



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 729065 R000

Manufacturer: Shenzhen LEPU Intelligent Medical Equipment Co., Ltd.

Address:

North Side of Floor 3, BLD 9 BaiWangxin High-Tech Indust rial Park Songbai Road, Xili Street Nanshan District, Shenzhen Guangdong, 518055 China

Single Registration Number: Not Available

EU Authorised Representative: Lepu Medical (Europe) Cooperatief U.A.

Address: Abe Lenstra Boulevard 36 8448 JB Heerenveen The Netherlands

Scope: See attached Device Schedule

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary C Stade

Gary E Slack, Senior Vice President Medical Devices

First Issued: 2020-06-17

Date: 2020-06-17

Expiry Date: 2025-06-16

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification	
Infrared Forehead Thermometer	Class IIa	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
Current	SMO 3207107	First Issue

First Issued: 2020-06-17

Date: 2020-06-17

Expiry Date: **2025-06-16** ...making excellence a habit.[™]

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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 Guangdong 518055 China 深圳乐普智能医疗器械有限公司 中国 广东省 深圳市 南山区西丽街道 松白公路百旺信工业区 9栋3层北侧 邮编:518055

Holds Certificate No: MD 729066

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and Development, Manufacture and Distribution of Infrared Forehead Thermometer. 红外额温计的设计开发、制造和分销。

jan

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-06-05 Latest Revision Date: 2020-06-05 Effective Date: 2020-06-05 Expiry Date: 2023-06-04

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780 BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands A Member of the BSI Group of Companies.