DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 89674-2010-CE-KOR-NA Rev. 10.0

This Certificate consists of 4 pages

This is to certify that the Quality Management System of

Lutronic Corporation

Lutronic Center, 219, Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, Korea

for design, production and final product inspection/testing of

Medical lasers, Phototherapy Unit, Intense Pulsed Light, Electrosurgical Unit and Short-wave Therapy Equipment

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 01 February 2017

For DNV GL BUSINESS ASSURANCE NORWAY AS

Cathrine Wisbech
Certification Manager

NORWEGIAN ACCREDITATION PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
21 December 2020

Sholeh Gheissar
Technical Reviewer

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original certificate 2006-OSL-MDD-0424	2005-12-21
	Recertification	2010-12-21
1.0	Scope extension- New Products and model added	2011-04-27
2.0	Scope extension- New product group added (Electrosurgical unit)	2011-11-30
3.0	Scope extension- New product group added (Pulsed diode laser)	2012-04-22
4.0	Scope extension- New product group added (CLARITY™)	2012-06-06
5.0	Scope extension- New product group added (ACTION II) & EU Rep changed	2012-12-04
6.0	Site relocation and Scope change (products withdrawal)	2013-04-23
7.0	Scope extension- New product group added (AM10)	2013-11-15
8.0	Model add- ACTION II accessory and SPECTRA XT	2014-05-30
9.0	Re-certification + new model add	2015-12-21
10.0	**Scope extension-New product group added (Short-wave Therapy Equipment(enCurve)) & Model add (PICOPLUS) (Bold)**	**2017-02-01**

Products covered by this Certificate

Product Description	Product	Class
Pulsed Er-YAG Laser	ACTION II Handpiece**:** Zoom,ShP,Fractional**,**Petit	IIb
Pulsed Nd-YAG Laser	ACCUSCULPT II Accessory : Optical Fiber, Cannula, Handpiece	IIb
Frequency Doubled Q-switched Nd-YAG Laser	Spectra VRM III SPECTRA SPECTRA XT **PICOPLUS**	IIb
Surgical CO_2 Laser (Tube Type)	SP II, DENTA II	IIb
Surgical CO_2 Laser (RF Type)	eCO2, eCO2 Plus	IIb
Er-GLASS Fiber Laser	MOSAIC HP	IIb
Pulsed Diode Laser	ADVANTAGE Power plus Handpiece: D1-800,D1-1064,D3-800	IIb
Alexandrite+Long-pulsed Nd:YAG	CLARITY ™ LPC	IIb

Laser/ Long-pulsed Nd:YAG Laser/ Alexandrite Laser	CLARITY ™ LPY CLARITY ™ LPA	
Phototherapy Unit	HEALITE II	IIa
Intense Pulsed Light	SOLARI	IIb
Electrosurgical unit	INFINI Disposable accessories; MFR Tip and SFR Tip	IIb
Ophthalmic Nd:YLF Laser	AM10,R:GEN Disposable accessory: Dosimetry sensor	IIb
Thulium laser	LASEMD	IIb
Short-wave Therapy Equipment	**enCurve**	**IIa**

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
Lutronic Corporation	Lutronic Center, 219, Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, Korea

EU Representative:
Obelis s.a., Bd. Général Wahis 53, 1030 Brussels, BELGIUM

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE