

Nasiff Associates, Inc. 841-1 County Route 37 Central Square, NY 13036 USA

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DECLARATION OF CONFORMITY

Name and Address of Product Owner:

Roger E. Nasiff, PhD Nasiff Associates, Inc. 841-1 County Route 37 Central Square, NY 13036 USA

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations.

Manufacturing Site:

Nasiff Associates, Inc. 841-1 County Route 37 Central Square, NY 13036 USA

Medical Device(s):

(CC-ECG1)CardioCard Resting ECG System(CC-ECG1-M)CardioCard Resting Mobile ECG System(CC-ECG1-W)CardioCard Resting Wi-Fi ECG System(CC-ECG1-BT)CardioCard Resting Bluetooth ECG System(CC-STRESS)CardioCard Stress Testing ECG System

(CC-STRESS-BT) CardioCard Stress Testing Bluetooth ECG System

(CC-SUITE) CardioCard Suite ECG System (Resting, Stress and Holter)

(CC-HOLTER) CardioCard Holter Monitor ECG System
(CC-HOLTER B12) CardioCard 12-Holter Monitor ECG System

(HR-VX3P) CardioCard Holter Plus Recorder (HR-B12) CardioCard 12-Holter Recorder (CC-NIBPECG-R) CardioCard Resting BP System (CC-NIBPECG-S) CardioCard Stress BP System

Risk Classification:

Regulatory Class: II (two)

Quality Management System Certificate:

FDA 510K, FDA USA, ISO13485, FM 668712, MDSAP 723513, Health Canada

This declaration of conformity valid from July 1, 2018 thru May 5, 2026

Signature:

01.03.2024

Roger E. Nasiff, PhD Owner and President