



## 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 ISO 13485:2016, EN ISO 13485:2016  
and Annex VII of European Medical Devices Directive 93/42/EEC.

Device name:	EN-Trode Self Adhesive Electrode
Description:	Electrotherapy accessory
Article number(s):	3444.056/057/058
Classification:	I (according to rule 1, Annex IX of MDD 93/42/EEC)
Record of conformity:	192-3444.056-4x
Device marking:	CE

We hereby declare that the above-mentioned device  
complies with the European Medical Devices Directive 93/42/EEC and it has been notified to the  
Dutch Ministry of Health.

Any modifications to the product not authorized by Enraf-Nonius will invalidate this declaration.

Rotterdam, date: 28 February 2019

Signature:

A handwritten signature in blue ink, appearing to be 'Th.J. Doodkorte'.

Th.J. Doodkorte  
Commercial Director