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

advancing Holter technology

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+, 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: December 21, 2007
Full Name: Sherry L. Strickland

Signature: Sherry L. Strickland