

**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.

**Vacuum bag cushions**

18055	18058/230EU	18200
18056	18058/230UK	18201
18057	18058/230CH	18202
18068	18058/100J	18203
18069	18076/230EU	18204
18070	18076/230UK	18205
18072	18076/230CH	18206
18079	18076/100J	18207
18080	18076/115	18208
18081	18064	18209
18082	18065	18210
18053	18059	18200/INDEX
18054	29036	18201/INDEX
18097	32030	18202/INDEX
18098		18203/INDEX
		18204/INDEX
		18205/INDEX
		18206/INDEX
		18207/INDEX

**Product description:**

Non active, noninvasive medical device class1.  
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, 9 August 2018

*Quality Assurance & Regulatory Affairs Manager*