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DNV-GL



KS. Nguyễn Văn Lịch

Technical Documentation Review Statement

Statement Number:
2012-RGC-MDD-0001

Place and Date:
Taipei, 2015.09.09

BenQ Medical Technology Corporation

Site Address:

Head Office : 7th Floor, No. 46, Zhou-Z Street, Nei-Hu, Taipei 114, Taiwan, R.O.C.
Gueishan Factory: 3F., No. 159, Shan-Ying Road, Shan-Ding Village, Gueishan Hsiang, Taoyuan County 333, Taiwan, R.O.C.

Product Name:

Surgical Light

Applicable EU Directive :

Medical Device Directive 93/42/EEC as Amended

Product Classification:

Class I (non-sterile, non-measuring function)

Project Number:

PRJC-58656-2008-PRC-TWN

Review result:

The manufacturer's technical documentation LS810-00-0-C526-001, Rev. A0, date 2015/8/31, as required for class I devices, has been reviewed and found to comply with the requirements in Annex VII, section 3.

The confirmation is validated until 2020-09-09. Any change of the technical documentation should be reported to the representative office of DNV GL Business Assurance Co., Ltd. in order to examine whether the statement remains valid.

DNV GL --Business Assurance

David Hsieh
District Manager,
Taipei, 09 September 2015

The technical documentation examination is based on the stated data made available to DNVGL and the firm's documentation is presented to meet the



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Appendix to Statement

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 Manufacturer : BenQ Medical Technology Corporation
 Product group : Surgical Light

Statement 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
3.0	Remove the Lin Kou site	2014-05-26
4.0	Add new type- TriLite LS810 Series	2015-09-09

The Statement referred to above covers the following products:

Product Type(s)/Model(s):

Dr. Lite 2066 series

Dr. Lite 2066- XY₁Y₂Y₃

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

-Y₁Y₂Y₃ 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 X₁X₂X₃X₄、TriLite LED S600-700 X₁X₂X₃X₄、TriLite LED S600-550 X₁X₂X₃X₄

TriLite LED S600-770 X₁X₂X₃X₄、TriLite LED S600-750 X₁X₂X₃X₄、TriLite LED S600-555 X₁X₂X₃X₄

TriLite LED S600-755 X₁X₂X₃X₄

-X₁X₂X₃X₄ 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)



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TriLite LS800 series

TriLite LS800-500 X₁X₂X₃X₄ , TriLite LS800-550 X₁X₂X₃X₄ , TriLite LS800-555 X₁X₂X₃X₄

TriLite LS800-700 X₁X₂X₃X₄ , TriLite LS800-750 X₁X₂X₃X₄ , TriLite LS800-755 X₁X₂X₃X₄

TriLite LS800-770 X₁X₂X₃X₄

-X₁X₂X₃X₄ 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)

TriLite LS810 Series

Single Arm : TriLite LS810-500 、 TriLite LS810-700 、 TriLite LS810-700H

Dual Arm : TriLite LS810-550 、 TriLite LS810-750 、 TriLite LS810-770 、 TriLite LS810-750H 、 TriLite LS810-770H 、 TriLite LS810-500T 、 TriLite LS810-700T 、 TriLite LS810-700HT 、 TriLite LS810-500C 、 TriLite LS810-700C

Triple Arm : TriLite LS810-555 、 TriLite LS810-755 、 TriLite LS810-755H 、 TriLite LS810-550T 、 TriLite LS810-750T 、 TriLite LS810-770T 、 TriLite LS810-770HT 、 TriLite LS810-750HT 、 TriLite LS810-550C 、 TriLite LS810-750C 、 TriLite LS810-770C 、 TriLite LS810-500CT 、 TriLite LS810-750HC 、 TriLite LS810-700CT

Code Description : H (Build-in Camera) 、 T (TFT Display) 、 C (External Camera)

Other Optional items : Camera Function Provision / Wall Control / Ceiling Tube / Electric Focus / IQOR / Laser Point

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DomeLux series

DomeLux- XY₁Y₂Y₃

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

-Y₁Y₂Y₃ 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:

W97-006-000/W97-017-000/W97-005-000/W97-018-000/LS810-00-0-C526-001



DNV GL -Business Assurance

David Hsieh
 District Manager,
 Taipei, 09 September 2015