



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 06 21697 017

Manufacturer:

EnviteC - Wismar GmbH

Alter Holzhafen 18
23966 Wismar
GERMANY

Facility(ies):

EnviteC - Wismar GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Product Category(ies):

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

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713063594

Valid from:

2015-09-02

Valid until:

2020-09-01



Date, 2015-08-28

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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