

# 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

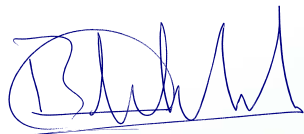
Documents, that form the basis of this certificate:

**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.



Managing Director



J.A. van Vugt  
Certification Manager

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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  
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 2013886CE01

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## 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)

- elos Plus and Motif LHR and Motif Vantage applicators (Laser, RF)
- elos Plus with Motif HR and Motif HR Plus applicators (IPL, RF)

Superficial benign vascular and pigmented lesion treatment (Class IIb)

- elos Plus and LV applicator (Laser, RF)
- elos Plus and LVA applicator (Laser, RF)
- elos Plus with SR and SR Plus applicators (IPL, RF)
- elos 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)

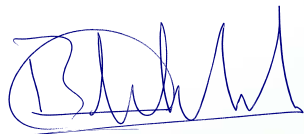
Wrinkle reduction (Class IIb)

- elos Plus and Sublime applicator (IPL, RF)
- elos Plus and Sublative RF applicator (RF)
- elos Plus and Motif IR applicator (Laser, RF)

Acne reduction (Class IIb)

- elos Plus and AC applicator (IPL, RF)

DEKRA Certification B.V.

A blue ink signature, likely belonging to the Managing Director, written in a cursive style.

Managing Director

A blue ink signature, likely belonging to the Certification Manager, written in a cursive style.

J.A. van Vugt  
Certification Manager

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

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Israel**

Non-invasive treatment system of temporarily reduction of cellulite (Class IIa)

- VelaShape II
- VelaShape III
- adeline V

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)

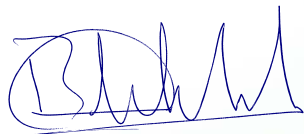
Treatment of acne scars (Class IIa)

- eTwo and Sublative RF applicator (RF)

Treatment of acne scars (Class IIb)

- elos Plus and Sublative RF applicator (RF)

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Managing Director



J.A. van Vugt  
Certification Manager

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

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

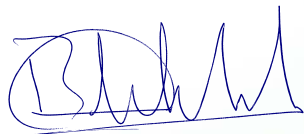
Accessories:

- Sublative ID tips (operated with the Sublative RF applicators)
- 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: 16 August 2018

DEKRA Certification B.V.

A blue ink signature of the Managing Director, consisting of a stylized, cursive name.

Managing Director

A blue ink signature of the Certification Manager, consisting of a stylized, cursive name.

J.A. van Vugt  
Certification Manager

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