



# NorthEast Monitoring, Inc.

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Maynard, MA 01754 U.S.A.  
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## *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*