DIN EN 60601-1:2007-07⊗ - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005); German version EN 60601-1:2006; including AC:2010 DIN EN 60601-1:1996-03⊗ - Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988 + A1:1991 + A2:1995); German version EN 60601-1:1990 + A1:1993 + A2:1995 VDE 0750-1:1996-03
DIN EN 60601-1-2:2016-05	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014); German version EN 60601-1-2:2015 DIN EN 60601-1-2:2007-12 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007, modified); German version EN 60601-1-2:2007 VDE 0750-1-2:2007-12 DIN EN 60601-1-2:2006-10⊗ - Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2001 + A1:2004); German version EN 60601-1-2:2001 + A1:2006-

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 + Corrigendum 1 : 2014
	IEC 60601-1 : 1988⊗ - Medical electrical equipment; part 1: general requirements for safety + Amendment 1 : 1991-11 + Amendment 2 : 1995-03 + Corrigendum 1 : 1995-06
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

Abbreviations used:

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

[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 90/385/EWG of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

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