Leader in thermoplastic innovations

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.

MRI solution for GE, MRI-G solution for Head, Neck & Shoulders.

29111-G

Product description:

Non active, noninvasive medical device class1.
Thermoplastic material, precut or in sheet form for patient Immobilization in radiotherapy.

Applied norms:

Directive 93/42/EC	ISO 10993
	ISO 13485
	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

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