

## 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: LOX100B(Hbo-Smart)

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.

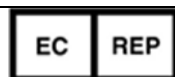
We are exclusively responsible for the DOC.

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): NA  
Start of CE-marking: NA  
Certificate validity: NA



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Place, Date of issue: Shenzhen City, Guangdong, P.R.China, 2018-11-29

Signature: Yi Qingjun

Name: Yi Qingjun

Position: Management Representative