

Verification

of Conformity with European Directives

Applicant: Shandong Chenhong Medical Technology Co., Ltd.
Address of Applicant: East of Nanshou Road, Jinlan Road, Qufu City, Jining City, Shandong Province, China
Product Name: Surgical Shadowless Lamp
Model: CHGZF700, CHGZF500, CHGZF700/700, CHGZF700/500, CHGZF500/500, CHYZF700, CHYZF500, CHGLED700, CHGLED500, CHGLED700/700, CHGLED700/500, CHGLED500/500, CHYLED700, CHYLED500
Test Requested: Medical Device Regulation(EU) 2017/745(MDR)
EN 1041:2008+A1:2013, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 15223-1:2016, EN ISO 14971:2019, EN 60601-1:2006+A12:2014, EN 60601-1-2:2015
Classification of medical device: Medical Devices – Class I
TCF Reference: TMSD21070532005
Date of Issue: July 09th, 2021
Date of expiry: July 08th, 2026

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)

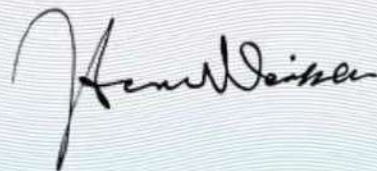
Conclusion

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

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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CERTIFICATE OF REGISTRATION

The Quality Management Systems of
**SHANDONG CHENHONG
MEDICAL TECHNOLOGY CO.,LTD**

Unified Social Credit Code: 913708813128682983

East of South Head of Jinlan Road, Qufu City, Jining City, Shandong Province

has been assessed by GIC and complying with

GB/T19001-2016/ISO9001:2015

For the following activities

Design, production and service of LED operation shadowless lamp, operation shadowless lamp, electric operating table, led operation lamp, manual hospital bed, normal hospital bed, medical treatment table and transfer vehicle; Design, development, production, installation and service of medical pendant and suspension bridge

Date of Issue: 21 October 2021

Date of Expiry: 06 October 2024

Date of Initial Certification: 08 October 2018

Certificate No.: U21Q28010574R1S

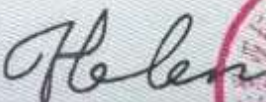


Scan for certificate status

The granting of this certificate does not mean that the certificate holder can avoid any legal obligation. If the products or activities covered in the scope of certification require administrative license, the certificate shall be only valid within the scope of administrative licensing. The registered organization shall be subject to regular annual supervision by GIC, and the continual validity of the certificate is base upon conformity of audit. Please scan two-dimension code at lift to find the certificate information. This certificate can be queried at Certification and Accreditation Administration of the People's Republic of China official website (www.cnca.gov.cn) & GIC website (www.gicg.com.cn)



GIC WeChat public number

Signature: 

Guardian Independent Certification Ltd

Registered in England

Sovereign House 212-224 Shaftesbury Avenue London England WC2H 8HQ

Accredited by Member of IAF MLA



0045



CERTIFICATE OF REGISTRATION

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SHANDONG CHENHONG MEDICAL TECHNOLOGY CO.,LTD

Unified Social Credit Code:913708813128682983

East of South Head of Jinlan Road, Qufu City, Jining City, Shandong Province

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YY/T0287-2017/ISO13485:2016

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Date of Issue: 21 October 2021

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Date of Initial Certification: 08 October 2018

Certificate No.: G21Q20206R1S



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GIC WeChat public number

Signature:

Guardian Independent Certification (Beijing) Co., Ltd.
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Chaoyang District, Beijing City
Post. Code: 100124

