Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-20829-01-00 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **22.01.2020**

Date of issue: 22.01.2020

Holder of certificate:

Qualitätsplan 24 GmbH
Isaac-Newton-Str. 4, 23562 Lübeck

Tests in the fields:

Field: Medical devices

Testing fields/test items: Safety testing of active medical devices

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

Safety Test

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Safety tests	Medical devices, active	Verification of compliance Components and ME systems Electrical tests and protection against electrical hazards Mechanical strength and protection against mechanical hazards Protection against excessive temperatures including fire prevention Environmental simulation tests	DIN EN 60601-1 IEC 60601-1
Safety tests	Information provided by the manufacturer - On components and assemblies - On Biocompatibility - Instructions for use/Accompanying documents - Usability file - On programmable electrical medical systems (PEMS) - Riskmanagement file	Verification of compliance	DIN EN 60601-1 IEC 60601-1

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 Europeanregulations (DIN EN). Where the referenced International versions of the standards are not explicitlylisted in the appendix to the notice, the normative references of international regulations (IEC, ISO) were not taken into account.

Standards[2]

DIN EN 60601-1:2013-12	Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale (IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012); Deutsche Fassung EN 60601-1:2006 + Cor. :2010 + A1:2013
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

Abbreviations used:

DIN	Deutsches Institut für Normung [German Institute for Standardisation]
EN	Europäische Norm [European Standard]
IEC	International Electrical Committee
ISO	International Organization for Standardization
Medical devices, active	Medical electrical devices, medical electrical systems and components

[1] DIN EN ISO/IEC 17025:2018: General requirements for the competence of testing and calibration laboratories

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