



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
Accessories
Blocks and Wedges – Low Density**

**35703
35706
35704
32424
35707
32709
32700
32712**

**32130-COMBI1
32110-COMBI1
32150-COMBI1
32130-COMBI2
32110-COMBI2
32150-COMBI2**

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, 19 February 2019

Quality Assurance & Regulatory Affairs Manager