



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 15 01 49957 023

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

EC-Representative:

**Shanghai International Holding
Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

**Product
Category(ies):**

**Patient Monitor, Electrocardiograph,
Pulse Oximeter, Fetal Monitor,
Central Monitoring System Software,
Electronic Thermometer,
SpO2 Sensor, Temperature Probe**

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.:

SH15258EXT01

Valid from:

2015-03-20

Valid until:

2020-03-19

Date, 2015-03-09

Hans-Heiner Junker



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

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