



# Certificate

No. Q5 067303 0018 Rev. 01

**Holder of Certificate:** **Shenzhen Med-link Electronics Tech Co., LTD.**

4th and 5th Floor, Building Two  
Hualian Industrial Zone  
Xinshi Community, Dalang Street  
Longhua District  
518109 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

**Design and Development, Production and Distribution of Pulse Oximeter Probes, Temperature Probes, Non-sterilized Disposable Electrosurgical Pencils, Disposable Neutral Electrodes, Temp-Pulse Oximeters, Digital Blood Pressure Monitors, Digital Infrared Thermometers, ECG Recorders, ETCO2 Mainstream and Sidestream Sensors, Micro Capnometer and Incontinence Probes; Production and Distribution of Oximeter Probe Adapter Cables, ECG Cable with Leadwires, EMG Cables with Leadwires, NIBP Cuff and Air Hose, ECG Electrodes, EEG Electrodes, IBP Cables and Pressure Infusion Bag**

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 067303 0018 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 067303 0018 Rev. 01)

**Report No.:** GZ2013601

**Valid from:** 2020-10-09

**Valid until:** 2023-10-08

**Date,** 2020-10-09

Christoph Dicks

Head of Certification/Notified Body

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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):**

Shenzhen Med-link Electronics Tech Co., LTD.  
4th and 5th Floor, Building Two, Hualian Industrial Zone, Xinshi  
Community, Dalang Street, Longhua District, 518109 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA

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Transfer Park, Taiping Town, Shixing County, 512500 Shaoguan,  
Guangdong Province, PEOPLE'S REPUBLIC OF CHINA