



**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® Masks for Head, Neck and Shoulder Fixation for other hardware without profiles**

<b>35772/16MI/NP</b>	<b>35774/16MI/NP</b>	<b>35674</b>
<b>35772/2MA/NP</b>	<b>35774/2MA/NP</b>	<b>35675</b>
<b>35773/16MI/NP</b>	<b>35791/16MI/NP</b>	
<b>35768/16MI/NP</b>	<b>33770/2MA/NP</b>	
<b>35776/16MI/NP</b>	<b>35791/2MA/NP</b>	
<b>33761/16MI/NP</b>	<b>33770/2MI/NP</b>	
<b>35773/2MA/NP</b>	<b>35791/2MI/NP</b>	
<b>35768/2MA/NP</b>		
<b>35776/2MA/NP</b>		
<b>35773/2MI/NP</b>	<b>33690/2MA/NP</b>	
<b>35768/2MI/NP</b>	<b>33691/2MA/NP</b>	
<b>35776/2MI/NP</b>		

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*