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 fulfils all the essential and other requirements put forward in the directive with respect to medical devices of class 1.

HP PRO Solution

25000/1	**25000/26**	**25100/16MI+N/NH**
25000/18	**25000/19**	**25105/2MI+N/NH**
25000/20	**25000/25**	**25103/16MI+N/NH**
25000/6	**25070**	**25107/2MI+N/NH**
25000/7/20	**25000/30**	**25101/16MI+N**
25000/17/A	**25000/33**	**45204/32MA/EFF**
25000/17/B	**25100/2MI+**	**18090**
25000/27	**25100/16MI+N**	**18091**
25000/39/20	**25105/2MI+**	**18092**
25000/1/MR	**25105/2MI+N**	**18094**
25000/22	**25100/2MI+/NH**	**32390**
25000/16	**25105/2MI+/NH**	**32391**
25000/28	**25000/36**	**32392**
		25071/10

Product description: Non active, non-invasive medical device class1.
Positioning accessories for patient immobilization in radiotherapy.

Applied norms: Directive 93/42/EC ISO 10993
ISO 13485
ISO 14971

Per annex VII of the Royal Decree of 18/03/1999 for Medical Devices.

Eddy Marivoet,
Wijnegem, 20 August 2019

Quality Assurance & Regulatory Affairs Manager

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