



**Leader in  
thermoplastic  
innovations**

### 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  
Accessories  
Head Supports – Regular Density**

**35758-MD  
35758ZF-MD  
35713-MD  
35713ZF-MD  
35714-MD  
35714ZF-MD  
32702-MD  
32399-MD**

**32706-MD  
32701-MD**

**Product description:**

Non active, noninvasive medical device class 1.  
Positioning accessories 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