

## EC Declaration of Conformity

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: **Pulse Oximeter**

Typ: **OxiPen®**

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

CE mark: 

Notified Body: TÜV SÜD Product Service GmbH, Munic, 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: **2012-10-01**

Place, Date: **Wismar, 2012-10-01**

Authorized Signature:   
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Marcus Ostländer  
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