

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
Head, Neck and Shoulder Fixation for other hardware**

35772/16MI	35774/2MA	33755/2MA/12MI+N
35772/2MA	35791/16MI	33755/2MA/12MI+N/NH
35773/16MI	33770/2MA	33784/16MI/12MI+N
35768/16MI	35791/2MA	33766/2MA/12MI+N/NH
35776/16MI	33770/2MI	33786/16MI/12MI+N
35768/16MI+N	35791/2MI	33777/2MA/12MI+N/NH
35773/2MA	33770/2MI+N	
35773/2MA/3D	33690/2MA	
35768/2MA	33691/2MA	
35776/2MA	33780/16MI/12MI+N	
35773/2MI	33747/2MA/12MI+N	
35768/2MI	33747/2MA/12MI+N/NH	
35768/2MI/3D	33781/16MI/12MI+N	
35776/2MI	33739/2MA/12MI+N	
35774/16MI	33739/2MA/12MI+N/NH	

Product description: Non active, noninvasive medical device class 1.
Thermoplastic material, precut or in sheet form for patient
Immobilization in radiotherapy.

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