



# Certificate

No. Q5 049957 0030 Rev. 03

**Holder of Certificate:** **Guangdong Biolight Meditech Co., Ltd.**  
No.2 Innovation First Road  
Technical Innovation Coast  
Hi-tech Zone, Zhuhai  
519085 Zhuhai, Guangdong  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** Design and Development,  
Production and Distribution of  
Patient Monitor, Fetal Monitor,  
Central Monitoring System,  
Pulse Oximeter, Electrocardiograph,  
Electronic Thermometer,  
Electronic Sphygmomanometer,  
Ultrasonic Doppler Fetal Heartbeat Detector,  
Syringe Pump used for intravenous injection administration,  
Infusion Pump used for intravenous infusion administration,  
ECG Cables, NIBP Cuffs, SpO2 Sensors,  
Temperature Probes, Haemodialysis Equipment,  
Dialysis Fluid Filter, Hollow Fiber Dialyzer,  
Infrared Thermometer

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 049957 0030 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5 049957 0030 Rev. 03)

**Report No.:** SH2025802

**Valid from:** 2021-03-10  
**Valid until:** 2023-01-31

**Date,** 2021-03-10

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):** Guangdong Biolight Meditech Co., Ltd.  
No.2 Innovation First Road, Technical Innovation Coast, Hi-tech  
Zone, Zhuhai, 519085 Zhuhai, Guangdong, PEOPLE'S REPUBLIC  
OF CHINA

See scope of certificate