



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.

Thermofit

32390

32391

32392

32405/10

32406/10

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, 22 June 2018

Quality Assurance & Regulatory Affairs Manager