EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2215159-1

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

EUDAMED Single Registration No.: US-MF-000009719

Products: Products of Class IIa:
Z110590 - VARIOUS MAGNETIC RESONANCE IMAGING INSTRUMENTS

Authorised representative(s): **Emergo Europe B.V.**
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Certificate history		
Revision:	Description:	Issue date:
1	Initial Revision	2021-11-22

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 234177924-20

Effective date: 2021-11-22

Expiry date: 2026-10-07

Issue date: 2021-11-22

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierstelle

S. Liu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.