intertek
Total Quality. Assured.

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:

Tobin Sweden AB

Main Site: Arntorpsgatan 26, SE-442 45 Kungälv, Sweden

Product Category:

- Irrigation kit, Eye

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

Certificate Number:
41314061-03

Initial Certification Date:
December 11, 2001

Certificate Valid from:
April 20, 2018

Certificate Expiry Date:
December 11, 2021

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

April 20, 2018
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.