

### 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  
Base Plates

<b>32110</b>	<b>32150/HX</b>	<b>32124/MR</b>
<b>32111</b>	<b>32148</b>	<b>32110/MR</b>
<b>32113</b>	<b>29099</b>	<b>32809</b>
<b>32113MR</b>	<b>32110/7</b>	<b>32110/12</b>
<b>32117</b>	<b>32110/8</b>	<b>32130-COMBI1</b>
<b>32117MR</b>	<b>32110/9</b>	<b>32110-COMBI1</b>
<b>29102</b>	<b>32044</b>	<b>32150-COMBI1</b>
<b>32064</b>	<b>35751N</b>	<b>32130-COMBI2</b>
<b>29105</b>	<b>35754/6N</b>	<b>32110-COMBI2</b>
<b>32130</b>	<b>32122</b>	<b>32150-COMBI2</b>
<b>32140</b>	<b>32123</b>	<b>35751N-COMBI1</b>
<b>32150</b>	<b>32124</b>	<b>35751N-COMBI2</b>
<b>32150-PED</b>	<b>32130/MR</b>	<b>35754/6N-COMBI</b>
<b>32150/3</b>		

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, 16 August 2018

Quality Assurance & Regulatory Affairs Manager