



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 Patient Support Cushions

**32005/2-V2
32005/8-V2
32005/8A-V2
32005/4-V2
32005/5-V2
32005/6-V2
32005/10-V2
32005/11-V2**

**32005/14-V2
32005/15-V2
32006-V2
32118
32317/4
32317/4/1
32317/5
32317/5/1**

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, 30 August 2017

Quality Assurance & Regulatory Affairs Manager