



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® Eco

8938N.1
8938N.4
8934N.1
8934N.4
8954N.1
8954N.4
35818/ECO
35820/ECO
35821/ECO
35822/ECO

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 18/03/199 for Medical Devices.

Eddy Marivoet,
Wijnegem, 20 February 2018

*Quality Assurance & Regulatory Affairs
Manager*