Certificate

Certificate No.:	MD 1419035-1-2
Manufacturer:	**RAPID Biomedical GmbH** Kettelerstr. 3-11 97222 Rimpar 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.:	1176611-690
Issue Date:	2025-02-20
Effective Date:	2025-02-22
Expiry Date:	2028-02-21

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. Fabian Pilatus
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124