

Shandong Mingtai Medical Equipment Group Co., Ltd.

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ERCE

Certificate No. 2020103

CERTIFICATE OF CONFORMITY

Product Name : Operating Light
Category : Class I
Model : See the Annex
Applicant : Shandong Mingtai Medical Equipment Group Co.,Ltd
TCF Number(s) : ERCE-2020-103
Date of Issue : Sep. 03, 2020
Expiry data : Sep. 02, 2025
Applicable Directive : 93/42/EEC

Conclusion

Based upon a review of the worksheets and the Technical Construction File, the apparatus is deemed to meet the requirements of the above standards and hence fulfils the requirements of:

Medical Device Directive 93/42/EEC

Standard: EN ISO 14971:2012, EN ISO 15223-1:2012, EN 1041:2008, EN 60601-1:2006/AC:2010, EN 60601-1-2:2007/AC:2010, EN 60601-2-46:2016, EN 60601-2-41-2000, EN 60695-2-1:1997

Note : The certificate is only valid for the equipment and configuration described, and in conjunction with the test data detailed above

Authorized Signatory

Chris Shi



ERCE INTERNATIONAL

General Manger / Chris Shi

Annex to Certificate: 2020103

Product name	Type
Operating Light	LED520, LED720, LED720/520, LED720/720, LED520/520, LED500, LED700, LED700/500, LED700/700, LED510, LED710, LED710/510, LED710/710, LED530, LED730, LED730/530, LED730/730, LED530/530, LED530H, LED730H, LED730/530H, LED730/730H, LED550, LED750, LED750/550, LED750/750, LED550H, LED650H, LED750H, LED650/550H, LED750/550H, LED750/750H, LED560, LED760, LED760/560, LED760/760, LED770, LED670, LED770/670, LED580, LED780, LED780/580, LED780/780, LED800/600, LED800, LED100, LED200, LED300, LED1000, LED2000, LED3000, LED3700, LED3800, LED4500, LED5200, LED5350, LED5500, ZF700/700, ZF700/500, ZF500/500, ZF700, ZF500, ZF700L, ZF500L, ZF700B, ZF500B

Accessory	Type
Operating Light Spring Arm	PHB1, PHB2, PHB3
Operating Light Sterilizing Handle	XDB1, XDB2, XDB3
Operating Light Bulb Cup	DB1, DB2, DB

End of the Annex