



**Leader in
thermoplastic
innovations**

EC – Declaration of Conformity

We hereby declare that for the products listed below Orfit Industries NV is in compliance with the directive 93/42/EC of the European Community and that it fulfills all the essential and other requirements put forward in the directive with respect to medical devices of class 1.

**Raycast® High Precision
Nanor® Thermoplastic Material for Patient Immobilisation
Masks for Head, Neck and Shoulders**

**35763/16MI+N
33700/2MI+N**

Product description: Non active, noninvasive medical device class1.
Thermoplastic material, precut or in sheet form for patient
Immobilization in radiotherapy.

Applied norms: Directive 93/42/EC ISO 13485
ISO 10993
ISO 14971

Per annex VII of the Royal Decree of 18/03/1999 for medical devices.

Eddy Marivoet,
Wijnegem, 28 February 2018

*Quality Assurance & Regulatory Affairs
Manager*