

**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 Upnmed 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

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



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

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