



### 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 fulfils all the essential and other requirements put forward in the directive with respect to medical devices of class 1.

**Raycast® High Precision  
Efficast Masks for Head, Neck and Shoulders  
Hybrid Masks**

33759/16MI/12MI+N  
33740/NH  
33740/2MA/12MI+N  
33740/2MA/12MI+N/NH  
33740/2MI/NH  
33737/NH  
33733/16MI/12MI+N  
33730/NH  
33730/NH/G17  
33730/2MA/12MI+N  
33730/2MA/12MI+N/NH  
33730/2MA/12MI+N/G17  
33730/2MA/12MI+N/NH/G17

33782/16MI/12MI+N  
33783/16MI/12MI+N  
33748/2MA/12MI+N/NH  
33749/2MA/12MI+N/NH  
33785/16MI/12MI+N  
33787/16MI/12MI+N  
33750/2MA/12MI+N/NH  
33748/NH  
33749/NH  
33750/NH  
33737/2MA/12MI+N/NH  
33791/2MA/12MI+N

Product description: Non active, non-invasive medical device class 1.  
Thermoplastic material, pre-cut or in sheet form for patient immobilization in radiotherapy.

Per annex VII of the Royal Decree of 18/03/1999 for Medical Devices.

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

Eddy Marivoet,  
Wijnegem, 25 January 2018

*Quality Assurance & Regulatory Affairs  
Manager*