

# 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

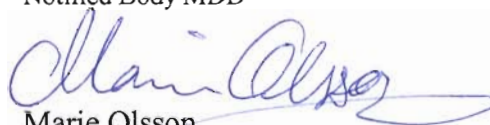
Date of expiry: 18 January 2010

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

Stockholm  
12 April 2006

**Intertek Semko AB**  
Notified Body MDD

The original certificate issued on  
19 January 2005

  
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.

**Intertek** ETL SEMKO

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

<b>Purpose</b>	Revision of certificate due to change of address. Suite 360 has been changed to Suite 555.
<b>Issue Date</b>	12 April 2006
<b>Scope of assessment</b>	Electrocardiographic Holter Recorders and Analysis Software, Class IIa
<b>Conclusions/Decisions</b>	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.
<b>Follow-up assessments</b>	Follow-up assessments are going to be performed minimum once a year.
<b>Appeals</b>	Any appeal shall be submitted to the manager of Medical Engineering, Intertek Semko AB, Box 1103, SE-164 22 Kista, Sweden
<b>Others</b>	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

