

## EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer in accordance with the Council Directive 93/42/EEC in its currently valid version (Annex I) concerning medical devices.

Product: **Pulse Oximeter**

Type: **MySign®S**  
**Inkl. Zubehör**

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

CE mark: 

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany

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

Particular product standard applied: ISO 80601-2-61

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

Valid from: **2016-10-26**  
Valid until: **2019-10-25**

Place, Date: Wismar, 2016-10-28

Authorized Signature:   
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