

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41314934

Initial Certification Date
April 12, 2006

Certificate Valid from
February 11, 2010

Certificate Expiry Date
January 18, 2015

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 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.

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*

Organization:

NorthEast Monitoring, Inc.

Two Clock Tower Place, Suite 555, Maynard, MA 01754

Product Category:

- Electrocardiographic Holter Recorders and Analysis Software

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

February 11, 2010

Signed date



Marie Olsson, Certification Manager MDD
Intertek Semko AB, Kista, Sweden

Certificate No: 41314934
Date: April 18, 2011
Handled by: Viktoria Hammarstedt
E-mail: medtechsweden@intertek.com

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

Purpose Assessment of results from surveillance audit according to the MDD 93/42/EEC (Swedish implementation LVFS 2003:11) performed by Lyle Lohrmeyer in Maynard, MA on March 31, 2011. The audit included the change directive 2007/47/EC (LVFS 2009:18).

Result No non conformities were noted during the audit.

Conclusions/Decisions Your certificate with number 41314934, Annex II is valid on unchanged terms. The certificate is valid for the products that are listed on the document "MDD – Product list" which has been issued by Intertek Semko AB.

Follow-up assessments Follow-up assessments will be conducted every 12 months.

Appeals Any appeal shall be submitted to the manager of Medical Regulatory Services, Intertek Semko AB, Box 1103, SE-164 22 Kista, Sweden.

Intertek Semko AB
Notified Body MDD



Marie Olsson
Certification Manager MDD

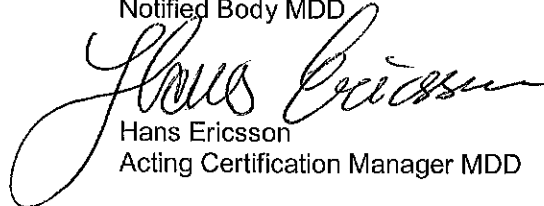
Products included in the Certificate No: 41314934
 Issued to: **NorthEast Monitoring, Inc.**
 Two Clock Tower Place, Suite 555
 Maynard, MA 01754
 USA

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
Electrocardiographic Holter Recorder and Analysis Software		Ila	-		
	LX Analysis				*
	LX Holter Analysis				*
	Holter for Windows				*
	Holter LX Analysis, <i>includes:</i> Remote, Basic, Enhanced, Enhanced Plus, Pro				*
	DR180-II				*
	DR180+				*
	DR180+ Oxy				*
	DR180				*
	DR181				Dec 20, 2010
	Telaheart				*
	DR200/Ea				*
	DR200/HE				*
	DR200/HEa				*
	DR220				*

* Product added before February 11, 2010.

Date of Issue: December 20, 2010

Intertek Semko AB
 Notified Body MDD



Hans Ericsson
 Acting Certification Manager MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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

Product List for Certificate No: 41314934
 Date: December 20, 2010
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NorthEast Monitoring, Inc.

2 Clock Tower Place, Suite 555
Maynard, MA 01754 U.S.A.
www.nemon.com

phone: 978-461-3992
fax: 978-461-5991
toll free: 866-346-5837

Declaration of Conformity

Application of Council Directive(s): Medical Device Directive 93/42/EEC
Swedish Regulations: LVFS 2003:11

Standards to which Conformity is declared: ISO 13485, ISO 14971, EN/IEC 60601-1,
IEC 60601-1-2-47, EN 60601-1-2

Manufacturer's Name: NorthEast Monitoring, Inc.

Manufacturer's Address: Two Clock Tower Place, Suite #555
Maynard, MA 01754 USA

Community Representative: MediMark Europe, 11, rue Emile Zola, BP 2332
38033 Grenoble Cedex 2, France

Notified Body: Intertek Semko AB, Torshamnsgatan 43
Box 1103
SE-164 22 Kista, Sweden

Type of Equipment: Electro Cardiographic Holter Recorder and
Analysis Software

Device Classification per MDD 93/42/EEC: Class IIa, Rule 10

Model Numbers: DR180+, DR181, SD360, Telaheart, DR200/E,
DR200/HE, DR200/HEa, DR220 Digital
Recorders, Holter LX Analysis Software and
LX Event Software
(See MDD Product List and MDD Decision
report Attached).

Serial Numbers: N/A

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).

Place: Maynard, MA 01754 USA
Position: Director of Quality Assurance & Regulatory Affairs
Date: February 22, 2011
Full Name: Sherry L. Strickland

Signature:

Sherry L. Strickland
