



Full Vision, Inc.

3017 Full Vision Drive
Newton, KS 67114

Phone: 316-283-3344
Fax: 316-283-9522
www.full-vision.com

DECLARATION OF CONFORMITY

I, Tim Rikoff, hereby declare under our sole responsibility that the Trackmaster product, by Full Vision Incorporated, 3017 Full Vision Drive, Newton Kansas USA, is in conformity with 2004/108/EC EMC Directive and Council Directive MDD 93/42/EEC (Medical Device Directive) as modified by 2007/47/EC.

Particulars of Medical Device

Part Number:

2097357-001
2097357-002

Name:

T2100-ST1 "Treadmill 110V"
T2100-ST2 "Treadmill 220V"

Manufacturer:

Full Vision Incorporated

Country of origin:

United States of America

Manufacturing site:

3017 Full Vision Drive, Newton Ks 67114

Risk based classification:

Class A(M)

GMDN code:

17895 "Stress exercise trolley"

Accessories:

2097357-003	ADJUSTABLE HANDRAIL FOR T2100 ST1 AND ST2
2097829-001	POWER CORD 125VAC 20A NEMA 5-20P
2097829-002	POWER CORD 250VAC 15A NEMA 6-15P
2097829-003	POWER CORD 250VAC 16A CEE 7/7 EURO SCHUKO
2097829-004	POWER CORD 250VAC 13A BS1363
2097829-005	POWER CORD 250VAC 15A BS546 3 PIN
2097829-006	POWER CORD 250VAC 15A AS/NZS 3112
2097829-007	POWER CORD 250VAC 15A GB 1002
2097829-009	CABLE RS232 9 PIN M/F X 25'
2097829-010	CABLE RS232 9 PIN M/M X 25'
2097829-012	POWER CORD 250VAC 13A TYPE K-DANISH
2097829-013	POWER CORD 250VAC 16A TYPE J-SWISS
2097829-014	POWER CORD 250VAC 16A TYPE H-ISREAL
2097829-015	POWER CORD 250VAC 15A TYPE L-ITALY
2097829-016	POWER CORD 250VAC 15A TYPE N-BRAZIL



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Quality Management System Certificate ("QMS")

Quality Management System: ISO 13485:2016
Conformity Assessment Body: Intertek Testing Services NA, Inc.
Certificate No.: 0080126-00
Effective Date: August 24, 2018
Expiry Date: August 23, 2021

Medical Equipment Safety

IEC 60601-1:2012 Ed: 3.1 (Basic Safety and Essential Performance)
AAMI ES60601-1 2010/05 (Basic Safety and Essential Performance)
ANSI/UL 1647 2011/04 Ed: 5 (Motor-Operated Massage and Exercise Machine)
CSA C22.2#60601-1 2011/06 Ed: 3 (Basic Safety and Essential Performance)

Electromagnetic Compatibility (EMC)

IEC CISPR 11-1 (EMC)
IEC CISPR 11-2 (EMC Part 2 Immunity)
FCC 47CFR 15B (Unintentional Radiators Class A)
IEC 003 (Issue No.4 Interference-Causing Equipment Standard)
IEC 62233:2008 (EMC Human Exposure)

In recognition of conformity to the MDD93/42/EEC Directive, the product is marked with the symbol. CE This product is Class 1 according to Rule 12 of MDD Annex IX.

The T2100-ST1 and T2100-ST2 are designed to be interfaced with ECG systems used for cardiac stress and pulmonary function testing.

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 27-November-2018.

Authorized Signatory:



Product Manager