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:	CEpartner4U B.V. Esdoornlaan 13 3951 DB Maarn 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) GentleMax Pro Plus (Model no. 9914-CE-9036) GentleMax Pro Small Spot DCD HP (Model no. 7122-00-9602, 7122-00-9616) GentleMax Pro Medium ACC HP (Model no. 7122-00-9404, 7122-00-9615) GentleMax Pro Medium DCD HP (Model no. 7122-00-9401) GentleMax Pro Large Spot ACC HP (Model no. 7122-00-9752) GentleMax Pro Large Spot DCD HP (Model no. 7122-00-9748) GentleMax Pro Plus Small Spot DCD HP (Model no. 7123-CE-0633, 7123-CE-0650) GentleMax Pro Plus Medium ACC HP (Model no. 7123-CE-0629, 7123-CE-0648) GentleMax Pro Plus Medium DCD HP (Model no. 7123-CE-0632) GentleMax Pro Plus Large Spot ACC HP (Model no. 7123-CE-0628, 7123-CE-0653) GentleMax Pro Plus Large Spot DCD HP (Model no. 7123-CE-0631, 7123-CE-0652) Dynamic Cooling Device (DCD)/Cryogen Canister HFC-134a /1000g, ALUM, 15 pack (Model no. 1600-00-0219) Dynamic Cooling Device (DCD)/Cryogen Canister HFC-134a/1000 gram (Model no. 1600-00-0210) Dynamic Cooling Device (DCD)/Cryogen Canister HFC-134a /980g, ALUM, 15 pack (Model no. 1600-00-0224) Dynamic Cooling Device (DCD)/Cryogen Canister HFC-134a / 980g, ALUM (Model no. 1600-00-0223)
Type of Equipment:	Dermatology Laser System
Classification – ANNEX IX:	CLASS IIb, RULE 9
Conformity Assessment Route:	ANNEX II, EXCLUDING (4)

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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:	**DNV Product Assurance AS** Veritasveien 3 1363 Høvik, Norway
GMDN Code:	47883 (system), 65509 (handpiece)
Identification Number:	2460
(EC) Certificate(s):	10000464246-PA-NoMA-DNK
Start of CE-Marking:	December, 2011 (GentleMax Pro) July, 2012 (GentleMax Pro (755), GentleMax Pro (1064)) September, 2020 (GentleMax Pro Plus)
Place and Date of Declaration:	Candela Corporation, Wayland, MA. USA, 01778 May 13, 2022
Signature:	 **Lisa Pray** **Director, Regulatory Affairs**

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1. EN 60601-1:2006/A1:2013 - Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
2. EN 60601-1-2:2015 - Medical Electrical Equipment Part 2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
3. EN 60601-1-6:2010 - Medical Electrical Equipment Part 2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
4. EN 60601-2-22:2013- Medical Electrical Equipment Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment
5. EN 60825-1:2014 - Safety of Laser Products Part 1: Equipment Classification and Requirements
6. EN 62304:2006/A1:2015- Medical Device Software-Software Life-Cycle Processes
7. EN 62366-1:2015&AC:2015 - Medical devices - Part 1: Application of usability engineering to medical devices
8. EN ISO 13485:2016 - Medical Devices – Quality Management Systems-Requirements for Regulatory Purposes
9. EN ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices
10. EN ISO 10993-1:2009 – Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process
11. EN ISO 20417: 2021 –Medical devices Information to be supplied by the manufacturer
12. EN ISO 15223-1:2016 – Medical Devices – Symbols to be used with medical device labels and information to be supplied – Part 1: General Requirements
13. MEDDEV 2.7/1 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC