

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

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

Certificate Number
41315637-01

Initial Certification Date
May 21, 2007

Certificate Valid from
May 22, 2017

Certificate Expiry Date
May 21, 2022

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.

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.

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Organization:

Optical Integrity

19408 Panama City Beach Parkway, Panama City Beach, Florida,
32413, USA

Product Category:

- Laser fiber optical cables

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



Ackred. nr 1003
ISO/IEC 17021

May 22, 2017

Signed date


Peter Nermander, Certification Authority MDD
Intertek Semko AB, Kista, Sweden