

### 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® Classic

8332.S01  
8332.S02  
8333.S01  
8333.S02  
8333.S02+  
8333.S03  
8333.S04  
8338.S02  
8334.S01  
8334.S03  
8334.S04

8334.ST1  
8334.ST4  
8354.S01  
8354.S03  
8354.S04  
8354.ST1  
8354.ST4  
8355.S01  
8355.S04  
8355.ST1  
8355.ST4

#### 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*