



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.

#### Orfibrace™ NS

##### Sheets

8854.1/NS

8854.6/NS

##### Pre-cuts

35981/OB/NS

35982/OB/NS

35983/OB/NS

35984/OB/NS

#### 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.

Per annex VII of the Royal Decree of 18/03/1999 for Medical Devices.

#### Applied norms:

Directive 93/42/EC    ISO 13485  
                                  ISO 10993  
                                  ISO 14971

Eddy Marivoet,  
Wijnegem, 26 March 2019

Quality Assurance & Regulatory Affairs  
Manager