Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. TR-4 din 14.07.2023

Solicitantul TRIUMF MOTIV SRL, cu sediul or. Chișinău str. Grenoble 193
(adresa)
_____, tel./fax: 022768462, e-mail triumf.motiv@mail.ru,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Denumire generică (denumirea dispozitivului)	Modelul
CardioCard Resting ECG System	(CC-ECG1)
CardioCard Resting Mobile ECG System	(CC-ECG1-M)
CardioCard Resting Wi-Fi ECG System	(CC-ECG1-W)
CardioCard Resting Bluetooth ECG System	(CC-ECG1-BT)
CardioCard Stress Testing ECG System	(CC-STRESS)
CardioCard Stress Testing Bluetooth ECG System	(CC-STRESS-BT)
CardioCard Suite ECG System (Resting, Stress and Holter)	(CC-SUITE)
CardioCard Holter Monitor ECG System	(CC-HOLTER)
CardioCard 12-Holter Monitor ECG System	(CC-HOLTER B12)
CardioCard Holter Plus Recorder	(HR-VX3P)
CardioCard 12-Holter Recorder	(HR-B12)
CardioCard Resting BP System	(CC-NIBPECG-R)
CardioCard Stress BP System	(CC-NIBPECG-S)

Se anexează următoarele acte:
DECLAȚIE DE CONFORMITATE CE
CERTIFICATUL DE CONFORMITATE CE
Scrisoare de autorizare de la producător

Data 14.07.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Digitally signed by Jighili Tatiana Date: 2023.07.14 10:45:20 EEST Reason: MoldSign Signature Location: Moldova

Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: _____TRIUMF MOTIV SRL_____, cu sediul _____or. Chișinău str. Grenoble 193_____,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Denumire generică (denumirea dispozitivului)	Modelul
CardioCard Resting ECG System	(CC-ECG1)
CardioCard Resting Mobile ECG System	(CC-ECG1-M)
CardioCard Resting Wi-Fi ECG System	(CC-ECG1-W)
CardioCard Resting Bluetooth ECG System	(CC-ECG1-BT)
CardioCard Stress Testing ECG System	(CC-STRESS)
CardioCard Stress Testing Bluetooth ECG System	(CC-STRESS-BT)
CardioCard Suite ECG System (Resting, Stress and Holter)	(CC-SUITE)
CardioCard Holter Monitor ECG System	(CC-HOLTER)
CardioCard 12-Holter Monitor ECG System	(CC-HOLTER B12)
CardioCard Holter Plus Recorder	(HR-VX3P)
CardioCard 12-Holter Recorder	(HR-B12)
CardioCard Resting BP System	(CC-NIBPECG-R)
CardioCard Stress BP System	(CC-NIBPECG-S)

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia Jighili Tatiana, Administrator
Semnătura _____

Data _14.07.2023___

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

LETTER OF AUTHORIZATION

Date: June 23, 2023

To whom it may concern:

Hereby we

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

Certify that

Triumf Motiv SRL
Address: Republic of Moldova, MD 2043-str. Grenoble 193, et.13, of.1
Tel: (+373 22) 76 84 62, 76 88 41

They are our authorized representative and distributor in the territory of the Republic of Moldova. We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, and distribute our products in the Republic of Moldova. We will provide all necessary assistance to expand the market for medical supplies and devices of Nasiff CardioCard Diagnostic Management Systems in your country.

This letter of authorization remains valid for five years, starting from March 10, 2023 and expiring on March 09, 2028.

Name: Roger E. Nasiff
Title: President and Owner
Nasiff Associates, Inc.

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):

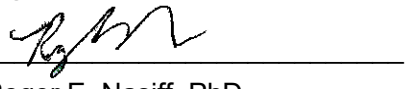
(CC-ECG1)	CardioCard Resting ECG System
(CC-ECG1-M)	CardioCard Resting Mobile ECG System
(CC-ECG1-W)	CardioCard Resting Wi-Fi ECG System
(CC-ECG1-BT)	CardioCard Resting Bluetooth ECG System
(CC-STRESS)	CardioCard Stress Testing ECG System
(CC-STRESS-BT)	CardioCard Stress Testing Bluetooth ECG System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

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.™

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

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

...making excellence a habit.™