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Verification No.: CMSD21070532005



# 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 09<sup>th</sup>, 2021  
 Date of expiry: July 08<sup>th</sup>, 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  
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