

## 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: **Mouthpiece**

Typ: **S / D**

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

CE mark: 

Conformity  
Assessment Process: **Annex VII, section 2 of the Directive 93/42/EEC**

Issued by: **ENVITEC-WISMAR GMBH  
Alter Holzhafen 18  
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Place, Date: **Wismar, 2012-10-01**

Authorized Signature:   
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**Marcus Ostländer  
Managing Director**