

BenQ Medical Technology Corporation

EU Declaration of Conformity

Page 1 of 3

Manufacturer: BenQ Medical Technology Corp.
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 Dist., Taoyuan City 333, Taiwan, R.O.C.

SRN Code : TW-MF-000012212

Authorized Representative: MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany

Medical Device: Surgical light
GMDN code : 37332, 32244, 32240
TriLite LED S600 Series, TriLite LS800 Series, TriLite LS810 Series,
TriLite LS800-500 Series, TriLite LS810-500 Series, TriLite LS510 Series

Product detail information see next page.

This declaration of conformity is issued under the sole responsibility of BenQ Medical Technology Corp, is herewith confirmed to comply with the requirements set out in the Regulation (EU) MDR 2017/745, Annex IV (EU Declaration of Conformity), Class I Medical Device (non-sterile, non-measuring function, on-reusable surgical instrument), the classification rule according to Annex VIII of the MDR, Rules 13, and the applicable conformity procedure according to Annex II and III of the MDR.

This declaration is supported by the Quality System approval to ISO 13485 issued by SGS. All supporting documentation is retained at the premises of the manufacturer.

For the evaluation regarding the product safety aspects, the following CS and standards were applied:

*EN ISO 13485:2016, ISO 13485:2016, EN ISO 14971:2012, ISO 14971:2019,
IEC 60601-1:2005+A1:2012, EN 60601-1:2006+A1:2013, IEC 60601-1-2:2014, EN 60601-1-2:2015,
IEC 60601-2-41:2009, EN 60601-2-41:2009, IEC 62366:2015, EN 62366:2008, EN 1041:2008,
IEC 62304:2006, EN 62304:2006, EN ISO 15223-1:2016, ISO 15223-1:2016, EN ISO 17664:2017,
ISO 17664:2017*

Signature:

Place and date (yyyy.mm.dd) of issue:



Nei-Hu 2022.03.07

Michael Kuan
President

BenQ Medical Technology Corporation

EU Declaration of Conformity

Page 2 of 3

Product Detail Information

Medical Device: Surgical light

Intended Purpose:
(if applicable)

The surgical light is a device intended to be used to provide visible illumination of the surgical field or the patient.

Product Series	Basic UDI-DI	Product Code	Reference Number
TriLite LED S600	471987988TriLiteS60029	Z12010701	研 W97-507-000
TriLite LS800	471987988TriLiteLS800N5	Z12010701	研 W97-508-000
TriLite LS810	471987988TriLiteLS810N8	Z12010701	LS810-00-1-C527-001
TriLite LS800/810-500 Mobile	471987988TriLiteLS800MEP 471987988TriLiteLS810MEU	Z12010702	LS800-01-1-C527-001
TriLite LS510	471987988TriLiteLS510MR	Z12010701	LS510-00-1-C527-001

The DOC referred to above cover the following models:

TriLite LED S600

Single Arm: TriLite LED S600-500, TriLite LED S600-700

Dual Arm: TriLite LED S600-550, TriLite LED S600-770, TriLite LED S600-750

Triple Arm: TriLite LED S600-555, TriLite LED S600-755, TriLite LED S600-775, TriLite LED S600-777

Each may have optional function: C (CCD Camera), T (TFT display system), W (Wall control box system),

TriLite LS800

Single Arm: TriLite LS800-500, LS800-700

Dual Arm: TriLite LS800-550, TriLite LS800-770, TriLite LS800-750

Triple Arm: TriLite LS800-555, TriLite LS800-755, TriLite LS800-775, TriLite LS800-777

Each may have optional function : H (Built-in CCD Camera), C (External CCD Camera), T (TFT display system),

W (Wall control box system), F (Electric focusing system), Q (iQOR control), R (Reserved Built-in CCD module)

TriLite LS810

Single Arm: TriLite LS810-500, TriLite LS810-700

Dual Arm: TriLite LS810-550, TriLite LS810-770, TriLite LS810-750

Triple Arm: TriLite LS810-555, TriLite LS800-755, TriLite LS810-775, TriLite LS810-777

Each may have optional function : H (Built-in CCD Camera), C (External CCD Camera), T (TFT display system),

W (Wall control box system), F (Electric focusing system), Q (iQOR control), R (Reserved Built-in CCD module)

TriLite LS800/810-500 Mobile

Single Arm: TriLite LS800-500, TriLite LS810-500

Each may have optional function : M (Mobile Stand system), B (Battery system)

BenQ Medical Technology Corporation

EU Declaration of Conformity

Page 3 of 3

TriLite LS510

Single Arm: TriLite LS510-600

Dual Arm: TriLite LS510-600C, TriLite LS510-600T, TriLite LS660

Triple Arm: TriLite LS510-600CT, TriLite LS510-660C, TriLite LS510-660T

Each may have optional function : T (TFT display system) B (Battery system) , C (External CCD Camera)
Q (iQOR control)

End of list