

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

Typ:

EnviteC	Viamed	EnviteC	Viamed	EnviteC	Viamed
OOM101	R-15V	OOM105	T-7V	OOM201	R-23V
OOM102	R-22Vi	OOM106	R-45V	OOM202	R-49V
OOM102-1	R-17Vi	OOM110	R-30V	OOM202-1	R-41V
OOM103	R-22MEDV	OOM111	R-75V	OOM202-2	R-44V
OOM103-1	R-17V	OOM112	R-43V	OOM202-2S	R-42V
OOM104	R-23Vi	OOM113	R-48V	OOM204	R-47V

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

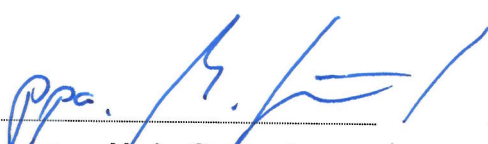
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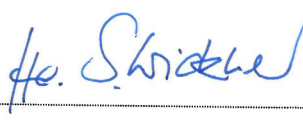
2019-04-04
2021-04-03

Place, Date:

Wismar, 2019-04-04

Authorized Signature:


ppa. Marko Sprössel


ppa. Steffen Wickner