Digitally signed by Trocin Caterina
Date: 2021.03.09 13:55:29 EET
Reason: MoldSign Signature
Location: Moldova

By Royal Charter

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 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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EU Quality Management System Certificate

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

MDR 729065 R000

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

Device(s)	Risk Classification
Infrared Forehead Thermometer	Class IIa

First Issued: **2020-06-17** Date: **2020-06-17** Expiry Date: **2025-06-16**

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EU Quality Management System Certificate

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

MDR 729065 R000

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**

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By Royal Charter

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。

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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