

EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Quicklase Ltd

18 Dover Street, Canterbury, Kent CT1 3HD United Kingdom

Product Category:

- Dental diode lasers for soft tissue management

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:

41371409-02

Initial Certification Date:

31 January 2018

Certificate Valid from:

26 March 2020

Certificate Expiry Date:

26 May 2024



A handwritten signature in blue ink, appearing to read 'Bob Andersson'.

Bob Andersson

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

20 March 2020

Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

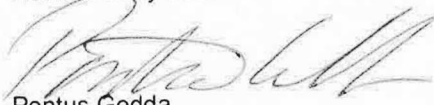


Products included in the certificate no: 41371409-02
Issued to: **Quicklase Ltd**
8 Dover Street,
Canterbury,
Kent CT1 3HD
United Kingdom

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Dental diode lasers for soft tissue management					
	Soft Tissue Laser QWLASER3	Ila	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER4	Ila	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER5	Ila	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER6D	Ila	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER8D	Ila	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER10D	Ila	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER12D	Ila	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER6	Ila	No	60340	Mar 27, 2020
	Soft Tissue Laser QWLASER8	Ila	No	60340	Mar 27, 2020
	Soft Tissue Laser QWLASER12DP	Ila	No	60340	Mar 27, 2020

Sign Date: 30 March 2020
Valid Date: 30 March 2020

Intertek Semko AB
Notified Body MDD


Pontus Gedda
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

Product list for certificate no: 41371409-02
Date: 30 March 2020
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DECLARATION OF CONFORMITY FOR THE PRODUCT

QuickLase Limited.

18 Dover Street,
Canterbury
Kent CT1 3HD
United Kingdom

Tel: 01227 80009
www.quicklase.com

CE 0413

EC Declaration of Conformity

Document Number: DoC DentaLase18_01

We QuickLase Ltd at the above address declare that the products detailed below are in compliance with the requirements of the following EU directives,

- *Medical Devices Directive 93/42/EEC** and LVFS2003:11 transposing the MDD into Swedish law*
- *Restriction on Hazardous Substances Directive (RoHS) 2011/65/EU (please note this is related to the UKAS and not SEMKO)*

***as amended by all applicable directives and regulations.*

Equipment description	Dental Diode Laser System for Soft Tissue Management System
Make/Brand	QuickLase/DentaLase
Models	QWLASERX (X = 3.0, 5.0, 6.0 ,8.0, 6.0D, 8.0D, 10.0D, 12.0D or 12.0DP)
MDD Classification	Ila
Laser Classification	Class 4
Notified Body:	Intertek Semko Kista Sweden

Compliance has been demonstrated by an assessment with respect to the essential requirements set out in Annex I of Directive and by reference to the following harmonized standards

- *EN 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*
- *EN 60601-2-22 Medical electrical equipment. Particular requirements for safety. Specification for diagnostic and therapeutic laser equipment*
- *EN60601-1-2 Medical Electrical Equipment – Electromagnetic Compatibility*
- *EN60825-1 Safety of laser products. Equipment classification and requirements*

Technical documentation for the product is retained by the Manufacturer at the above address.

EU authorised representative: Dentsur Avda. Ortega y Gasset 152, 29006 Málaga, Spain
Canterbury, March 2021

Original is Signed

Fadi Nahab, Managing Director

QuickLase Limited.

18 Dover Street,
Canterbury CT1 3HD
United Kingdom
Tel: 0044 1227 80009
www.quicklase.com



510k

K100474

FDA Declaration

We QuickLase Ltd at the above address declare that the products detailed below are in compliance with the requirements of the FDA 510(k) , see attached.

Re: K100474

Trade/Device Name: QuickLaseTM DUAL+ Dental Laser
QuickLaseTM (810nm) Dental Lasers
QuickLaseTM (980nm) Dental Lasers

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and
Plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: February 27, 2010

Received: March 09, 2010

Technical documentation for the product is retained by the Manufacturer at the above address.

Canterbury, March 2010

A handwritten signature in black ink, reading 'F. Nahab' with a stylized flourish at the end.

Fadi Nahab
Sales Manager

Indications for Use

510(k) Number: K100474

Device Name: QuickLase™DUAL+ Dental Laser, QuickLase™ 810 Dental Lasers,
QuickLase™ 980 Dental Lasers

Indications for Use: For the incision, excision, ablation, vaporization, hemostasis, and treatment of oral soft tissue.

Examples:

Excisional and incisional biopsies	Frenectomy and Frenotomy
Exposure of unerupted teeth	Gingival Troughing for crown impressions
Fibroma removal	Gingivectomy
Gingivoplasty	Gingival incision and excision
Hemostasis and coagulation	Implant Recovery
Incision and drainage of abscess	Leukoplakia
Operculectomy	Oral papillectomies
Pulpotomy	Pulpotomy as an adjunct to root canal therapy
Reduction of gingival hypertrophy	Reduction of bacterial level (decontamination) and inflammation
Soft Tissue crown lengthening	Treatment of aphthous ulcers
Vestibuloplasty	Lesion (tumor) removal
Laser Soft Tissue Curettage	Treatment of canker sores, herpetic and other ulcers of the oral mucosa
Tissue Retraction	

Removal of Diseased, Infected, Inflamed and necrotic soft tissue within the periodontal pocket

Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium

Sulcular debridement (removal of necrotic, diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

Light activation of bleaching materials for teeth whitening

Laser-assisted whitening/bleaching of teeth

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device

Neil R. Pyle for man
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices