EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate Number
41317999-01

Initial Certification Date
July 1, 2010

Certificate Valid from
December 12, 2016

Certificate Expiry Date
December 11, 2021

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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Ackred. nr 1003
ISO/IEC 17021

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:

Apotek Produktion och Laboratorier AB
Trade name: **APL**
Prismavägen 2, SE-141 75 Kungens Kurva, Sweden

Product Category:

- Lubricants
- Cleaning and disinfectant liquid for vein catheters
- Additive to haemodialysis concentrate
- Products for disinfection of medical devices
- Dental treatment products, invasive or non invasive

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

December 9, 2016
Signed date

Mats Premfors, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2015-09-30