orfit 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:	5420028700555B
Name of the Device(s):	Vacuum pumps
Intended use:	To create a vacuum in the vacuum bags which are used for Patient Positioning and Immobilization for Radiation Oncology
Product code(s):	18054, 18097, 18098, 18058/230EU, 18058/230UK, 18058/230CH, 18058/100J, 18058/115, 18076/230EU , 18076/230UK, 18076/230CH, 18076/100J, 18076/115, 18076/230CN, 18058/230CN
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 61010-1 EN 61000-3-2/3 EN 55014-1/2 EN 50581

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 April 2025

Quality Assurance & Regulatory Affairs Manager