



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® Thermoplastic Material for Patient Immobilisation
Masks for Head, Neck and Shoulders**

35763/16MI	35760/EFF2MA/EM	33700/2MA/EM
35763/16MI/NH	35779/2MA	33730/4
35763/16MI/M	35779/2MA/M	33710/2MA
35763/16MI/EM	35779/2MA/EM	33710/2MA/NH
35760/EFF16MI	35764/16MI	33688/2MA
35760/EFF16MI/M	35764/16MI/M	33705/2MA
35760/EFF16MI/EM	35764/16MI/EM	35763/2MI
35779/16MI	35764/2MA	33700/2MI
35779/16MI/M	35764/2MA/NH	33702/2MA
35779/16MI/EM	35764/2MA/M	33710/2MI
35763/2MA	35764/2MA/EM	
35763/2MA/NH	33700/16MI	
35763/2MA/M	33700/16MI/M	
35763/2MA/EM	33700/16MI/EM	
35763/2MA/G35	33700/2MA	
35760/EFF2MA	33700/2MA/NH	
35760/EFF2MA/M	33700/2MA/M	

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, 30 August 2017

Quality Assurance & Regulatory Affairs
Manager