



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.

Soft-Fit® NS

8434.1/NS

8434.4/NS

8454.1/NS

8454.4/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 18/03/1999 for Medical Devices.

Eddy Marivoet,
Wijnegem, 31 August 2017

*Quality Assurance & Regulatory Affairs
Manager*