



### 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 Positioning aids for Arms and Shoulders**

**32042**

**32107**

**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 13485  
                                  ISO 10993  
                                  ISO 14971

Per annex VII of the Royal Decree of 18/03/1998 for medical devices.

Eddy Marivoet,  
Wijnegem, 30 August 2017

*Quality Assurance & Regulatory Affairs Manager*