
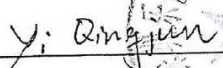


Declaration of Conformity			
To council Directive 93/42/EEC			
Manufacturer: Shenzhen LEPU Intelligent Medical Equipment Co., Ltd. North side of floor 3, BLD 9, BaiWangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, Shenzhen, China			
Product:	Fingertip pulse oximeter		
Model:	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:	 0123		
(EC) Certificate(s): G11012510002 REV.00			
Start of CE-marking: 2018-12-03			
Certificate validity: 2023-12-02			
<table border="1"><tr><td>EC</td><td>REP</td></tr></table>	EC	REP	
EC	REP		
European Representative: Lepu Medical (Europe) Cooperatief U.A Abe Lanstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands 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			