Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Ms. Cheryl Ledden
Nova Medical Inc.
150 West Street, Suite 201
WILMINGTON 01887
USA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date November 07, 2016

Application for : Vollst. QMS, Anhang II MDD
Certificate No. : HD 60113078 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Ms. Ledden,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. HD 60113078 0001.

Kind regards

Certification body

Jürgen Welte

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60113078 0001

Report No.: 31690714 002

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

Products: MRI Coils

Expiry Date: 2021-11-06

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-11-07

Date: 2016-11-07

Notified Body

TÜV Rheinland LGA Products GmbH

Jürgen Welte

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.