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.

Orfitrans™ Extra Soft Silicone

37SIL/4490
37SIL/44120

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, 24 October 2017

Quality Assurance & Regulatory Affairs Manager

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