

Certificate

Certificate No.: MD 2215159-1

Manufacturer: **Nova Medical Inc.**
150 West Street, Suite 201
Wilmington MA 01887
USA

REPs Facility ID: F004487

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
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

TÜV 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.: 234173639-33

Issue Date: 2021-10-18

Effective Date: 2021-10-20

Expiry Date: 2024-10-17



Certification officer: S. Liu
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/0000000000?locale=en
or calling 1-888-743-4652.