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.

Proton Immobilization System (HP PRO Solution)

25000	**25040**	**25100/2MI+**
25000/1	**25000/1/MR**	**25100/16MI+N**
25000/18	**25000/22**	**25105/2MI+**
25000/20	**25000/16**	**25105/2MI+N**
25000/6	**25000/26**	**25100/2MI+/NH**
25000/7/20	**25000/19**	**25105/2MI+/NH**
25000/17/A	**25000/29**	**25100/16MI+N/NH**
25000/17/B	**25000/25**	**25105/2MI+N/NH**
25020	**25070**	**25100/16MI+N**
25030	**25000/30**	**45204/32MA/EFF**
25000/27	**25000/35**	**25000/28**
25000/16/MR	**25000/33**	**25000/27/MR**

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, 22 June 2018

Quality Assurance & Regulatory Affairs Manager

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