DAkkS
Deutsche
Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV
Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

Accreditation

The Deutsche Akkreditierungsstelle GmbH attests that the testing laboratory

MR COMP GmbH
Buschgrundstraße 33, 45894 Gelsenkirchen

is competent under the terms of DIN EN ISO/IEC 17025:2018 to carry out tests in the following fields:

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

The accreditation certificate shall only apply in connection with the notice of accreditation of 27.09.2021 with the accreditation number D-PL-13383-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 03 pages.

Registration number of the certificate: **D-PL-13383-01-00**

Frankfurt am Main, 27.09.2021	Dipl.-Ing. (FH) Ralf Egner Head of Division	Translation issued: 27.09.2021	Head of Division

The certificate together with the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH https://www.dakks.de/en/content/accredited-bodies-dakks.

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

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Spittelmarkt 10
10117 Berlin

Office Frankfurt am Main
Europa-Allee 52
60327 Frankfurt am Main

Office Braunschweig
Bundesallee 100
38116 Braunschweig

The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). DAkkS is a signatory to the Multilateral Agreements for Mutual Recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

The up-to-date state of membership can be retrieved from the following websites:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu

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Annex to the Accreditation Certificate D-PL-13383-01-00 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **27.09.2021**

Date of issue: 27.09.2021

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

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 the annex reflects the status as indicated by the date of issue.
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Abbreviations used: see last page

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On-site tests in the field of physical testing and safety testing

Scope

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

Valid from: 27.09.2021
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Regulations

ASTM F640 - 20	Standard Test Methods for Determining Radiopacity for Medical Use
ASTM F2052 - 15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2119 - 07(2013)	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2182 - 19e2	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213 - 17	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2503 – 20	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
IEC 62570:2014-02	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ISO/TS 10974:2018-04	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
MR	Magnetresonanz
TS	Technical Specification

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