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

Valid from: **2013-04-30**

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

Authorized Signature:

Marcus Ostländer
Managing Director