Declaration of Conformity

The submitted sample of the following equipment has been tested for CE marking according to the following European Directives: the EMC Directive 2014/30/EU.

Applicant name & address	:	**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**
Manufacturer name & address	:	**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**
Factory name & address		**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	:	**Infrared Thermometer**
Model/Type reference	:	**LFR30B**
Trade mark	:	**LEPU**
Ratings	:	**DC 3V**
Order No. / Report No.	:	**EED32M000449/EED32M000449**

Test Standards	EN 61326-1: 2013

This Declaration is for the exclusive use of CTI's Client and is provided pursuant to the agreement between CTI and its Client. The observations and test results referenced from this Declaration are relevant only to the sample tested. This Declaration by itself does not imply that the material, product, or service is or has ever been under a CTI certification program.

Note: This Declaration is part of the full test report(s) and should be read in conjunction with it.

CE EMC tested

CENTRE TESTING INTERNATIONAL GROUP CO., LTD. Report Seal

David Wang
Date: Mar. 27, 2020

Check No.: 3177495956

CENTRE TESTING INTERNATIONAL GROUP CO., LTD.
Hongwei Industrial Zone, Bao'an 70 District, Shenzhen, Guangdong, China
www.cti-cert.com E-mail:info@cti-cert.com
Hotline 400-6788-333

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ZLG-BS-244.10.08

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

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

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

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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

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

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

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