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.

**Dry Heater**

**32501/230EU**
**32501/230UK**
**32501/230CH**
**32501/110US**
**32501/110J**
**32501/14**
**32501/115**
**32501**

Product description:

Non active, noninvasive 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, 31 August 2017

*Quality Assurance & Regulatory Affairs Manager*

www.orfit.com

**ORFIT INDUSTRIES**
Vosveld 9A | B-2110 Wijnegem | Belgium
T (+32) (0)3 326 20 26
welcome@orfit.com