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® NS

8332.SO1/NS	**8354.SO1/NS**
8332.SO2/NS	**8354.SO3/NS**
8333.SO1/NS	**8354.SO4/NS**
8333.SO2/NS	**8334.ST1/NS**
8333.SO2+/NS	**8334.ST4/NS**
8333.SO3/NS	**8354.ST1/NS**
8333.SO4/NS	**8354.ST4/NS**
8338.SO2/NS	**8355.SO1/NS**
8334.SO1/NS	**8355.SO4/NS**
8334.SO3/NS	**8355.ST1/NS**
8334.SO4/NS	**8355.ST4/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, 20 February 2018

Quality Assurance & Regulatory Affairs Manager

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