EC Certificate

TÜVRheinland®

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 Notified Body TÜVRheinland S. Liu Zertifizierungsstelle

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.

Digitally signed by Ermicev Alexandr
Date: 2019.04.02 17:17:34 EEST
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shenzhen Upnmed Equipment Co., Ltd.
5F, 6th Building
Rongtaijia Industrial Park
Lisonglang Village, GongMing Town
Shenzhen
518106 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 13485:2012
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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2016-05-27

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax. +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety