

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:

Oxygen Sensor

OOM101	OOM105	OOM201
OOM102	OOM106	OOM202
OOM102-1	OOM110	OOM202-1
OOM103	OOM111	OOM202-2
OOM103-1	OOM112	OOM202-2S
OOM103-1M	OOM113	OOM204
OOM104		

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

Class IIa

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 80601-2-55

Issued by:

ENVITEC-WISMAR GMBH
Alter Holzhafen 18
D-23966 Wismar
Germany

Valid from:

2020-03-08

Valid until:

2024-05-26

Place, Date:

Wismar, 2020-03-06

Authorized Signature:


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