Leader in thermoplastic innovations

EC – Declaration of Conformity

Manufacturers Name:	Orfit Industries N.V.
SRN (Single Registration Number):	Pending until EudaMed implementation
Manufacturers Address:	Vosveld 9a, 2110 Wijnegem, Belgium
Basic UDI-DI:	0542002870012ME
Name of the Device(s):	Orfit® Colors NS
Product code(s):	8133PU.1/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, 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, 8134GO.1/NS, 8134GO.4/NS, 8113MG.1/NS, 8113GO.1/NS, 8113GOMG.1/NS, 8124GO.1/NS, 8124MB.1/NS, 8124MBGO.1/NS, 35810B/NS, 35811B/NS, 35812B/NS, 35810MB/NS, 35811MB/NS, 35812MB/NS, 35810MG/NS, 35811MG/NS, 35812MG/NS, 35810Z/NS, 35811Z/NS, 35812Z/NS, 35814B/NS, 35815B/NS, 35816B/NS, 35814MB/NS, 35815MB/NS, 35816MB/NS, 35814MG/NS, 35815MG/NS, 35816MG/NS, 35814Z/NS, 35815Z/NS, 35816Z/NS, 35830B/NS, 35831B/NS, 35832B/NS, 35830MB/NS, 35831MB/NS, 35832MB/NS, 35830MG/NS, 35831MG/NS, 35832MG/NS, 35830Z/NS, 35831Z/NS, 35832Z/NS, 35900B/NS, 35901B/NS, 35902B/NS, 35900MB/NS, 35901MB/NS, 35902MB/NS, 35900MG/NS, 35901MG/NS, 35902MG/NS, 35900Z/NS, 35901Z/NS, 35902Z/NS
Classification:	Class I, according the rules of Annex VIII
Conformity assessment route:	Orfit Industries N.V. uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745: Class I: EC conformity declaration according to Annex IV.
Applied norms:	ISO 13485:2016 NBN ISO 14971: 2012 ISO 14971:2007 ISO 15223-1:2016 Corrected version 2017-03 ISO 10993-5:2010 ISO 10993-10:2010

This declaration of conformity is issued under the sole responsibility of Orfit Industries N.V. We hereby declare that the medical device(s) specified above meet the provisions of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval ISO 13485:2016 issued by Lloyd's Register EMEA – LRQA.
All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 22 October 2020

Quality Assurance & Regulatory Affairs Manager

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