Leader in thermoplastic innovations

# EC – Declaration of Conformity

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|---|---|
| **Manufacturers Name:** | Orfit Industries N.V. |
| **SRN (Single Registration Number):** | BE-MF-000007872 |
| **Manufacturers Address:** | Vosveld 9a, 2110 Wijnegem, Belgium |
| **Basic UDI-DI:** | 54200287003657 |
| **Name of the Device(s):** | Raycast® High Precision - Base Plate-To-Couch Fixation Devices |
| **Intended use:** | Patient Positioning and Immobilization for Radiation Oncology |
| **Product code(s):** | 32154, 32166, 32070/17, 32151, 32191, 32197, 32165, 32208, 32190, 33213, 32207, 32209, 33213, 33220, 35744/6, 33106, 33119, 33217, 33109, 33221, 35747, 35747/6, 32063, 35747/4, 35747/8, 38228, 32126, 32813, 38221, 32317/16, 32066, 33167, 32822, 32045, 32043, 32814, 32815, 32816, 32817, 33163, 35745, 33219, 32002, **38250** |
| **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:<br><br>Class I: EC conformity declaration according to Annex IV. |
| **Applied norms:** | ISO 13485:2016<br>ISO 14971:2019<br>ISO 15223-1:2021<br>ISO 10993-5:2009<br>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, 13 December 2022

*Quality Assurance & Regulatory Affairs Manager*


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