



Product Service

CERTIFICATE

No. Q5 17 12 21697 018

Holder of Certificate: EnviteC - Wismar GmbH

 Alter Holzhafen 18
 23966 Wismar
 GERMANY

Facility(ies):

 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, 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). See also notes overleaf.

Report No.:

713119332

Valid from:

2018-02-06

Valid until:

2021-01-30

Date, 2018-02-06

Stefan Preiß



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