



### 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 18/03/1999 for Medical Devices.

Eddy Marivoet,  
Wijnegem, 25 January 2019

*Quality Assurance & Regulatory Affairs  
Manager*