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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 049957 0033 Rev. 02

Manufacturer:

**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

Product Category(ies):

**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,
SpO2 Sensors, Temperature Probes,
Infrared Thermometer**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. 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:G1_049957_0033_Rev_02

Report No.:

SH2025802

Valid from:

2021-03-10

Valid until:

2024-05-26

Date,

2021-03-10

Christoph Dicks
Head of Certification/Notified Body



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

Report No.: SH2025802

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

Date, 2021-03-10

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 049957 0030 Rev. 03

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