



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 Sheet Materials
Efficast®**

8332Y.2/R

8333Y.3/R

8333Y.2/R

8334Y.3/R

8352Y.2/R

8353Y.3/R

8353Y.2/R

8354Y.3/R

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