bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nasiff Associates, Inc
841-1 County Route 37
Central Square
New York
13036
USA

Digitally signed by Jighili Tatiana
Date: 2023.07.14 10:44:45 EEST
Reason: MoldSign Signature
Location: Moldova

Holds Certificate Number: FM 668712

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, service and distribution of PC ECG, Holter and NIBP Systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-05-11
Latest Revision Date: 2023-05-08

Effective Date: 2023-05-11
Expiry Date: 2026-05-10

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nasiff Associates, Inc
841-1 County Route 37
Central Square
New York
13036
USA

Facility ID Number: F005197

Holds Certificate No: **MDSAP 723513**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Canada: Medical Devices Regulations - Part 1 - SOR 98/282
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, manufacture, service and distribution of PC ECG, Holter and NIBP Systems

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-11-09 Effective Date: 2023-05-11 Expiry Date: 2026-05-10

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Nasiff Associates, Inc.
841-1 County Route 37
Central Square, NY 13036 USA
tel: 315.676.2346
fax: 315.676.4711
toll: 866.627.4332
www.nasiff.com

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):

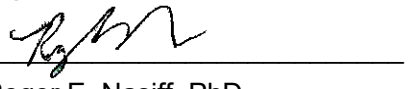
(CC-ECG1)	CardioCard Resting ECG System
(CC-ECG1-M)	CardioCard Resting Mobile ECG System
(CC-ECG1-W)	CardioCard Resting Wi-Fi ECG System
(CC-ECG1-BT)	CardioCard Resting Bluetooth ECG System
(CC-STRESS)	CardioCard Stress Testing ECG System
(CC-STRESS-BT)	CardioCard Stress Testing Bluetooth ECG System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



01.03.2023

Roger E. Nasiff, PhD
Owner and President

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14952-9-2021

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(One Page)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 22, 2021 to September 21, 2023.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14952-9-2021
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

NASIFF ASSOC., INC.
841-1 COUNTY ROUTE 37
Central Square, NY
USA 13036

Name of Manufacturer

NASIFF ASSOC., INC.
841-1 COUNTY ROUTE 37
CENTRAL SQUARE, NY
USA 13036

----END OF MANUFACTURER/DISTRIBUTOR LIST----

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14952-9-2021

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Owner Operator

NASIFF ASSOC., INC.
841-1 COUNTY ROUTE 37
Central Square, NY
USA 13036

Name of Manufacturer

NASIFF ASSOC., INC.
841-1 COUNTY ROUTE 37
CENTRAL SQUARE, NY
USA 13036

Name of Product(s)

Cardio Non-Invasive Blood Pressure Monitoring System (CC-ECGNP)
CardioHolter ECG Monitoring System(CC-Holter,CC-HolterPlus,CC-HolterB12,HR-VX3P,HR-B12)
Cardio ECG/Stress Test(CC-ECG1,CC-ECG1-BT,CC-ECG1-W,CC-ECGBTM,CC-STRESS,CC-STRESS-BT)
----------END OF PRODUCT LIST----------

Annual Registration Successful

Facility: NASIFF ASSOC., INC., CENTRAL SQUARE, New York, UNITED STATES

You have successfully updated your registration and listing information for 2023.

Your registration will be valid through Dec 31, 2023.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 9001556.

Facility Information

Registration Number:
1319390

Initial Importer:
N

Facility Name:
NASIFF ASSOC., INC.

Legal Name:

Address:
841-1 COUNTY ROUTE 37,
CENTRAL SQUARE, New York, 13036, UNITED STATES

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:
9001556

Contact Name:
ROGER E NASIFF

Company:
NASIFF ASSOC., INC.

Address: **841-1 COUNTY ROUTE 37, --**
Central Square, NEW YORK, 13036, UNITED STATES

Telephone:
315 - 6762346

Fax:
-

E-mail: **nasales@nasiff.com**

DUNS Number:

Official Correspondent Information

Contact Name:
ROGER E NASIFF

Company:
NASIFF ASSOC., INC.

Address: **841-1 COUNTY ROUTE 37, --**
Central Square, NEW YORK, 13036, UNITED STATES

Telephone:
315 - 6762346

Fax:
-

E-mail: **nasales@nasiff.com**

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
E597835	K920020		DPS	Electrocardiograph	Manufacturer Contract Manufacturer
D005958	K972795		DXN	System, measurement, blood-pressure, non-invasive	Manufacturer

D005971	K960544		DRT	MONITOR, CARDIAC (INCL. CARDIOTACHOMETER & RATE ALARM)	Manufacturer

Date of Initial Registration: 1990-08-20 09:42:26.0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Roger E. Nasiff
President
Nasiff Associates, Inc.
P.O. Box 88
Brewerton, NY 13029

FEB 20 1998

Re: K972795
Cardio-Card Management System II
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: November 21, 1997
Received: November 24, 1997

Dear Mr. Nasiff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972795

Device Name: Cardio-Card Management System II

Indications For Use:

The Cardio-Card system monitors heart rhythms and reports ECGs, rhythm conditions, ECG printouts, ECG measurements, NIBPs and patient demographic information (e.g. patient name, ssn, physician name, address, physician notes, test notes). The system stores the patient's data to computers for later easy retrieval from its database. The computers can be networked to allow sharing of the information also. Studies can be typical short 12-sec ECG strips and NIBPs or very long term studies.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)