

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 II of European Medical Devices Directive 93/42/EEC.

Device name:

Radarmed 650+

Description:

Microwave therapy Equipment

Article number(s):

1435.901

Classification:

IIa (according to rule 9, Annex IX of MDD 93/42/EEC)

Record of conformity:

026-400-095-4x ER

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 authorised by Enraf-Nonius will invalidate this declaration.

Rotterdam, date:

28 February 2019

Signature:

Th.J. Doodkorte

Commercial Director