



EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of ENRAF-NONIUS B.V., Vareseweg 127, 3047 AT Rotterdam, The Netherlands

Quality Management System according to EN ISO 13485:2016 and Annex II (excl. section 4) of European Medical Devices Directive 93/42/EEC.

Registration No. HD 1274285-1

Notified body: TÜV Rheinland LGA Products GmbH (0197), Tillystraße 2, 90431 Nürnberg, Germany

Device name:	Endomed 482
Description:	Electrotherapy Equipment
Article number(s):	0498920 (base unit) 1498920
Classification:	Ila (according to rule 9, Annex IX of MDD 93/42/EEC)
Record of conformity:	026-400-253-46 ERC
Device marking:	CE0197

We hereby declare that the above-mentioned device complies with the European Medical Devices Directive 93/42/EEC.

This declaration of conformity is valid in combination with the test certificate of the device. Any modifications to the product not authorized by Enraf-Nonius will invalidate this declaration.

Rotterdam, 25 February 2021

Signature:

A handwritten signature in blue ink, appearing to be 'Th. J. Doodkorte', written over a horizontal line.

Th. J. Doodkorte
Commercial Director