



# Certificate

No. Q5 098084 0004 Rev. 02

**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

**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**

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. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 098084 0004 Rev. 02) □

**Report No.:** GZ2328001

**Valid from:** 2023-09-05  
**Valid until:** 2026-09-04

**Date,** 2023-08-18



Christoph Dicks  
Head of Certification/Notified Body



Product Service

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

**Facility(ies):** **Orantech Inc.**  
Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community,  
GongMing, Guangming New District, 518106 Shenzhen,  
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See Scope of Certificate