Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13383-01-00 according to DIN EN ISO/IEC 17025:2005[1] and the Directive 93/42/EEC[2] and 90/385/EEC[3]

Valid from: 22.11.2018

Date of issue: 22.11.2018

Holder of certificate:

MR COMP GmbH
Buschgrundstraße 33, 45894 Gelsenkirchen

Field:	Medical devices
Testing fields/test items:	Physical measurements and safety measurements of medical devices and implants within an electromagnetic field

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

Testing field	**Test item Device(category)**	**Type of testing Test**	**Regulation Testing method**
Physical measurements	Medical devices and implants	Measurement of Induced Displacement Force	ASTM F2052 ISO/TS 10974 Clause 11
		Measurement of Induced Torque	ASTM F2213 ISO/TS 10974 Clause 12
		Measurement of Induced Heating	ASTM F2182 ISO/TS 10974 Clause 8, 9
		Evaluation of MR Image Artifacts	ASTM F2119
		Radiopacity Determination	ASTM F640
		Measurement of Induced Vibrations	ISO/TS 10974 Clause 10
		Measurement of Induced Electrical Potential	ISO/TS 10974 Clause 13
		Measurement of Induced Malfunction	ISO/TS 10974 Clause 14, 15, 16
		Measurement of Combined Field Effects	ISO/TS 10974 Clause 17
Safety measurements	Medical devices and implants - -Documentation provided by the manufacturer	MR Conformity Mark Determination	ASTM 2503 IEC 62570:2014 ISO/TS 10974 Clause 18

Regulations[4]

ASTM F2052 - 14	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2052 - 15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2213 - 06(2011)	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2213 - 17	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2182 - 11a	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2119 - 07(2013)	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F640 - 12	Standard Test Methods for Determining Radiopacity for Medical Use
ASTM F2503 - 13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
IEC 62570 : 2014	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ISO/TS 10974 : 2018	Assessment of the safety of Magnetic Resonance Imaging for Patients with an active implantable medical device

abbreviations used:

ASTM	American Society for Testing and Materials
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MRT	Device for magnetic resonance imaging
TS	Technical Specifications

-Translation-

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

[4] For the transition periods, see the list of harmonized standards on the homepage of the EU.