



## **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

**Patient Monitor, Fetal Monitor, Product Category(ies):** 

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

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Valid from: 2021-03-10 Valid until: 2024-05-26

2021-03-10 Date,

Christoph Dicks

Head of Certification/Notified Body