Leader in thermoplastic innovations

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, 35097/RE, 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, 22 May 2024

Quality Assurance & Regulatory Affairs Manager

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