

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
D-23966 Wismar
Germany**

Valid from: **2012-10-01**

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

Authorized Signature: 

**Marcus Ostländer
Managing Director**