



# Certificate

No. Q5 021697 0021 Rev. 01

**Holder of Certificate:** **EnviteC - Wismar GmbH**

Alter Holzhafen 18  
23966 Wismar  
GERMANY

**Facility(ies):**

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

See Scope of Certificate

**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, measurement devices and sensors for alcohol blood concentration**

**Applied Standard(s):**

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:Q5 021697 0021 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 021697 0021 Rev. 01)

**Report No.:** 713212906

**Valid from:** 2021-07-31

**Valid until:** 2024-01-30

**Date,** 2021-07-28



Christoph Dicks

Head of Certification/Notified Body