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

This Certificate Extended until :
31 December 2028 (see extension letter)

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

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.

intertek
Total Quality. Assured.

MDD – Product List

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	IIa	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER4	IIa	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER5	IIa	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER6D	IIa	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER8D	IIa	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER10D	IIa	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER12D	IIa	No	60340	Jan 31, 2018
	Soft Tissue Laser QWLASER6	IIa	No	60340	Mar 27, 2020
	Soft Tissue Laser QWLASER8	IIa	No	60340	Mar 27, 2020
	Soft Tissue Laser QWLASER12DP	IIa	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.

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00 , Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

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	*IIa*
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: Dentalsur Avda. Ortega y Gasset 152, 29006 Málaga, Spain

Canterbury, March 2021

Original is Signed

Fadi Nahab, Managing Director

QuickWhite
QuickLase

QuickLase QuickWhite,
18 Dover Street
Canterbury
CT1 3HD United Kingdom

21 May 2024

Notified Body Confirmation Letter
Reference: CN00494-02

To whom it may concern,

Certificates included:
MDD EC Certificate Annex V 41371409-02
See attached tables for details of devices.

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

QuickLase QuickWhite,
18 Dover Street
Canterbury
CT1 3HD United Kingdom

SRN Number (if available): Not available

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Brian Mather
Certification Manager
Intertek Medical Notified Body AB

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
QWLASER3	Class IIb excluding Class IIb implantable non-WET	N/A	41371409-02 NB 0413
QWLASER4	Class IIb excluding Class IIb implantable non-WET	N/A	41371409-02 NB 0413
QWLASER5	Class IIb excluding Class IIb implantable non-WET	N/A	41371409-02 NB 0413
QWLASER6D	Class IIb excluding Class IIb implantable non-WET	N/A	41371409-02 NB 0413
QWLASER8D	Class IIb excluding Class IIb implantable non-WET	N/A	41371409-02 NB 0413
QWLASER10D	Class IIb excluding Class IIb implantable non-WET	N/A	41371409-02 NB 0413
QWLASER12D	Class IIb excluding Class IIb implantable non-WET	N/A	41371409-02 NB 0413
QWLASER12DP	Class IIb excluding Class IIb implantable non-WET	N/A	41371409-02 NB 0413

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

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

FDA K100474
510k

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: QuickLase™ DUAL+ Dental Laser
QuickLase™ (810nm) Dental Lasers
QuickLase™ (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

F. Nahab

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	Gingval Troughing for crown impressions
Fibroma removal	Gingivectomy
Gingivoplasty	Ginigival 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 apthous 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 epithlium
Sulcular debridement (removal of necrotic, diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices ingluding 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__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K100474