Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 021697 0017 Rev. 01

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.: 713172795

Valid from: 2020-02-17
Valid until: 2024-05-26

Date, 2020-02-17

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT ◆ ZERTIFIKAT

Digitally signed by Grabazu Alexandru
Date: 2021.02.08 15:17:27 EET
Reason: MoldSign Signature
Location: Moldova