TRACKMASTER®
by Full Vision, Inc.

MEDICAL GRADE TREADMILLS

Full Vision, Inc.

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Declaration of Conformity

MANUFACTURER			
Name of company		**Address**	**Representative**
Full Vision, Inc		3017 Full Vision Drive Newton, KS 67114 USA	Doug Pauls, Compliance Manager
SRN:	US-MF-000002038		

AUTHORIZED REPRESENTATIVE		
Name of company		**Address**
Emergo Europe		Westervoortsedijk 60 6827 AT Arnhem The Netherlands
SRN:	NL-AR-000000116	

PRODUCT IDENTIFICATION		
Product name	**Model/number**	**Basic UDI**
Trackmaster Treadmill	TMX428 110V / 317-07926 TMX428 220V / 317-07927 TMX428CP 110V / 317-07928 TMX428CP 220V / 317-07929 T2100-ST1 / 317-07926GE / 2097357-001 T2100-ST2 / 317-07927GE / 2097357-002	08601760006FVITMR4

Intended Purpose	**Photo**
The medical treadmills are intended as stressing devices, by providing motion to patient, to be interfaced with a variety of cardiac and pulmonary stress testing systems. The treadmill is intended to be operated by the physician, therapist, or operator acting under authorization of the physician with training per IFU under the supervision of a physician and / or therapist, with sufficient knowledge of the indications and contraindications. The medical treadmills are intended to be used in a medical facility or wellness center. Certain models have a control panel to operate the treadmill. Caution: Treadmill does not provide any kind of medical treatment diagnostic or assessment.	

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class I Rule 13	Annex II and III of MDR 2017/745	See List below

STANDARDS APPLIED			
Standard Number	**Standards Organisation**	**Standard Title**	**Version**
13485	ISO	Medical Devices Quality Management Systems Requirements	2016
14971	ISO	Medical Devices – Application of risk management to medical devices	2019
15223-1	ISO	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	2021
17664	ISO	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices	2017
20416	ISO	Medical devices – Post-market surveillance for manufacturers	2020
20417	ISO	Medical devices – Information to be supplied by the manufacturer	2021
10993-1	ISO	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	2018
62304	IEC	Medical device software – Software life-cycle processes	2006+A1:2016
62366-1	IEC	Medical devices – Application of usability engineering to medical devices	2015+A1:2020
60601-1	IEC	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2005+A1:2012
60601-1-2	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests	2014
60601-1-6	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	2010+A1:2013
61000-3-2	IEC	Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	(Ed:4.0): 2014
61000-3-3	IEC	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 ≤ 16 A per phase and not subject to conditional connection	(Ed:3.0): 2013
D4169-16	ASTM	Standard Practice for Performance Testing of Shipping Containers and Systems	16
14-1	CISPR	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	2014
14-2	CISPR	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard	2015 Ed:2.0
C22.2 # 60601-1	CSA	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2005+A1

RoHS Compliance

The previously listed products, manufactured by Full Vision Inc, as well as the accessories and options available, are in compliance with the RoHS Directive (EU Directive 2002/95/EC and subsequent amendments). RoHS Compliant means that the substances restricted by the EU Directive 2011/65/EU (RoHS 2) and EU Directive 2015/863/EU (RoHS 3) and subsequent amendments of the European Parliament are not contained in a finished product above threshold limits stated below.

Restricted Substance	Maximum Threshold Limit
Lead	0,1 %
Mercury	0,1 %
Cadmium	0,01 %
Hexavalent chromium	0,1 %
Polybrominated biphenyls (PBB)	0,1 %
Polybrominated diphenyl ethers (PBDE)	0,1 %
Bis (2-ethylhexyl) phthalate (DEHP)	0,1 %
Butyl benzyl phthalate (BBP)	0,1 %
Dibutyl phthalate (DBP)	0,1 %
Diisobutyl phthalate (DIBP)	0,1 %

REACH Compliance

The EU REACH Regulation (EC) No 1907/2006 of the European Community, concerning the Registration, the Evaluation and the Authorization of the Chemical substances (REACH), was released in June 2007. The instruction of the regulation establishes specific duties and obligations for Companies in the European Union (EU) that manufacture or import substances on their own, in preparations, as well as in articles. Under the structure of the REACH regulation, **Full Vision Inc**, is a manufacturer and supplier of "articles" to our EU Customers, and is therefore not obliged to register or pre-register the products we supply. Full Vision Inc products (articles) do not contain Substances of Very High Concern (SVHC) above the threshold value declared as per ECHA. Customers are encouraged to visit the site https://echa.europa.eu/candidate-list-table for the most up to date information on the current list of SVHCs under REACH.

This declaration of conformity is issued under the sole responsibility of **Full Vision, Inc**. **Full Vision, Inc** declares the device(s) that is covered by the present declaration is in conformity with this Regulation (EU) MDR 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Authorized Signatory

Signature	Date of issue: 3/1/2023
Doug Pauls	
Name	
Compliance Manager, PRRC	Newton, KS
Title	Place of Issue

Company Stamp

Full Vision, Inc.

DOCUMENT CHANGE HISTORY			
Revision	**Description**	**Author**	**Date**
1	Initial Release to EU MDR 2017/745	B. Tucker	2021/02/02
2	Added Full Vision SRN number, corrected Route to compliance to Annex II and III instead of Annex IV, added RoHS directive (EU) 2015/863, Added REACH regulation 1907/2006,	B. Tucker	2021/03/15
3	Added additional model numbers to product identification for the T2100-ST1 and ST2	B. Tucker	2021/04/27
4	Updated Standards Applied table with applicable standards for state of the art and required testing (updated revisions 15223-1, 62304, 62366, 61000-3-2, 61000-3-3, 14-1, 14-2, C22.2 # 60601-1; removed 60601-1-1), updated Authorized representative Address	B. Tucker	2023/02/20