

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:

Unique Technologies, Inc.

Main Site: 8 Corporate Boulevard, Sinking Spring, PA 19608 USA

Product Category:

- Ophthalmic microsurgical knives

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

*Previously certified by Intertek AMTAC (NB0473) to date 29 June 2018

Certificate Number:

41377486-02

Initial Certification Date:

09 March 2004*

Certificate Valid from:

26 April 2021

Certificate Expiry Date:

08 March 2024



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


Peter Nermander

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

26 April 2021

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.

