EC CERTIFICATE

Number: 2013886CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Syneron Medical LTD.

P.O.Box 550 Industrial Zone Tavor Building
Yokneam Illit 2069200
Israel

For the product category(ies)

Dermatological treatment systems

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2013886CN, initially dated 15 November 2001
Addendum, initially dated 1 June 2002

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 15 November 2001
Revised: 1 November 2016
Reissued: 1 November 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2013886CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Dermatological treatment systems

Issued to:

Syneron Medical LTD.
P.O.Box 550 Industrial Zone Tavor Building
Yokneam Illit 2069200
Israel

This certificate covers the following product(s):

Hair removal device (Class IIb)
- elōs Plus and Motif Vantage applicators (Laser, RF)
- elōs Plus with Motif HR Plus applicators (IPL, RF)

Superficial benign vascular and pigmented lesion treatment (Class IIb)
- elōs Plus with SR Plus applicators (IPL, RF)
- elōs Plus with SRA and SRA Plus applicators (IPL, RF)

Wrinkle reduction (Class IIa)
- eTwo System (RF, IPL) and sublative RF applicator and Sublime applicator (RF, IPL)

Wrinkle reduction (Class IIb)
- elōs Plus and Sublime applicator (IPL, RF)
- elōs Plus and Sublative RF applicator (RF)

Acne reduction (Class IIb)
- elōs Plus and AC applicator (IPL, RF)

Non-invasive treatment system of temporarily reduction of cellulite (Class IIa)
- VelaShape II
- VelaShape III
- adeline V

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Non-invasive body contouring via temporary circumferences reduction (Class IIa)
- VelaShape II
- VelaShape III
- adeline V

Electrocoagulation and facial wrinkle reduction
- ePrime (class IIb)
- Profound with Dermal and SubQ Applicators (class IIb)

Treatment of acne scars (Class IIa)
- eTwo and Sublative RF applicator (RF)

Treatment of acne scars (Class IIb)
- elōs Plus and Sublative RF applicator (RF)

Striae treatment (Class IIa)
- eTwo and Sublative RF applicator (RF)

Striae treatment (Class IIb)
- elōs Plus and Sublative RF applicator (RF)

Accessories:
- Sublative ID tips (operated with the Sublative RF applicators)

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MEDICAL DEVICES

Dermatological treatment systems

Issued to:

Syneron Medical LTD.
P.O.Box 550 Industrial Zone Tavor Building
Yokneam Illit 2069200
Israel

- Vela Large and small covers (operated with the VelaShape system)
- ePrime (25°) and Profound (25° and 75°) Cartridges (operated with the ePrime and Profound systems)

Initial date: 1 June 2002
Revision date: 13 August 2020

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