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.

The AIO Solution®

All-in-one patient positioning system

32204	**29014**	**29025**	**32301/HX**	**32316**
32204-PED	**29015**	**29021**	**32306**	**32315**
32301	**29016**	**29022**	**32221**	**32301-PED/NOLS**
32301/NOLS	**29017**	**29026**	**32321**	**32301-PED/SS/NOLS**
32301/MR	**29018**	**29027**	**32271**	**32301-PED/SS**
32301-PED	**29019**	**29028**	**32371**	**32371-PED**
35754/6N	**29112**	**29029**	**32251**	**29037**
32140	**29000**	**32015/9**	**32351**	**29040**
32702-MD	**29003**	**32015/10**	**32261**	**29041**
35754/8	**29004**	**32015/5**	**32361**	
32704	**29005**	**32015/9/1**	**32211**	
32700	**32054**	**32015/9/2**	**32311**	
32393	**29001**	**32015/9/3**	**32055**	
29007	**29002**	**32015/9/5**	**32056**	
29008	**29006**	**32015/8**	**32057**	
29009	**29050**	**32030**	**32058**	
29010	**32291**	**32037**	**32158**	
29011	**29020**	**32008**	**32311/HX-PED**	
29012	**29023**	**29051**	**32311/PED**	
29013	**29024**	**29100**	**32211/PED**	

Product description:

Non active, noninvasive medical device class 1.
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, 22 June 2018

Quality Assurance & Regulatory Affairs Manager

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