

## 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® Colors NS

8133MG.1/NS  
8133MG.2/NS  
8134MG.1/NS  
8134MG.4/NS  
8133MB.1/NS  
8133MB.2/NS  
8134MB.1/NS  
8134MB.4/NS  
8133GO.1/NS  
8133GO.2/NS  
8133PU.1/NS

8134GO.1/NS  
8134GO.4/NS

8133PU.2/NS  
8133GR.1/NS  
8133GR.2/NS  
8133Z.1/NS  
8133Z.2/NS  
8133R.1/NS  
8133R.2/NS  
8133B.1/NS  
8133B.2/NS  
8133FP.1/NS  
8133FP.2/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.

#### 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*