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.

Orfit® Colors NS Precuts

35810B/NS	**35902MB/NS**	**35831MG/NS**
35811B/NS	**35814MB/NS**	**35832MG/NS**
35812B/NS	**35815MB/NS**	**35810Z/NS**
35900B/NS	**35816MB/NS**	**35811Z/NS**
35901B/NS	**35830MB/NS**	**35812Z/NS**
35902B/NS	**35831MB/NS**	**35900Z/NS**
35814B/NS	**35832MB/NS**	**35901Z/NS**
35815B/NS	**35810MG/NS**	**35902Z/NS**
35816B/NS	**35811MG/NS**	**35814Z/NS**
35830B/NS	**35812MG/NS**	**35815Z/NS**
35831B/NS	**35900MG/NS**	**35816Z/NS**
35832B/NS	**35901MG/NS**	**35830Z/NS**
35810MB/NS	**35902MG/NS**	**35831Z/NS**
35811MB/NS	**35814MG/NS**	**35832Z/NS**
35812MB/NS	**35815MG/NS**	
35900MB/NS	**35816MG/NS**	
35901MB/NS	**35830MG/NS**	

Product description:

Non active, noninvasive medical device class 1.
Thermoplastic material in sheet form tor 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

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