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.

Orfilight® Black NS

Sheets	Pre-cuts
8332Z.2/L/NS	35810Z/L/NS
8338Z.2/L/NS	35811Z/L/NS
8334Z.1/L/NS	35812Z/L/NS
8334Z.4/L/NS	35814Z/L/NS
	35815Z/L/NS
	35816Z/L/NS
	35820Z/L/NS
	35821Z/L/NS
	35822Z/L/NS

Product description:

Non active, noninvasive medical device class 1.
Thermoplastic material in sheet form tor the production of splints, orthoses and other limb supporting elements.

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, 31 August 2017

Quality Assurance & Regulatory Affairs Manager

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