



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 Thermoplastic Bolus Material

**8336.SO1/R/53
8336.SO1/R/58
8336.SO1/R/59
8336.SO1/R/60
8333.SO1/R
8333N.SO1/R
8313N.SO1/R
703011/1
8336.SO1/R/53-1CM
8336.SO1/R/58-1CM
8336.SO1/R/59-1CM
8336.SO1/R/60-1CM
8333N.SO3/R
18034
18035**

Product description:

Non active, noninvasive medical device class 1.
Thermoplastic material, precut or in sheet form 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