Intertek

EC Certificate

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

Certificate Number
41314934-02

Initial Certification Date
April 12, 2006

Certificate Valid from
January 19, 2015

Certificate Expiry Date
January 18, 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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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:

NorthEast Monitoring, Inc.

141 Parker Street, Suite 111, Maynard, MA 01754, USA

Product Category:

- Electrocardiographic Holter Recorders and Analysis Software

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

January 16, 2015
Signed date

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

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