ENVITEC
by Honeywell

# EU - Conformity Statement

We declare with sole responsibility that following product comply with the basic requirements according the Council Directive 93/42/EEC in the current valid version (Annex I) concerning medical devices.

Product: **Reusable Pulse Oximetry Sensors**

Typ:

**Soft®Tip large**
R-3211-12MySign®
R-3211-31 MySign®
R-3211-12 plus MySign®
R-3211-31plus MySign®
R-3212-9 MySign®
R-3212-9plus MySign®

**SoftTip® medium**
RM-3211-12 MySign®
RM-3211-31 MySign®
RM-3211-12plus MySign®
RM-3211-31plus MySign®
RM-3212-9 MySign®
RM-3212-9plus MySign®

**SoftTip® small**
RS-3211-12 MySign®
RS-3211-31 MySign®
RS-3211-12plus MySign®
RS-3211-31plus MySign®
RS-3212-9 MySign®
RS-3212-9plus MySign®

**Fingerclip Sensor**
F-3211-12 MySign®
F-3211-31 MySign®
F-3212-9 MySign®

**Ear Sensor**
ES-3211-12 MySign®
ES-3211-31 MySign®
ES-3212-9 MySign®

Classification: **Class IIb**
(RL 93/42/EEC, Annex IX)

CE marking: CE 0123

Notified Body: TÜV SÜD Product Service GmbH, Munich, Germany

Conformity Assessment Process: Annex II, section 3 of the Directive 93/42/EEC

Issued by:
**ENVITEC-WISMAR GMBH**
**Alter Holzhafen 18**
**D-23966 Wismar**
**Germany**

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Place, Date: **Wismar, 2013-04-30**

Authorized Signature:

Marcus Ostländer
Managing Director