



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.

Orfitrans™ Soft

37SU/4447
37SU/4463
37SU/4485
37SU/44115

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, 24 October 2017

Quality Assurance & Regulatory Affairs
Manager