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

Benannt durch/Designated by
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. 01

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

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

Product Category(ies):

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,
SpO2 Sensors, Temperature Probes

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. See also notes overleaf.

Report No.: SH1925803

Valid from: 2019-10-17
Valid until: 2024-05-26

Date, 2019-10-17

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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