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