

# 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:	Sponges
Catalogue number(s):	1460266 (Moist pads for rubber electrodes 6x8 cm, 4 pcs) 1460273 (Moist pads for rubber electrodes 4x6 cm, 4 pcs) 1460275 (Moist pads for rubber electrodes 8x12 cm, 4 pcs) 3444505 (Sponges for vacuum electrode Ø 60 mm, 4 pcs) 3444506 (Sponges for vacuum electrode Ø 90 mm, 4 pcs) 3444516 (Sponges for vacuum electrode Ø 30 mm, 4 pcs)
Basic UDI-DI:	8719992508146026643
Intended purpose:	Electrotherapy accessory Contact medium between electrode and the body to ensure efficient transfer of energy.
Risk class:	I, according to rule 1 in Annex VIII of (EU) 2017/745
Device marking:	<b>CE</b>

The device covered by this declaration is in conformity with:  
(EU) 2017/745 (Medical Device Regulation)

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

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

T. Doodkorte  
Commercial Director

Place: Rotterdam  
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