

**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: PicoWay (Model no. 9914-00-9060)

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: November 2014

Place and Date of Declaration: Candela Corporation, Wayland, MA, USA
November 14, 2014

Signature:



Sam Wade
Vice President, Regulatory Affairs and Quality Assurance

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EN 60601-1:2006/A1:2013
EN 60601-1-2:2007/AC:2010
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