



**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 for push pin hardware**

**35768/16MI+N  
33770/2MI+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*