

**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**

35772/16MI	33770/2MA	35774/16MI
35772/2MA	35768/2MA	35774/2MA
35773/16MI	33770/16MI	35791/16MI
35768/16MI	33789/16MI	33770/2MA
35776/16MI	33789/2MA	35791/2MA
35773/2MA	33790/16MI	33770/2MI
35768/2MA	33790/2MA	35791/2MI
35776/2MA		35773/2MA/3D
35773/2MI	32199	35768/2MI/3D
35768/2MI		33690/2MA
35776/2MI		33691/2MA

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, 15 November 2018

*Quality Assurance & Regulatory Affairs Manager*