



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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