



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.

Colorfit® NS

8333B.1/NS

8333B.2/NS

8334B.1/NS

8333Z.1/NS

8333Z.2/NS

8334Z.1/NS

8333R.1/NS

8333R.2/NS

8333FP.1/NS

8333FP.2/NS

8333PU.1/NS

8333PU.2/NS

Product description:

Non active, noninvasive medical device class 1.
Thermoplastic material in sheet form for 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 18/03/199 for Medical Devices.

Eddy Marivoet,
Wijnegem, 31 August 2017

*Quality Assurance & Regulatory Affairs
Manager*