

# EC CERTIFICATE

Number: 3900138CE01

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

(Devices in Class IIa, IIb or III)

Manufacturer:

**Venus Concept Ltd.**

HaYozma street, bld. 6

Yokneam Illit 2069203

Israel

For the product category(ies)

**Non-invasive dermatological treatment system for non-invasive body circumference reduction, cellulite reduction, wrinkle reduction, Acne reduction (Acne vulgaris), skin tightening treatment, Superficial benign vascular and pigmented lesions treatment and Treatment of hirsutism (hair removal) and pseudofolliculitis barbae and Alleviation of muscle injury and pain relief**

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

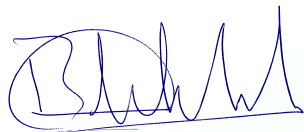
Documents, that form the basis of this certificate:

**Certification Notice 3900062CN, initially dated 4 December 2009**  
**Addendum, initially dated 24 February 2010**

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: 1 March 2024  
Issued for the first time: 24 February 2010  
Revised: 3 April 2020  
Reissued: 1 March 2019

DEKRA Certification B.V.



B.T.M. Holtus  
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: 3900138CE01

1/2

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Non-invasive dermatological treatment system for non-invasive body circumference reduction, cellulite reduction, wrinkle reduction, Acne reduction (Acne vulgaris), skin tightening treatment, Superficial benign vascular and pigmented lesions treatment and Treatment of hirsutism (hair removal) and pseudofolliculitis barbae and Alleviation of muscle injury and pain relief

Issued to:

### Venus Concept Ltd.

HaYozma street, bld. 6

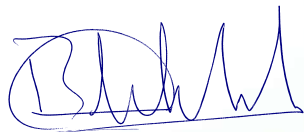
Yokneam Illit 2069203

Israel

This certificate covers the following product(s):

- Venus Freeze Plus (Class IIa) : Magnetic Pulse and Multi Polar RF
- Venus Legacy (Class IIa): Magnetic Pulse and Multi Polar RF
- Venus Viva (class IIb): Viva applicator with RF and Diamondpolar applicator with Magnetic Pulse and Multi Polar RF
- Venus Versa (class IIb):
- Intense pulsed light (IPL) Based applicators: SR515, SR580, HR650, HR690, HR650XL, HR690XL and ACDUAL
- RF and Magnetic Pulse (MP2) Based applicators: Diamondpolar, Octipolar
- Fractional RF Based applicator: Viva
- Venus Velocity (Class IIb): Diode Laser:
  - Small Light Guide applicator
  - Medium Light Guide applicator
  - Large Light Guide applicator
- Venus Epileve (Class IIb)
- Venus Epileve XL (Class IIb): Diode Laser:
  - Medium Light Guide applicator

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B.T.M. Holtus  
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## CE MARKING OF CONFORMITY MEDICAL DEVICES

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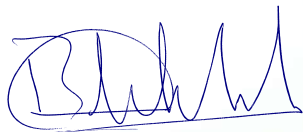
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Yokneam Illit 2069203  
Israel

- Venus Bliss (Class IIb):
  - Body Laser Applicator
  - MP<sup>2</sup> Applicator
- Venus Heal (Class IIa):
  - Small applicator
  - Large applicator

Initial date: 24 February 2010

Revision date: 3 April 2020

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