证 明 书

CERTIFICATE

中 国 国 际 贸 易 促 进 委 员 会

中 国 国 际 商 会

China Council for the Promotion of International Trade

China Chamber of International Commerce

中国国际贸易促进委员会
中国国际商会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书
CERTIFICATE

号码 No. 241100B0/H21081

兹证明：在所附声明上的宁波海立方医疗科技有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of NINGBO HI-LIFE MEDICAL TECHNOLOGY CO., LTD. on the annexed STATEMENT is genuine.

China Council for the Promotion of International Trade

商事证明专用章 CCPIT

签证员：
Authorized Official: Sun Jia

日期：2024年05月30日
(Date: May. 30, 2024)

证明网址 Website for verifying the certificate: http://www.rzccpit.com/validate.html

STATEMENT

We, NINGBO HI-LIFE MEDICAL TECHNOLOGY CO,LTD, located in No.371 Zhenshi Road,Jiangshan Town, 315191 Ningbo,China. We are going to Exporting our Products of Medical Thermometers to Chile. We state that we had got MDR(CE) Confirmation Letter(Ref No.CLNB-CN/HGH/5365) which is issued by SGS Belgium NV,a Notified Body (1639) See the attachment for the detailed certificate, which is use for our clients register and sell our goods purpose.

Hereby declare!

NINGBO HI-LIFE MEDICAL TECHNOLOGY CO,LTD,

2024-5-24

SGS

Ningbo Hi-life Medical Technology Co., Ltd.
Qiaoli Village, Jiangshan Town, Yinzhou District, Ningbo City,
Zhejiang Province, 315191
P.R. China

2024/12/11

Confirmation Letter Reference: CLNB1639 – CN/HGH/5365

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Ningbo Hi-life Medical Technology Co., Ltd.
Qiaoli Village, Jiangshan Town, Yinzhou District, Ningbo City,
Zhejiang Province, 315191
P.R. China
SRN Number: CN-MF-000020033

Authorized representative:
Shanghai International Holding Corp.Gmbh(Europe)
Eiffestrasse 80,20537 Hamburg
Germany
SRN Number: DE-AR-000000001

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;

- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Pp[Sean Kelly]
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Medical Electronic Thermometer for measuring/monitoring of body temperature Infrared Forehead	Class IIa	N/A	Certificate CN19/41063 NB1639

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Thermometer (Model: FHT-1& RT-101) Basic UDI-DI: 697370923106L7			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/05	Version 1	Initial issue

本附加证明书仅证明公文书上的签名、签署人签名时的身份，需要时可证明公文书上的印鉴属实。附加证明书不对公文书内容予以证明。
This Apostille only certifies the authenticity of the signature, the capacity of the person who has signed the public document and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued.
Visit https://consular.mfa.gov.cn/VERIFY/ and scan the QR code to verify the issuance of this Apostille.

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附加证明书
APOSTILLE

（1961年10月5日海牙公约）
（Convention de La Haye du 5 octobre 1961）

1. 文书出具国：
Country: 中华人民共和国
People's Republic of China

本公文书 This public document

2. 签署人
has been signed by 孙嘉
Sun Jia

3. 签署人身份
acting in the capacity of 签证员
Authorized Official

4. 印鉴名称
bears the seal/stamp of 中国国际贸易促进委员会
China Council for the Promotion of International Trade

证明 Certified

5. 签发地
at 北京
Beijing

6. 签发日期
the 2024年06月03日
June 03,2024

7. 签发人
by 耿毅超，三等秘书/ Geng Yichao，Third Secretary
外交部领事司
Department of Consular Affairs of the Ministry of Foreign Affairs

8. 附加证明书编号
No 认字第240000215324号

9. 签发机关印鉴：
Seal/Stamp:

10. 签名：
Signature: 耿毅超