

Certificate

Certificate No.: MD 1419035-1-1

Manufacturer: **RAPID Biomedical GmbH**
Kettelerstr. 3-11
97222 Rimpfing
Germany

REPs Facility ID: F004004

Certification criteria: ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure
Canada Medical Devices Regulations – Part 1 – SOR 98/282
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD
Act
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and development, production and distribution of RF coils, RF
coils interfaces, patient rests and positioning aids for magnetic
resonance tomography

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 1124595-230

Issue Date: 2023-09-05

Effective Date: 2023-09-05

Expiry Date: 2025-05-21



Daniela Wiedemuth

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/0000053394?locale=en
or calling 1-888-743-4652.