



### 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.

#### Orficast™ Thermoplastic Tape – Orficast™ More Thermoplastic Tape

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#### 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, 31 August 2017

*Quality Assurance & Regulatory Affairs  
Manager*