Verification No.: CMSD21070532005





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 July 08th, 2026 Date of expiry:

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

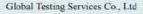
The referred test report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements.

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

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