



**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  
Masks for Extracranial Immobilization**

33715/2MA  
33716/2MA  
33775/2MI/12MI+N  
33683/32MA  
33788/2MI/12MI+N  
35727/32MA  
35728/32MA  
35790/2MA  
33723/32MA/L  
33723/32MA/R  
33778/2MA/NP  
35797/2MA/NP  
35788/32MA  
35787/32MA

35784/32MA  
35780/32MA  
35710/32MA  
35711/32MA  
35712/32MA  
33774/2MA/12MI+N  
35792/32MA  
35793/32MA  
35794/2MI  
35795/2MI  
35796/2MI  
33717/2MA  
33724/32MA  
35799/2MI/R  
35799/2MI/L

**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, 20 August 2019

*Quality Assurance & Regulatory Affairs Manager*