EC Certificate

TÜVRheinland®

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

Registration No.: HD 1274285-1

Manufacturer: Enraf-Nonius B.V.
Vareseweg 127
3047 AT Rotterdam
Netherlands

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Enraf-Nonius B.V. Vareseweg 127 3047 AT Rotterdam Netherlands	- Devices for stimulation - Active rehabilitation devices
/02	Enraf-Nonius B.V. Voltaweg 22 6101 XK ECHT Netherlands	- Devices for stimulation - Active rehabilitation devices

Report No.: 3336773-30

Effective date: 2021-04-16

Expiry date: 2024-05-26

Issue date: 2021-04-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Dipl.-Ing. F. Schwingen
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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Products:
- Devices for stimulation
- Active rehabilitation devices

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.

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