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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

TÜV SÜD Product Service

# EC Certificate

**Production Quality Assurance System**
**Directive 93/42/EEC on Medical Devices (MDD), Annex V**
**(Devices in Class IIa, IIb or III)**

## No. G2 002145 0001 Rev. 00

**Manufacturer:**

**Shenzhen IMDK Medical Technology CO., Ltd**
C Zone,10F, Building 16
Yuanshan Industrial B Area
Gongming Street
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Shenzhen IMDK Medical Technology CO., Ltd
C Zone,10F, Building 16, Yuanshan Industrial B Area, Gongming Street, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):**

**Pulse Oximeter and Ultrasonic Doppler Fetal Heart Rate Detector**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** GZ1828301

**Valid from:** 2018-09-25
**Valid until:** 2023-09-24

**Date,** 2018-09-25

I. Preiß

Stefan Preiß


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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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# DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER: Shenzhen IMDK Medical Technology Co.,ltd
C Zone,10F,Building 16,Yuanshan Industrial B Area,Gongming Street,Guangming District,518106, Shenzhen.

MEDICAL DEVICE: *PULSE OXIMETER, C101H1/C101A2/C101A3/C101B1/ C101B2*

CLASSIFICATION - *ANNEX IX*: *CLASS IIA, RULE11*

*CONFORMITY ASSESSMENT ROUTE:* *ANNEX VII + V.3*

WE, THE MANUFACTURER, EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY, AND HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

*IDENTIFICATION NUMBER* CE 0123

(EC) CERTIFICATE(S):

EC REP
EUROPEAN REPRESENTATIVE: MedNet GmbH, Borstrasse 10, 48163.Muenster, Germany.

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: Shenzhen,09/08/2018

SIGNATURE: XinYun Xie 謝信允 2018.8.9.
*POSITION:* GENERAL MANAGER

MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.

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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 101251 0002 Rev. 00**

**Manufacturer:**

**Shenzhen LEPU Intelligent Medical Equipment Co.,Ltd.**
North side of floor 3, BLD 9
BaiWangxin High-Tech Industrial Park
Songbai Road, Xili Street, Nanshan District
518055 Shenzhen, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:**

Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448 JB Heerenveen, THE NETHERLANDS

**Product Category(ies): Fingertip pulse oximeter, Digital ultrasonic imaging scanner.**

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.:** BJ1812101

**Valid from:** 2018-12-03
**Valid until:** 2023-12-02

**Date,** 2018-12-03

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD 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 101251 0002 Rev. 00**

**Facility(ies):**

Shenzhen LEPU Intelligent Medical Equipment Co.,Ltd.
North side of floor 3, BLD 9, BaiWangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518055 Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA


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

# Declaration of Conformity

## To council Directive 93/42/EEC

**Manufacturer:** Shenzhen LEPU Intelligent Medical Equipment Co., Ltd.
North side of floor 3, BLD 9, BaiWangxin High-Tech Industrial Park,Songbai Road,Xili Street, Nanshan District,Shenzhen,China

Product: Fingertip pulse oximeter

Model: LOX100A, LOX100B, LOX100C, LOX100D

Classification: **IIa, According to MDD 93/42/EEC Annex IX, Rule 10**

Conformity assessment route: **MDD 93/42/EEC, Annex II (excluding Section 4)**

We, Shenzhen LEPU Intelligent Medical Equipment Co., Ltd., herewith declare that the above mentioned product(s) meet the transposition international law, The provisions of Council Directive 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.

All Supporting documentation is retained at the premises of the manufacturer.

We are exclusively responsible for the DOC.

And are in conformity with the national standards transposing harmonized standards: EN ISO 13485: 2016, EN ISO 14971: 2012, EN 1041:2008+A1: 2013, EN ISO 15223-1:2016, EN 60601-1:2006+A1:2013+A12: 2014, EN 60601-1-2:2015, EN 62304:2006+A1:2015, EN 60601-1-6:2010+A1:2015, EN 62366-1:2015, EN ISO 10993-1:2009/AC: 2010, EN ISO 10993-5 :2009, EN ISO 10993-10:2013, EN ISO 80601-2-61: 2011, EN 62471:2008.

Notified body: TÜV SÜD Product service GmbH
Ridlerstr 65, D-80339 München. Germany

Identification number: CE **0123**

(EC) Certificate(s): G11012510002 REV.00
Start of CE-marking: 2018-12-03
Certificate validity: 2023-12-02

**EC REP**

European Representative: Lepu Medical (Europe) Cooperatief U.A
Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherland
Tel: +31-515 573399, Fax: +31-515 760020

Place,Date of issue: Shenzhen City,Guangdong, P.R.China,2019-9-10

Signature: Yi Qingjun

Name: Yi Qingjun
Position: Management Representative