

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 Industrial 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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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.
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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



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