



EC – Declaration of Conformity

We hereby declare that for the products listed below Orfit Industries NV is in compliance with the directives of the European Community and that it fulfils all the essential and other requirements put forward in the directive.

Dry Heater II

32503/230EU

32503/230UK

32503/230CH

Product description:

Active, non-invasive medical device class 1.

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, 8 April 2019

Quality Assurance & Regulatory Affairs
Manager