

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:	Gelpad StatUS
Catalogue number(s):	3442941 (Gelpad StatUS flow wrap of 240 pcs (5x48))
Basic UDI-DI:	871999250834429405E
Intended purpose:	Ultrasonic therapy accessory for StatUS Pack
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)

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
Date of issue: 30 April 2021

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