



EC CERTIFICATE

Full Quality Assurance System

Certificate no.:
10000464246-PA-NoMA-DNK

Initial certification date:
21 May 2021

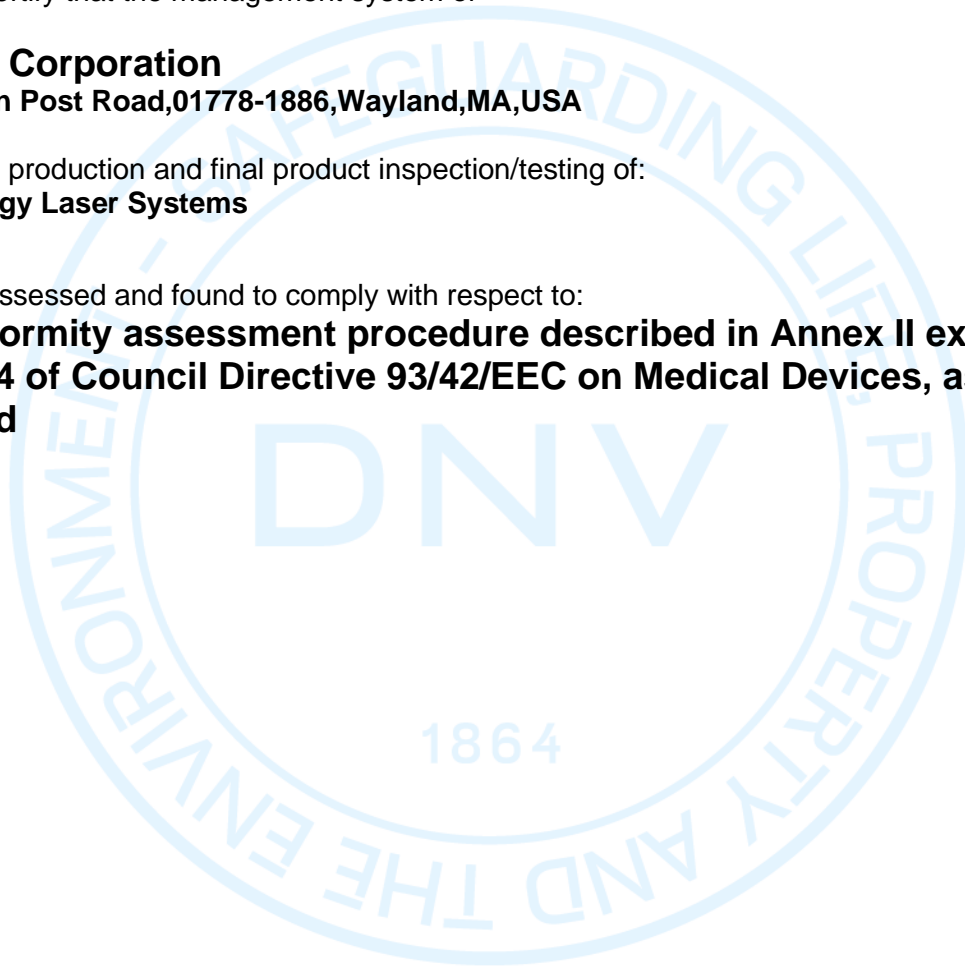
Valid Until:
27 February 2024

This is to certify that the management system of

Candela Corporation
530 Boston Post Road, 01778-1886, Wayland, MA, USA

For design, production and final product inspection/testing of:
Dermatology Laser Systems

has been assessed and found to comply with respect to:
the conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended



Place and date:
Høvik, 25 May 2021



For the issuing office:
DNV Product Assurance AS - Notified Body
2460
Veritasveien 3, 1363 Høvik, Norway

Veena Gunashekaran

Jurisdiction

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

Certificate History		
Revision	Description	Issued Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM-942 to DNV Product Assurance AS (NB 2460)	21 May 2021
1.0	Editorial change	25 May 2021

Product Description	Product Name	Class
Gentle	GentleMax Pro Plus, GentleMax Pro Plus Small Spot DCD HP, GentleMax Pro Plus Medium ACC HP, GentleMax Pro Plus Medium DCD HP, GentleMax Pro Plus Large Spot ACC HP, GentleMax Pro Plus Large Spot DCD HP, GentleLase Pro-U, GentleMax Pro, GentleMax Pro Small Spot DCD HP, GentleMax Pro Medium ACC HP, GentleMax Pro Medium DCD HP, GentleMax Pro Large Spot ACC HP, GentleMax Pro Large Spot DCD HP, GentleYAG Pro-U, Canister HFC-134a /1000g, ALUM, 15 pack, Canister HFC-134a/1000 gram, Canister HFC-134a /980g, ALUM, 15 pack, Canister HFC-134a / 980g, ALUM	IIb
PicoWay	PicoWay, 785 nm HP, 730 nm HP, 1064 Resolve HP, 532 Resolve HP, 532 Resolve HE HP, 1064 Resolve Fusion HP, 532 Resolve Fusion HP, 532/1064 Zoom HP	IIb
Vbeam	VBEAM PERFECTA, VBEAM PLATINUM, VBEAM AESTHETICA	IIb
Vbeam Prima	VBEAM PRIMA Full Configuration, VBEAM PRIMA Basic Configuration, VBEAM PRIMA EverCool Configuration VBEAM PRIMA Nd: YAG Configuration	IIb



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Sites covered by this certificate	
Site Name	Site Address
Candela Corporation	530 Boston Post Road, Wayland, MA, 01778-1886, USA

EU Representative
CEpartner4U, Esdoornlaan 13, 3951 DB Maarn, The Netherlands



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 Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body 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.