DET NORSKE VERITAS

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 89674-2010-CE-KOR-NA Rev. 2.0
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Lutronic Corporation

Room 403-1,2,3,4,5, 404 Ilsan Technotown 1141-1, Baekseok-dong, Ilsandong-gu,
Goyang-si, Gyeonggi-do, Korea

for design, production and final product inspection/testing of

Medical lasers, Infrared Lamp for Therapeutic Heating, Phototherapy Unit, and Intense Pulsed Light Electrosurgical Unit

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, 29 December 2011

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Aud Løken Eiklid
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
21 December 2015

Cecilie Gudesen Torp
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

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 (in Bold)	2011-04-27
2.0	**Scope extension- New product group added (Electrosurgical unit)**	**2011-11-30**

Products covered by this Certificate

Product Description	Product	Class
Pulsed Er-YAG Laser	Spectra-ACTION	IIb
Pulsed Nd-YAG Laser	ACCUSCULPT, ACCUSCULPT I ACCUSCULPT II Accessory : Optical Fiber, Cannula, Handpiece CLARIA	IIb
Frequency Doubled Q-switched Nd-YAG Laser	Spectra VRM III SPECTRA	IIb
Surgical CO_2 Laser (Tube Type)	eCO2, Spectra-SP, SP II, DENTA II, MOSAIC eCO2, SP IIa	IIb
Surgical CO_2 Laser (RF Type)	eCO2, eCO2 Plus, SP III, DENTA III, DENTA III+	IIb
Er-GLASS Fiber Laser	MOSAIC MOSAIC HP	IIb
Infrared lamp for therapeutic heating	HEALITE	IIb
Phototherapy Unit	HEALITE II	IIb
Intense Pulsed Light	SOLARI	IIb
Electrosurgical unit	**INFINI** **Disposable accessories; MFR Tip and SFR Tip**	IIb

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

Sites covered by this certificate

Site Name	Address

Lutronic Corporation	Room 403-1,2,3,4,5, 404 Ilsan Technotown 1141-1, Baekseok-dong, Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea

EU Representative : Orcos Medical AG

Untere Heslibachstrasse 41A CH-8700 Küsnacht, Switzerland

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