

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: 54200287002858

Name of the Device(s): Raycast® High Precision – Thermoplastic Bolus Material

Intended use: Patient Positioning and Immobilization for Radiation Oncology

Product code(s): 703011/1, 8336.S01/R/53, 8336.S01/R/58, 8336.S01/R/59, 8336.S01/R/60, 8336.S01/R/53-1CM, 8336.S01/R/58-1CM, 8336.S01/R/59-1CM, 8336.S01/R/60-1CM, 8333N.S01/R, 8313N.S01/R, 18033

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
ISO 10993-5:2009
ISO 10993-10:2010

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 Lloyd's Register EMEA – LRQA.

All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 7 September 2022

Quality Assurance & Regulatory Affairs Manager