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.

Vacuum bag cushions

18200	**18202/INDEX**
18201	**18203/INDEX**
18202	**18204/INDEX**
18203	**18205/INDEX**
18204	**18206/INDEX**
18205	**18207/INDEX**
18206	**18059**
18207	**29036**
18208	**32030**
18209	**18099**
18210	**18212**
18200/INDEX	**18211**
18201/INDEX	

Product description:

Non active, noninvasive medical device class1.
Positioning accessories for patient immobilization in radiotherapy.

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, 1 August 2019

Quality Assurance & Regulatory Affairs Manager

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