DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC of 14 JUNE 1993
CONCERNING MEDICAL DEVICES

Manufacturer:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
European Representative:	Scanlan Group B.V. Aalsmeerderweg 610 1437 EJ Schiphol-Rozenburg The Netherlands
Medical Device:	GentleMax Pro (Model no. 9914-00-9035) GentleMax Pro (755) (Model no. 9914-00-9030) (GentleLase Pro-U) GentleMax Pro (1064) (Model no. 9914-00-9020) (GentleYAG Pro-U)
Type of Equipment:	Dermatology Laser System
Classification – ANNEX IX:	CLASS IIb, RULE 9
Conformity Assessment Route:	ANNEX II, CLAUSE 3

We, the Manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices – as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.

Standards Applied:	SEE ATTACHED LIST OF (HARMONIZED – EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE FOR COMPLIANCE CAN BE PROVIDED RoHS compliance is ensured under the sole responsibility of the manufacturer.
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 München Germany
Identification Number:	0123
(EC) Certificate(s):	G1 14 01 34736 021
Start of CE-Marking:	December, 2011 (GentleMax Pro) July, 2012 (GentleMax Pro (755), GentleMax Pro (1064))
Place and Date of Declaration:	Candela Corporation, Wayland, MA, USA September 30, 2014
Signature:	

Sam Wade
Vice President, Regulatory Affairs/Quality Assurance

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EN 60601-1:2006/A1:2013
EN 60601-1-2:2007
EN 60601-1-6:2010
IEC 60601-2-22:2007
EN 60825-1:2007
EN 62304:2006/AC:2008
EN 62366:2008
EN ISO 13485:2012
EN ISO 14971:2012
EN ISO 10993-1:2009
EN 1041:2008
MEDDEV 2.7.1