

EC Certificate

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

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.


Report No.: 3336773-30

Effective date: 2021-04-16

Expiry date: 2024-05-26

Issue date: 2021-04-16




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.

EC Certificate



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

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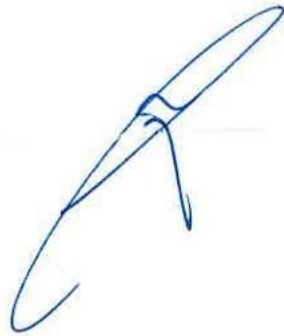


A handwritten signature in blue ink, appearing to read 'F. Schwingen'.
Dipl.-Ing. F. Schwingen
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Seen for legalization of the signature of Mr. Thomas Jozef Doodkorte, born at Nieuwer-Amstel on the 7th day of March 1962, passport number NV4CD9026, which signature is placed at the other side of this document, by me, Mr R.R. Rijnvis, Notary Public, practicing at Krimpen aan den IJssel (The Netherlands) on the 26th day of May 2021.

This legalization provides no guarantee whatsoever of the content, authenticity or execution of the document on which the legalized signature is placed, nor does it implicate any responsibility or liability with regard to this document.



Legalisation

Seen for legalisation of the signature of

mr. R.R. Rijnvis
acting in the capacity of notary at Krimpen aan den IJssel

Date: 01-07-2021
No.: 21 219

By me, President of the District Court of Justice
Rotterdam,

mr. R.G. de Lange-Tegelaar



Ministerie van Buitenlandse Zaken

Gezien voor legalisatie van de handtekening
The undersigned legalises the signature

van/of **R.G. de Lange-Tegelaar**

De minister van Buitenlandse Zaken, voor deze,
For the minister of Foreign Affairs,



02 jul 2021 - L. Stuijtzand



CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ CONSULAR AUTHENTICATION

- Quốc gia/ Country: **VIỆT NAM**
Giấy tờ, tài liệu này / This public document
- do ông/bà **L. STUIJFZAND** ký
has been signed by
- với chức danh **Viên chức BNG Hà Lan**
acting in the capacity of
- và con dấu của: **Bộ Ngoại giao Hà Lan**
bears the seal/stamp of
được chứng nhận/hợp pháp hóa lãnh sự / certified
- tại/ at: **The Hague**
- Ngày/ the: **05/07/2021**
- Cơ quan cấp/ by: **Đại sứ quán Việt Nam tại Hà Lan**
- Số/ No: **213B** /2021

TL. Đại sứ
Bí thư thứ Hai



Nguyễn Quỳnh Hoa