



# Certificate

No. Q5 067303 0018 Rev. 03

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

2nd, 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 Probe, Temperature Probe, Non-sterilized Disposable Electrosurgical Pencil, Disposable Neutral Electrode, Pulse Oximeter, Digital Blood Pressure Monitor, Digital Infrared Thermometer, ECG Recorder, ETCO2 Mainstream and Sidestream Sensors, Micro Capnometer, Incontinence Probe, Electrosurgery Cable, Neutral Electrode Cable, Disposable Non-invasive EEG Sensor, ICG Electrode and Water trap.  
Production and Distribution of Oximeter Probe Adapter Cable, ECG Cable and Leadwires, EMG Cable and Leadwires, NIBP Cuff and accessories, ECG Electrode, EEG Electrode, IBP Cable, Pressure Infusion Bag, Temperature Probe Adapter Cable, Disposable probe cover and Non-Sterile Disposable Connecting Tube.**

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\\_03](http://www.tuvsud.com/ps-cert?q=cert:Q5_067303_0018_Rev_03)

**Report No.:** GZ2313602

**Valid from:** 2023-10-18

**Valid until:** 2026-10-08

**Date,** 2023-10-18

Christoph Dicks

Head of Certification/Notified Body

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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Shenzhen Med-link Electronics Tech Co., LTD.**  
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Xinshi Community, Dalang Street, Longhua District, 518109  
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Pulse Oximeter Probe, Temperature Probe, Non-sterilized Disposable Electrosurgical Pencil, Disposable Neutral Electrode, Pulse Oximeter, Digital Blood Pressure Monitor, Digital Infrared Thermometer, ECG Recorder, ETCO2 Mainstream and Sidestream Sensors, Micro Capnometer, Incontinence Probe, Electrosurgery Cable, Neutral Electrode Cable, Disposable Non-invasive EEG Sensor, ICG Electrode and Water trap.  
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**Shixing Med-link Electronics Tech Co., Ltd.**  
No. 7 (factory building), Dongguan Shilong (Shixing) Industrial Transfer Park, Taiping Town, Shixing County, 512500 Shaoguan, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Production of Pulse Oximeter Probe, Temperature Probe, Non-sterilized Disposable Electrosurgical Pencil, Disposable Neutral Electrode, Electrosurgery Cable, Neutral Electrode Cable, Disposable Non-invasive EEG Sensor, ICG Electrode, Water trap, Oximeter Probe Adapter Cable, ECG Cable and Leadwires, EMG Cable and Leadwires, NIBP Cuff and accessories, ECG Electrode, EEG Electrode, IBP Cable, Pressure Infusion Bag, Temperature Probe Adapter Cable, Disposable probe cover and Non-Sterile Disposable Connecting Tube.