



**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®  
Uon™ - Duon™  
Base Plates**

**32097  
32097/9**

**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 18/03/1999 for Medical Devices.

Eddy Marivoet,  
Wijnegem, 30 August 2017

*Quality Assurance & Regulatory Affairs Manager*