

Certificate

Certificate No.: Manufacturer: MD 2215159-1-1

Nova Medical Inc

150 West St., Ste 201 Wilmington MA 01887 USA

REPs Facility ID: Certification criteria: F004487

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,

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Scope:

Design and Development, Manufacture, Distribution, and Service of MRI Coils

TUV Rheinland

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.:	234216012-12
Issue Date:	2024-09-16
Effective Date:	2024-10-18
Expiry Date:	2027-10-17



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Certification officer: Melissa Di Buono-Russo TUV Rheinland of North America, Inc.

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

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