



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:	Hot/Cold Packs
Description:	Thermal therapy accessory
Article number(s):	3448.207/208/209
Classification:	I (according to rule 1, Annex IX of MDD 93/42/EEC)
Record of conformity:	192-3448.207-4x
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:



Th.J. Doodkorte
Commercial Director