

DECLARATION OF CONFORMITY

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

Product Model: *GentleLASE, GentleLASE plus
GentleLASE LE*

Product Family: ALEX-1

Type Of Equipment: Dermatology Laser System

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
IEC601-2-22: 1995
EN60825-1: 1998
EN60601-1-2, Part 2: 1993
IEC 601-1-4: 1996

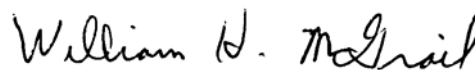
Decision according to Annex II, Clause 3 of Council Directive 93/42/EEC concerning medical devices.

Certificate Number: G1 04 01 34736 014

Start of CE-Marking: September 2000

Place and Date: Candela Corporation, Wayland, MA. USA
September 29, 2000

Signature:



William H. McGrail
Sr. Vice President, Operations