

DECLARATION OF CONFORMITY & EMC GUIDANCE

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

European Representative: Scanlan Group B.V.
Tupolevlaan 32
1119 NZ Schiphol-Rijk
The Netherlands

Model Name(s): GentleLASE
GentleLASE LE (Limited Edition)

Model Number(s): 9914-00-0880, GentleLASE w/DCD
9914-00-0890, GentleLASE w/o DCD
9914-00-0910, GentleLASE LE w/DCD
9914-00-0930, GentleLASE LE w/o DCD

Type of Equipment: Dermatology Laser System(s)

Device Classification: Class IIb (Rule 9), non invasive, active device.

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied: EN60601-1: 1990 + A1: 1993 + A2: 1995
EN60601-2-22: 1996
IEC 60825-1: 2001-08
IEC 60601-1-2: 2001-09
IEC 60601-1-4: 2000

Decision according to Annex II, Clause 3 of Council Directive 93/42/EEC concerning medical devices.

Certificate Number(s): Q1 02 04 34736 013
G1 04 01 34736 014

Start of CE-Marking: March 2003

Place and Date: Candela Corporation, Wayland, MA. USA
March 20, 2003

Signature:



Sr. Vice President, Operations

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Guidance and Manufacturers Declaration – Electromagnetic Emissions		
GentleLASE & GentleLASE LE are intended for use in the electromagnetic environment specified below. The customer or the user of these systems should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	GentleLASE & GentleLASE LE use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. GentleLASE & GentleLASE LE are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR 11	Class A	
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	

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Guidance and Manufacturers Declaration – Electromagnetic Immunity			
GentleLASE & GentleLASE LE are intended for use in the electromagnetic environment specified below. The customer or the user of these systems should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of GentleLASE or GentleLASE LE requires continued operation during power mains interruptions, it is recommended that GentleLASE or GentleLASE LE be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance and Manufacturers Declaration – Electromagnetic Immunity			
GentleLASE & GentleLASE LE are intended for use in the electromagnetic environment specified below. The customer or the user of these systems should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of GentleLASE & GentleLASE LE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = \left[\frac{3,5}{V1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = \left[\frac{3,5}{E1} \right] \sqrt{P}$ $d = \left[\frac{7}{E1} \right] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which GentleLASE or GentleLASE LE is used exceeds the applicable RF compliance level above, GentleLASE or GentleLASE LE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as orientating or relocating GentleLASE or GentleLASE LE.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

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Recommended separation distances between portable and mobile RF communications equipment and GentleLASE or GentleLASE LE			
GentleLASE & GentleLASE LE are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of GentleLASE or GentleLASE LE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and GentleLASE or GentleLASE LE as recommended below, according to maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power ration of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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