

## **CERTIFICATE**OF REGISTRATION

This is to certify that the management system of:

## NorthEast Monitoring, Inc.

(FIN F000906)

Main Site: 141 Parker Street, Suite #200

Maynard, Massachusetts 01754 USA

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

## ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

## The management system is applicable to:

The design, manufacturing, and service of ambulatory monitoring and recording devices and the associated analytical software.

**Certificate Number:** 

0087230-01

**Initial Certification Date:** 

2019-02-15

**Date of Certification Decision:** 

2022-04-06

**Certification Effective Date:** 

2022-04-06

**Certification Expiry Date:** 

2025-02-14



MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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