



Certificate

No. Q5 098084 0004 Rev. 01

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). 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 098084 0004 Rev. 01

Report No.: GZ2028001

Valid from: 2020-09-05

Valid until: 2023-09-04

Date, 2020-08-19

Christoph Dicks

Head of Certification/Notified Body