



EC-Certificate

No. G1 04 01 21697 007

Holder of Certificate: EnviteC - Wismar GmbH

Alter Holzhafen 18
23966 Wismar
Germany

Product Category:

Oxygen Saturation Sensors and Monitors,
Sensors and Control Units for Monitoring
of Respiratory Parameters and Gas Exchange,
Computerized ECG Equipment, Non-invasive
Blood Pressure Equipment, Temperature Sensors

The Certification Body of TÜV Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report no.:

70061475

Valid until:

2005-09-01

Date, 2004-01-23



TÜV PRODUCT SERVICE is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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