



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® Knee & Feet Cushions – Indexed

29053

29054

29055

29054/1

29054/2

29054/3

29054/4

29053/1

29053/2

29053/4

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, 30 August 2017

Quality Assurance & Regulatory Affairs Manager