

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

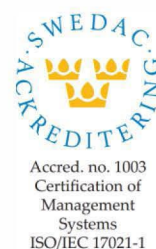
Certificate Valid from:

26 March 2020

Certificate Expiry Date:

26 May 2024

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



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.

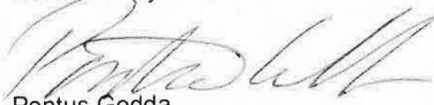


Products included in the certificate no: 41371409-02
Issued to: **Quicklase Ltd**
8 Dover Street,
Canterbury,
Kent CT1 3HD
United Kingdom

| 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
Page 1 of 1

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 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

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 that reads '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