



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 for Head, Neck and Shoulder Fixation for Push-Pin Hardware without Profiles

35772/16MI/NP	35774/16MI/NP	35674
35772/2MA/NP	35774/2MA/NP	35675
35773/16MI/NP	35791/16MI/NP	
35768/16MI/NP	33770/2MA/NP	
35776/16MI/NP	35791/2MA/NP	
33761/16MI/NP	33770/2MI/NP	
35773/2MA/NP	35791/2MI/NP	
35768/2MA/NP		
35776/2MA/NP		
35773/2MI/NP	33690/2MA/NP	
35768/2MI/NP	33691/2MA/NP	
35776/2MI/NP		

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 10993 ISO 13485 ISO 14971

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

Eddy Marivoet, Wijnegem, 30 August 2017

Quality Assurance & Regulatory Affairs Manager