



**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.

**Suspan 1 & Suspan 2**

**35097/230/1400  
35097/230/1400/UK  
35097/115/1400  
32500/0  
32502/230EU**

**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, 9 September 2019

Quality Assurance & Regulatory Affairs  
Manager