



Compliance Report

Applicant: Shanghai Weyuan Medical Device Co., Ltd
Address: No. 33 Fuqing Rd, Qingcun Town, Fengxian District, Shanghai, China.
Product: LED Surgical Light, Halogen Operating Light, Shadowless Operating Lamp
Type: See annex for details
Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02743

Initial Issue Date: 17 July 2017

A handwritten signature in blue ink that reads 'Tony Chen'. The signature is written in a cursive style and is positioned above a horizontal line.

General Manager (Signature)



Annex to Report (No. 02743)

Shanghai Weyuan Medical Device Co., Ltd

Product Name	Type
LED Surgical Light	WYLED3, WYLED5, WYLED5/3, WYLED3/3, WYLED5/5, WYLEDK4, WYLEDKL4, WYLEDK5, WYLEDKL5, WYLEDK9, WYLEDK12, WYLEDZMD, WYLED500, WYLEDL500, WYLED700, WYLEDL700, WYLED700/500, WYLED500/500, WYLED700/700, WYLED200, WYLEDL200, WYJ-1, WYJ-3
Halogen Operating Light	WYZ500, WYZL500, WYZ700, WYZL700, WYZ700/500, WYZ500/500, WYZ700/700
Shadowless Operating Lamp	WYK4, WYK5, WYKL5, WYK9, WYK12, WYKZMD

This annex is only valid if attached to the report mentioned above.