Intertek

EC Certificate

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

Certificate Number
41314784-01

Initial Certification Date
September 21, 2004

Certificate Valid from
September 22, 2014

Certificate Expiry Date
September 21, 2019

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.

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

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:

Vista Medical Ltd.

Unit 3-55 Henlow Bay, Winnipeg, Manitoba, R3Y 1G4, Canada

Product Category:

- FSA Pressure Mapping Systems

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

September 12, 2014
Signed date

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

2012-10-31