orfit 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.

Orfit® Colors NS

8133PU.1/NS	**8133Z.2/NS**	**8134MB.4/NS**
8133GR.1/NS	**8133R.2/NS**	**8134GO.4/NS**
8133Z.1/NS	**8133B.2/NS**	
8133B.1/NS	**8133FP.2/NS**	
8133B.1/NS	**8133MG.2/NS**	
8133FP.1/NS	**8133MB.2/NS**	
8133MG.1/NS	**8133GO.2/NS**	
8133MB.1/NS	**8134MG.1/NS**	
8133GO.1/NS	**8134MB.1/NS**	
8133PU.2/NS	**8134GO.1/NS**	
8133GR.2/NS	**8134MG.4/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, 8 February 2019

Quality Assurance & Regulatory Affairs Manager

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