



America

CERTIFICATE

No. QS6 021697 0022 Rev. 00

Certificate Holder: **EnviteC - Wismar GmbH**
Alter Holzhafen 18
23966 Wismar
GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Sensors and Control Units for Monitoring of Vital Physiological Parameters, Sensors and Control Units for Monitoring of Respiratory Mechanics Parameters and Gas Exchange**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, USA FDA, MHLW / PMDA.**
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **33-094-3838**

Effective Date: **2021-03-10**

Expiry Date: **2022-01-28**

Page 1 of 2

Date of Issue: 2021-03-18

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS6 021697 0022 Rev. 00

Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

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

Facility Scopes:

Design and Development, Production and Distribution of Sensors and Control Units for Monitoring of Vital Physiological Parameters, Sensors and Control Units for Monitoring of Respiratory Mechanics Parameters and Gas Exchange
 DUNS No: 33-094-3838

Page 2 of 2

Date of Issue: 2021-03-18

(Tina Israel)
 Manager, US Certification Body,
 Medical and Health Services