ENVITEC
by Honeywell

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: CE 0123

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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Valid until: 2023-02-21

Place, Date: Wismar, 2021-02-22

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