



Product Service

# Certificate

No. Q5 067303 0018 Rev. 05

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

Zone A of 1st and 2nd Floor  
and 3rd Floor, Building A, No. 7  
Tongsheng Industrial Park Road  
Shanghenglang 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, Water Trap, Disposable Gas Sampling Line, Disposable Defibrillation Electrodes, Adhesive Electrodes, Flow Sensor, Sterile Disposable Electrosurgical Pencil, Sterile Disposable Blood Pressure Transducer, Sterile Temperature Probe, Sterile Pulse Oximeter Probe, Sterile Disposable Foley Catheter and Disposable Warming Blanket. 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, Certification, Validation and Verification Regulations 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\\_05](http://www.tuvsud.com/ps-cert?q=cert:Q5_067303_0018_Rev_05)



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No. Q5 067303 0018 Rev. 05

Report No.: GZ25013601

Valid from: 2025-05-07

Valid until: 2028-05-06

Date, 2025-05-07

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.**  
Zone A of 1st and 2nd Floor, and 3rd Floor, Building A, No. 7, Tongsheng  
Industrial Park Road, Shanghenglang 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, Water Trap, Disposable Gas Sampling Line, Disposable Defibrillation Electrodes, Adhesive Electrodes and Flow Sensor.

Design, Development and Distribution of Sterile Disposable Electrosurgical Pencil, Sterile Disposable Blood Pressure Transducer, Sterile Temperature Probe, Sterile Pulse Oximeter Probe, Sterile Disposable Foley Catheter and Disposable Warming Blanket. 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.

**Shixing Med-link Electronics Tech Co., Ltd.**  
No. 5, Industrial West Road, Industrial Transfer Industrial Park, Shixing  
County, 512500 Shaoguan City, 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, Non-Sterile Disposable Connecting Tube, Sterile Disposable Electrosurgical Pencil, Sterile Disposable Blood Pressure Transducer, Sterile Temperature Probe, Sterile Pulse Oximeter Probe, Sterile Disposable Foley Catheter and Disposable Warming Blanket.