

EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full 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 II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Microsurgical Technology Inc.

Main Site: 8415 154th Avenue NE, Redmond, Washington 98052,
United States

Product Category:

- Ophthalmic surgical instruments

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:

41377505-00

Initial Certification Date:

12 December 2011*

Certificate Valid from:

29 June 2018

Certificate Expiry Date:

11 December 2022



Ackred. nr 1003
ISO/IEC 17021

Bob Andersson

Certification Authority MDD

Intertek Semko AB, Kista, Sweden

29 June 2018

Signed Date

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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.

