EC Certificate

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

Certificate Number
41315225-02

Initial Certification Date
November 24, 2005

Certificate Valid from
September 23, 2016

Certificate Expiry Date
November 24, 2020

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:

AMVEX Canada

25B East Pearce Street, Richmond Hill, Ontario L4B 2M9
Canada

Product Category:

- Medical Flowmeter
- Hose assemblies
- Vaccum regulator

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

September 23, 2016
Signed date

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

2015-09-30