Full Vision, Inc.

3017 Full Vision Drive
Newton, KS 67114

Phone: 316-283-3344
Fax: 316-283-9522

DECLARATION OF CONFORMITY

I, Tim Rikoff, hereby declare under our sole responsibility that the 4Th Edition Trackmaster product, by Full Vision Incorporated, 3017 Full Vision Drive, Newton Kansas USA, is in conformity with 2014/30/EU EMC Directive and Council Regulation MDD (EU) 2017/745 (Medical Device Directive). Standards to which we declare conformity include:

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

Quality Management System Certificate ("QMS")

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

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Medical Equipment Safety

AAMI ES60601-1:2005 +A1
Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CSA C22.2#60601-1:2014 Ed.3
Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-6:2010 Ed.3 +A1
Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability

Electromagnetic Compatibility (EMC)

IEC 60601-1-2 Ed 4.0 (2014-02)
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 61000-3-2(Ed: 4.0): 2014-05, EN 61000-3-2: 2014-08
Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits For Harmonic Current Emissions (Equipment Input Current <= 16 A Per Phase);

IEC 61000-3-3(Ed: 3.0): 2013-05, EN 61000-3-3: 2013-08
Electromagnetic Compatibility (EMC) - Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems, for Equipment with Rated Current Less Than or Equal to 16 A Per Phase and Not Subject to Conditional Connection

In recognition of conformity to Regulation MDD (EU) 2017/745, the product is marked with the symbol. CE This product is Class 1 according to Rule 10 of MDD Annex VIII.

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 26-March-2019.

Authorized Signatory: _____
Product Manager