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:

OphthalMed LLC

Main Site: 1050 Northfield Court, Suite 280, Roswell, Georgia 30076, USA

Product Category:

- Fiberoptic probes for endo ocular photocoagulation treatments

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

Certificate Number:
41315055-02

Initial Certification Date:
17 August 2005

Certificate Valid from:
18 August 2020

Certificate Expiry Date:
26 May 2024

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

Lian Zhang

Digitally signed by Lian Zhang
DN: CN=Lian Zhang, O=Intertek Notified Body, E=lian.zhang@intertek.com
Reason: I am approving this document
Location: Kista, Sweden
Date: 2020-08-05 07:58:06

Lian Zhang
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

05 August 2020
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.