

**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

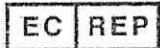
WE, THE MANUFACTURER, EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY,
AND HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE
93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS 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):



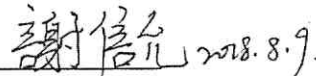
EUROPEAN REPRESENTATIVE: MedNet GmbH, Borstrasse 10, 48163.Muenster, Germany.

START OF CE-MARKING:

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

SIGNATURE:

XINYUN XIE



POSITION:

GENERAL MANAGER

MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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

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

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

TÜV®

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: **Ila, 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:  0123

(EC) Certificate(s): G11012510002 REV.00


Start of CE-marking: 2018-12-03

Certificate validity: 2023-12-02

EC	REP
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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: 

Name: Yi Qingjun

Position: Management Representative

