

EC – Declaration of Conformity

Manufacturers Name: Orfit Industries N.V.

SRN (Single Registration Number): BE-MF-000007872

Manufacturers Address: Vosveld 9a, 2110 Wijnegem, Belgium

Basic UDI-DI: 5420028700044S

Name of the Device(s): Thermoplastic-moulding water bath - Suspan 1 & Suspan 2

Intended use: For the heating of thermoplastic materials in physical rehabilitation

Product code(s): 35097/230/1400, 35097/230/1400/UK, 35097/115/1400, 32502/230EU, 32502/115US, 32502/230UK, 35123/120US, 35123/230EU

Classification: Class I, according the rules of Annex VIII

Conformity assessment route: Orfit Industries N.V. uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745:

Class I: EC conformity declaration according to Annex IV.

Applied norms:

- ISO 13485:2016
- ISO 14971:2019
- ISO 15223-1:2021
- EN 55011 - 2011
- EN 55011 - 2018 (Class B)
- EN 60601-1-2
- EN 61000 - 3
- EN 61000 - 4
- EN 61010 -1

This declaration of conformity is issued under the sole responsibility of Orfit Industries N.V. We hereby declare that the medical device(s) specified above meet the provisions of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval ISO 13485:2016 issued by LRQA. All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 16 October 2025



Quality Assurance & Regulatory Affairs Manager