

**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.

**S.B.R.T.  
(Stereotactic Body Radiation Therapy Immobilization System)**

<b>32317/1</b>	<b>32317/3</b>	<b>32317</b>
<b>32317/14</b>	<b>29029/SBRT</b>	<b>32327</b>
<b>32317/2</b>		<b>32336</b>
<b>32317/10</b>		<b>32337</b>
<b>32317/9</b>		<b>32333</b>
<b>32317/4</b>		<b>32334</b>
<b>32317/5</b>		<b>32331</b>
<b>32317/6</b>		<b>32332</b>
<b>32317/8</b>		<b>32342</b>
<b>32317/11</b>		<b>32015/9/2</b>
<b>32317/15</b>		<b>32015/9/3</b>
<b>32317/19</b>		<b>32317/4/1</b>
<b>32317/16</b>		<b>32317/5/1</b>
<b>32317/18</b>		<b>32317/1/HX</b>

**Product description:**

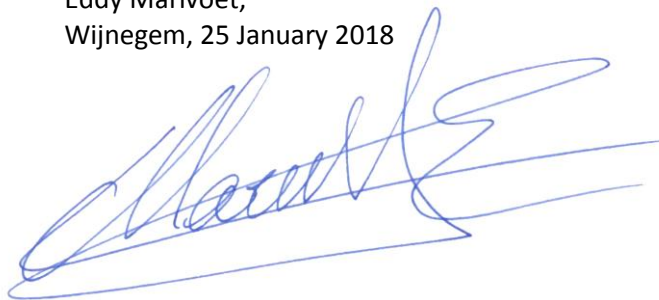
Non active, noninvasive medical device class 1.  
Positioning accessories for patient immobilization in radiotherapy.

**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, 25 January 2018



*Quality Assurance & Regulatory Affairs Manager*