



**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.

**The AIO Solution®  
All-in-one patient positioning system**

<b>32204</b>	<b>29014-V2</b>	<b>29025-V2</b>	<b>32301/HX</b>	<b>32316</b>
<b>32204-PED</b>	<b>29015-V2</b>	<b>29021-V2</b>	<b>32306</b>	<b>32315</b>
<b>32301</b>	<b>29016-V2</b>	<b>29022-V2</b>	<b>32221</b>	<b>32301-PED/NOLS</b>
<b>32301/NOLS</b>	<b>29017-V2</b>	<b>29026</b>	<b>32321</b>	<b>32301-PED/SS/NOLS</b>
<b>32301/MR</b>	<b>29018-V2</b>	<b>29027</b>	<b>32271</b>	<b>32301-PED/SS</b>
<b>32301-PED</b>	<b>29019-V2</b>	<b>29028</b>	<b>32371</b>	<b>32371-PED</b>
<b>35754/6N</b>	<b>29112-V2</b>	<b>29029</b>	<b>32251</b>	<b>29037</b>
<b>32140</b>	<b>29000-V2</b>	<b>32015/9</b>	<b>32351</b>	<b>29040</b>
<b>32702-MD</b>	<b>29003-V2</b>	<b>32015/10</b>	<b>32261</b>	<b>29041</b>
<b>35754/8</b>	<b>29004-V2</b>	<b>32015/5</b>	<b>32361</b>	<b>38001</b>
<b>32704</b>	<b>29005-V2</b>	<b>32015/9/1</b>	<b>32211</b>	<b>38002</b>
<b>32700</b>	<b>32054-V2</b>	<b>32015/9/2</b>	<b>32311</b>	<b>38005</b>
<b>32393</b>	<b>29001-V2</b>	<b>32015/9/3</b>	<b>32055</b>	<b>38003</b>
<b>29007-V2</b>	<b>29002-V2</b>	<b>32015/9/5</b>	<b>32056</b>	<b>38004</b>
<b>29008-V2</b>	<b>29006-V2</b>	<b>32015/8</b>	<b>32057</b>	<b>38006</b>
<b>29009-V2</b>	<b>29050</b>	<b>32030</b>	<b>32058</b>	<b>38100</b>
<b>29010-V2</b>	<b>32291</b>	<b>32037</b>	<b>32158</b>	<b>38101</b>
<b>29011-V2</b>	<b>29020-V2</b>	<b>32008</b>	<b>32311/HX-PED</b>	<b>38102</b>
<b>29012-V2</b>	<b>29023-V2</b>	<b>29051</b>	<b>32311/PED</b>	<b>38126</b>
<b>29013-V2</b>	<b>29024-V2</b>	<b>29100</b>	<b>32211/PED</b>	<b>38127</b>
<b>38128</b>	<b>38200</b>	<b>38201</b>	<b>38202</b>	<b>38204</b>
				<b>38205</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, 4 February 2019

*Quality Assurance & Regulatory Affairs Manager*