



Compliance Report

Applicant: Bowin Medical Co., Ltd.
Address: West Side, Xingci Second Road, New Area of Hangzhou Bay, Zhejiang, China

Product: LEDTECH Series Surgical Lighting System,
REFTECH Series Surgical Lighting System
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. 02774

Initial Issue Date: 30 Sep 2017

Reissue Date: 8 Mar 2018

Tony Chen

General Manager (Signature)



Annex to Report (No. 02774)

Bowin Medical Co., Ltd.

Product Name	Type
LEDTECH Series Surgical Lighting System	LEDTECH7050, LEDTECH7070, LEDTECH5050, LEDTECH7000, LEDTECH5000, LEDTECH3000 LEDTECH7000W, LEDTECH5000W, LEDTECH3000W LEDTECH7000M, LEDTECH5000M, LEDTECH3000M
REFTECH Series Surgical Lighting System	REFTECH5000, REFTECH5050, REFTECH6000, REFTECH6050, REFTECH6060, REFTECH6000W, REFTECH5000W, REFTECH5000M, REFTECH6000M

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

