

# 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:** *GentleYAG*

**Product Family:** YAG-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  
EN60601-2-22: 1996  
IEC 60825-1: 1998  
EN60601-1-2, Part 2: 1993  
IEC 60601-1-2/Ed. 2: 2000  
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:** June 2001

**Place and Date:** Candela Corporation, Wayland, MA. USA  
March 23, 2001

**Signature:**



**William H. McGrail**

**Sr. Vice President, Operations**