

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. 261100B0/H24550

兹证明：所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of
DOCUMENT is in conformity with the original.

China Council for the Promotion
of International Trade

商事证明专用章

CCPIT

签证员:

Authorized
Official:

Chen Yao

日期: 2026年05月18日
(Date: May. 18, 2026)

证明 网址 Website for verifying the certificate: <https://www.ccpitssrz.cn/validate.html>

Verification

of Conformity with European Directives

Applicant: Shandong SanYang Medical Equipment Co., Ltd.
Address of Applicant: No. 3 Lingnan Industrial Park, Lingcheng Town, Qufu City, Jining City, Shandong Province, China
Manufacturer: Shandong SanYang Medical Equipment Co., Ltd.
 No. 3 Lingnan Industrial Park, Lingcheng Town, Qufu City, Jining City, Shandong Province, China
Product Name: Shadowless Lamp
Model: SY-3011, SY-3021, SY-LEDHB5Y, SY-BK500Y, SY-LEDHB6Y, SY-LEDK5Y, SY-LSK5Y, SY-YDLED, SY-LED300Y, SY-LED200Y, SY-LED30Y, SY-LED700D, SY-LED500D, SY-LED700/500, SY-LEDHB5D, SY-LEDHB5/3, SY-LEDHB5/5, SY-BK500D, SY-BK700/500, SY-BK700D, SY-LEDHB6/6, SY-LEDHB6D, SY-LEDK5D, SY-LSK5D, SY-LED300D, SY-LED200, SY-LED30D, SY-BGLED, SY-LEDHB5B, SY-BK500B, SY-LEDHB6B, SY-LEDK5B, SY-LSK5B, SY-LED300B, SY-LED30B, SY-LED200B, SY-D7, SY-D9

Test Requested: Medical Device Regulation(EU) 2017/745(MDR)
 EN ISO 20417:2021, EN ISO 10993-1:2020,
 EN ISO 10993-5:2009+A11:2025, EN ISO 10993-10:2023,
 EN ISO 15223-1:2021, EN ISO 14971:2019+A11:2021,
 EN 60601-1:2006+A2:2021, EN 60601-1-2:2015+A1:2021,
 EN IEC 60601-2-41:2021

Classification
 of medical device: Medical Devices – Class I
TCF Reference: TMSD25112578746
Date of Issue: December 05th, 2025
Date of expiry: December 04th, 2030

The submitted sample of the above product has been tested for CE marking according to the following European Directive(s):

Medical Device Regulation(EU) 2017/745(MDR)

Conclusion

The referred test report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements.

The CE marking as shown below can be affixed on the product after preparation of necessary technical documentation.

Approved by: Hermann Weiher

Hermann Weiher



For and on behalf of
 Global Testing Services Co., Ltd



Global Testing Services Co., Ltd

E-mail: info@gts-lab.com http://www.gts-lab.com

Floor 2nd, Building D-1, No. 128, Shenfu Road, Minhang District, Shanghai, China.

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on No.: CMSD25112578746

GTS

and use: The surgical area is provided with sufficient, uniform, and shadow-free lighting

Parameter: Specification and model: SY-LED500D

The temperature rise of the surgeon's head is $\leq 1^{\circ}\text{C}$

Temperature rise in the surgical field working area $\leq 2^{\circ}\text{C}$

Operating radius $\geq 2200\text{mm}$

Working radius: 600-1800mm

Power supply voltage: 220V $\pm 22\text{V}$ 50HZ $\pm 1\text{HZ}$

Input power: AC 110-240V, 50/60Hz

The average lifespan of the bulb is $\geq 60,000$ hours

Bulb power: 1W/3V

Optimal installation height: 2800-3000mm

Specification and model: SY-LEDHB5/3

Illumination (LED5) 40000-16000 Lux

Illumination (LED3) 30000-120000 Lux

Color temperature: 3700K-5000K (adjustable)

Color rendering index 85-98 (adjustable)

Light spot diameter: 160mm-280mm (adjustable)

Focusing depth $\geq 1200\text{mm}$

Brightness adjustment: 1% -100%

The temperature rise on the surgeon's head is less than 1°C

The service life of LED is $\geq 80,000$ hours

Power Supply: AC100-240V 50/60Hz

Specification and model: SY-LED700/500

Illumination (LUX at a distance of 1 meter) 160000 120000

Color temperature: 4300 $\pm$ 500

Spot diameter: 100-300mm

Illumination depth $\geq 1200\text{mm}$

Brightness adjustment 1-100

Color rendering index CRI $\geq 97\%$

Color reproduction index RA $\geq 97\%$

Approved by: Hermann Weiher



For and on behalf of
Global Testing Services Co., Ltd



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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: 中华人民共和国
Country: People's Republic of China

本公文书 This public document

2. 签署人
has been
signed by 陈焱
Chen Yao

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 2026年05月22日
May 22, 2026

7. 签发人
by 于宁, 二等秘书/ Yu Ning, Second Secretary
外交部领事司

Department of Consular Affairs of the Ministry of Foreign Affairs

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