



**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  
Efficast® Masks, Nanor Masks and Hybrid Masks with Nanor for Patient Immobilisation  
Head, Neck and Shoulders**

33776/2MA	35760/EFF2MA	33700/2MA/EM	33782/16MI/12MI+N
35763/16MI	35779/2MA	33730/4	33783/16MI/12MI+N
35763/16MI/NH	35779/2MA/M	33700/2MI+N	33748/2MA/12MI+N/NH
35763/16MI/M	35779/2MA/EM	33710/2MA	33749/2MA/12MI+N/NH
35763/16MI/EM	35764/16MI	33710/2MA/NH	33785/16MI/12MI+N
35760/EFF16MI	35764/16MI/EM	33688/2MA	33787/16MI/12MI+N
35760/EFF16MI/M	35764/2MA	33705/2MA	33750/2MA/12MI+N/NH
35760/EFF16MI/EM	35764/2MA/NH	33702/2MA	33735/16MI/12MI+N
35779/16MI	35764/2MA/M	33759/16MI/12MI+N	
35779/16MI/M	35764/2MA/EM	33740/2MA/12MI+N/NH	
35763/16MI	35764/2MI+N	33737/2MA/12MI+N/NH	
35763/16MI+N	33700/16MI	33733/16MI/12MI+N	
35763/2MA	33700/16MI/M	33730/2MA/12MI+N	
35763/2MA/NH	33700/16MI/EM	33730/2MA/12MI+N/NH	
35763/2MA/M	33700/2MA	33730/2MA/12MI+N/G17	
35763/2MA/EM	33700/2MA/NH	33730/2MA/12MI+N/NH/G17	
35763/2MA/G35	33700/2MA/M	33791/2MA/12MI+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, 20 August 2019

Quality Assurance & Regulatory Affairs  
Manager