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® Flex NS

1338.1/NS
1338.6/NS
1334.1/NS
1334.6/NS
1354.1/NS
1354.6/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, 31 August 2017

Quality Assurance & Regulatory Affairs Manager

www.orfit.com

ORFIT INDUSTRIES
Vosveld 9A | B-2110 Wijnegem | Belgium
T (+32) (0)3 326 20 26
welcome@orfit.com