



**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™ Excel

37SS42/4480

37SS42/44100

37SS42/44120

37SS42/44150

37SS42/1225122530

37SS42/1225122540

37SS42/4225422550

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*