Declaration of Conformity

EU Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of **Enraf-Nonius B.V**.
Quality Management System according to EN ISO 13485:2016

Product name:	Flexible rubber electrodes
Catalogue number(s):	1460272 (Flexible rubber electrodes 4x6 cm, 4 mm female, 2 pcs) 3444106 (Silicon electrode 5x9 cm, 2mm female, 2 pcs) 3444128 (Flexible rubber electrodes 4x6 cm, 2 mm female, 2 pcs) 3444129 (Flexible rubber electrodes 6x8 cm, 2 mm female, 2 pcs) 3444130 (Flexible rubber electrodes 8x12 cm, 2 mm female, 2 pcs) 3444380 (Silicon electrode 5x5 cm, 1 pc)
Basic UDI-DI:	871999250814602653Z
Intended purpose:	Electrotherapy accessory Flexible rubber electrode for electrostimulation
Risk class:	I, according to rule 1 in Annex VIII of (EU) 2017/745
Device marking:	CE

The device covered by this declaration is in conformity with:
(EU) 2017/745 (Medical Device Regulation)
2011/65/EU as amended by (EU) 2015/863 (RoHS Directive)

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

Signed for and on behalf of Enraf-Nonius B.V.:

Tom
Doodkorte

T. Doodkorte
Commercial Director

Place: Rotterdam
Date of issue: 30 April 2021

Enraf-Nonius B.V.
Vareseweg 127
3047 AT Rotterdam
The Netherlands
SRN (NL-MF-000000429)