Intertek

EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41312638

Initial Certification Date
October 22, 1998

Certificate Valid from
October 23, 2013

Certificate Expiry Date
October 22, 2018

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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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:

NIDEK Medical Products, Inc

3949 Valley East Industrial Drive, Birmingham, AL 35217, USA

Product Category:

- Oxygen Concentrators, UMDNS# 12-873
- Flowmeter Kits, UMDNS# 12-855

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

October 4, 2013
Signed date

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