DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 049957 0030 Rev. 02

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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:

Design and Development,
Production and Distribution of
Patient Monitor, Fetal Monitor,
Central Monitoring System Software,
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

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). See also notes overleaf.

Report No.: SH1925801

Valid from: 2020-02-01
Valid until: 2023-01-31

Date, 2020-01-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

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No. Q5 049957 0030 Rev. 02

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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