

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

Registration No.: HD 60144433 0001

Report No.: 17054024 008

Manufacturer: Shenzhen Upnmed Equipment
Co., Ltd.
4th Floor, Building #1 East
Huihuang Industrial Area
Xitian Community, Gongming Town
Guangming New District
Shenzhen

Products: 518107 Guangdong
China
Oximeter Probes

Replaces Approval, Registration No.: HD 60126823 0001

Expiry Date: 2024-05-27

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: 2019-12-02

Date: 2019-12-02



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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518107 Shenzhen Guangdong
China

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 13485:2016

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

Effective Date: 2019-04-10
Certificate Registration No.: SX 60135525 0001
An audit was performed. Report No.: 17054024 005
This Certificate is valid until: 2022-02-28

Certification Body



Date 2019-04-10



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