

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

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|----------------------|---|
| Product name: | Colpac |
| Catalogue number(s): | 3448284 (Colpac 28x36 cm) |
| Basic UDI-DI: | 8719992508344828469 |
| Intended purpose: | Thermal therapy accessory |
| 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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