EC Certificate

PRODUCT QUALITY ASSURANCE
Directive 93/42/EEC on Medical Devices, Annex VI

Certificate Number
41310336-01

Initial Certification Date
December 11, 1998

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 product quality assurance system - restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements - has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex VI of the Directive 93/42/EEC on medical devices. We certify that the product 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:

Apotek Produktion & Laboratorier AB

Trade name: **APL**

Prismavägen 2, SE-141 74 Kungens Kurva, Sweden

Product Category:

- Dosing devices class I with a measuring function for oral administration of medicinal products

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