



**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 pumps

**18058/230EU
18058/230UK/CH
18058/100J
18058/115
18076/230EU
18076/230UK/CH
18076/100J
18076/115**

Product description:

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