

EC Declaration of Conformity

Manufacturer:

Shenzhen Comen Medical Instruments Co.,Ltd

Address:

Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China.

Whose Single Authorized Representative:

Lotus NL B.V.

Address:

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

We, the manufacturer, declare at our sole responsibility that following products

Product name	Model
LED Surgical Light	L6, L6A, L6B, L6SC, L6SCA, L6SCB, L5, L5A, L5B, L3

meet the provisions of Directive 93/42/EEC.

The medical device has been assigned to class I according to rule 1 in Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding Section 4) of Directive 93/42/EEC.

The product meet the following standard: (See Chapter 4 of File No. 0302-69)

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shenzhen Comen Medical Instruments Co.,Ltd.

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Shenzhen, 2017.12.21
Place, date

Legally binding signature Function