EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

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.

Main Site: 141 Parker Street, Suite 200, 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.

Certificate Number:
41314934-05

Initial Certification Date:
12 April 2006

Certificate Valid from:
27 March 2020

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

27 March 2020
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

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.

MDD – Product List

Products included in the Certificate No: 41314934-05

Issued to: **NorthEast Monitoring, Inc.**
141 Parker Street, Suite 200,
Maynard, MA01754
USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Electrocardiographic Holter Recorders and Analysis					
	Holter LX Analysis	IIa	No	-	*
	DR200/HE	IIa	No	-	*
	DR400/HE	IIa	No	-	Mar 13, 2019

* Product added before February 11, 2010.

Date of Issue: 27 March 2020

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority 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.

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Intertek Semko AB
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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41314934-05
Date: 27 March 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

NorthEast Monitoring, Inc.
Attn: Sherry L. Steele
141 Parker Street, Suite 200,
Maynard, MA01754
USA

Purpose	Assessment to issue a new certificate due to typing error. The certificate type was incorrectly named as EC DESIGN EXAMINATION CERTIFICATE. This has now been corrected to FULL QUALITY ASSURANCE SYSTEM This decision has been made according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Scope of assessment	Electrocardiographic Holter Recorders and Analysis Software, Class IIa
Certificate Valid from	27 March 2020
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. The Certificate is valid for products specified in the “MDD – Product List”.
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-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

Bob Andersson
Certification Authority MDD