



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60108622 0001

Report No.: 17054024 001

Manufacturer: Shenzhen Upmed Equipment
Co., Ltd.
5F, 6th Building
Rongtaijia Industrial Park
Lisonglang Village, GongMing Town
Shenzhen
518106 Guangdong
China

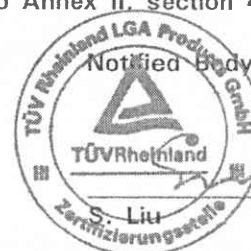
Products: Oximeter Probes

Expiry Date: 2021-03-21

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-05-27

Date: 2016-05-27



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and
Distribution of Oximeter Probes, ECG Cables**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**


are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2016-05-27
Certificate Registration No.: .SX 60108623 0001
An audit was performed. Report No.: 17054024 001
This Certificate is valid until: 2019-03-21

Certification Body



Date 2016-05-27



S. Liu



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