



# DET NORSKE VERITAS

## CERTIFICATE OF CONFORMITY

Application of Council Directive 93/42/EEC on Medical Devices, as amended

**Certificate No.: 2012-RGC-MDD-0001 Rev.2**

This is to certify that the technical documentation for the product:

### **Surgical Light**

*Manufactured by*

### **BenQ Medical Technology Corporation**

*at*

- (1) Head Office : 7th Floor, No. 46, Zhou-Z Street, Nei-Hu, Taipei 114, Taiwan, R.O.C.
- (2) Linkou Factory: No. 7,7-1, Kung 5 Rd., Kung 2 Industrial Zone, Linkou Dist., New Taipei City 244, Taiwan, R.O.C.
- (3) Gueishan Factory: 3F., No. 159, Shan-Ying Road, Shan-Ding Village, Gueishan Hsiang, Taoyuan County, 333, Taiwan, R.O.C.

#### **complies with the requirements applicable to it**

The manufacturer's technical documentation, as required for **Class I** devices, has been reviewed and found to comply with the requirements in Annex VII, section 3.

Further identification and description of the products covered by this certificate are given in the Appendix.

*Taipei: 11 January, 2013*

*Valid until: 06 April, 2017*

*for Det Norske Veritas  
Region Greater China*

#### **Limitations:**

Any changes of the medical devices shall immediately be reported to Det Norske Veritas Region Greater China in order to examine whether this Certificate remains valid.

*Dennis Lin  
Technical Director,  
DNV R.G.C. Product Certification*

*Any significant changes in design or construction of the product, or amendments to the Directive or Standards referenced above may render this receipt invalid. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.*



## CERTIFICATE OF CONFORMITY

## APPENDIX

**Appendix to Certificate No. : 2012-RGC-MDD-0001 Rev.2**

**Manufacturer : BenQ Medical Technology Corporation**

**Product group : Surgical Light**

### Certificate history:

Revision	Description	Issue Date
	Original Certificate – new issue	2012-01-04
1.0	Add the new type – TriLite LS800 series	2012-04-06
2.0	Add new address and change EU Representative	2013-01-11

The Certificate referred to above covers the following products:

#### Dr.Lite 2066 series

**Dr.Lite 2066- XY<sub>1</sub>Y<sub>2</sub>Y<sub>3</sub>**

-X can be 05、06、07、55、65、75、66、76、77、555、655、665、755、775、765、666、766、776、777

-Y<sub>1</sub>Y<sub>2</sub>Y<sub>3</sub> is optional:

C(Built-in CCD) 、 D(Separate-carrying arm CCD camera system) 、 HC(Built-in CCD of HD) 、  
HD(Separate-carrying arm CCD of HD) 、 T(TFT display system) 、 HT( TFT display system of HD) 、  
TT(Dual TFT display system) 、 HTT (Dual TFT display system of HD) 、 A (Wall control box system) 、  
I(ORLIS system) 、 I2(ORLIS system) 、 F(Endo Light) 、 P(Penetrating Light) 、 Y(3-Connecting Pins model) 、  
B(Reserved for Built-in CCD)

#### TriLite LED S600 series

**TriLite LED S600-500 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> · TriLite LED S600-700 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> · TriLite LED S600-550 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub>**

**TriLite LED S600-770 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> · TriLite LED S600-750 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> · TriLite LED S600-555 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub>**

**TriLite LED S600-755 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub>**

-X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> is optional:

C (CCD Camera) 、 T (TFT display system) 、 TT (Dual TFT display system) 、 W (Wall control box system) 、  
D (ORLIS system) 、 E (Built-in Endo. Lighting optical core assembly) 、 B (Battery) 、 M (Stand light system) 、  
S (Snake fiber optical assembly)

#### TriLite LS800 series

**TriLite LS800-500 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> · TriLite LS800-550 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> · TriLite LS800-555 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub>**

**TriLite LS800-700 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> · TriLite LS800-750 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> · TriLite LS800-755 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub>**

**TriLite LS800-770 X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub>**

-X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub> is optional :

H (Built-in CCD Camera) 、 C (External CCD Camera) 、 T (TFT display system) 、 TT (Dual TFT display system) 、  
W (Wall control box system) 、 S (Snake fiber optic assembly) 、 B (Battery system)  
M (Mobile Stand system\_ for TriLite LS800-500 only)



**CERTIFICATE OF CONFORMITY**

**APPENDIX**

**DomeLux series**

**DomeLux- XY<sub>1</sub>Y<sub>2</sub>Y<sub>3</sub>**

-X can be 50、62、72、5050、6250、7250、6262、7262、7272、505050、625050、626250、725050、727250、726250、626262、727272

-Y<sub>1</sub>Y<sub>2</sub>Y<sub>3</sub> is optional:

EX(Low Floor Type)、E(Mobile Stand Type with Battery Power System)、S(Mobile Stand Type)、

R(Remote Type)、L (Extension tube)、T (TFT display system)、H (Built-in CCD)、

C(Separate-carrying arm CCD camera system)、B(Reserved for Built-in CCD)、A (Wall control box system)、

G(Economic Type)、W(Wall Mounted type)

**EU Representative:**

Name	Address
BenQ Europe B.V.	Meerenakkerweg 1, 5652AR, Eindhoven, Netherlands

**Refer to Technical Construction File:**

W97-006-000A8/W97-017-000A1/W97-005-000A6/W97-018-000A0

11 January, 2013



Dennis Lin