EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE

(Annex II of the Directive 93/42/EEC on Medical Devices)

No. 41314934

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the 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 legislation.

Manufacturer:	NorthEast Monitoring, Inc. Two Clock Tower Place, Suite 555 Maynard, MA 01754 USA
Product category:	Electrocardiographic Holter Recorders and Analysis Software
Date of expiry:	18 January 2010

The Certificate is valid for the devices which are stated in the present MDD – Product list

Stockholm
12 April 2006

The original certificate issued on
19 January 2005

Intertek Semko AB
Notified Body MDD

Marie Olsson
Certification Manager MDD

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

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2004-05-14

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MDD - DECISION REPORT

Certificate no: 41314934
Date: 12 Apr. 2006

NorthEast Monitoring, Inc.
Two Clock Tower Place, Suite 555
Maynard, MA 01754
USA

Purpose	Revision of certificate due to change of address. Suite 360 has been changed to Suite 555.
Issue Date	12 April 2006
Scope of assessment	Electrocardiographic Holter Recorders and Analysis Software, Class IIa
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II, will be issued and application of the CE-mark may be done when the company's own procedures for CE-marking are fulfilled. The Certificate is valid for the product(s) specified in the "MDD-Product List" filed at Intertek Semko.
Follow-up assessments	Follow-up assessments are going to be performed minimum once a year.
Appeals	Any appeal shall be submitted to the manager of Medical Engineering, Intertek Semko AB, Box 1103, SE-164 22 Kista, Sweden
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Marie Olsson

CE