orfit 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.

Orfizip®

39099	**39312**	**39948**
39100	**39313**	**39949**
39101	**39305**	**39950**
39102	**39306**	**39951**
39105	**39316**	**39952**
39106	**39317**	**39953**
39107	**39318**	
39199		
39200	**39399**	
39201	**39400**	
39202	**39401**	
39205	**39402**	
39206	**39403**	
39207	**39404**	
39300	**39405**	
39301	**39406**	
39311		

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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