



Product Service

# CERTIFICATE

No. Q5 17 11 98084 004

**Holder of Certificate:** Orantech Inc.

Zone#A, 4F  
 1st Bld, 7th Industrial Zone  
 Yulv Community, GongMing  
 Guangming New District  
 518106 Shenzhen  
 PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Orantech Inc.  
 Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv  
 Community, GongMing, Guangming New  
 District, 518106 Shenzhen, PEOPLE'S  
 REPUBLIC OF CHINA



**Certification Mark:**



**Scope of Certificate:**

Design and Development, Production  
 and Distribution of Spo2 Sensor, NIBP Cuff,  
 Temperature Probe, ETCO2 Sensor, Fetal Transducer  
 and Patient Cables and Leadwires

**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.:** GZ1828001

**Valid from:** 2018-07-10  
**Valid until:** 2020-09-04

**Date,** 2018-07-10

*S. Preiß*  
 Stefan Preiß



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