



MAKING CARE EASIER



EU Declaration of Conformity

**Ceiling Track Hoist:
Transactive Extra Advance (TX+ range)**

**Technical file Reference: PMUK_TF01-02
Revision: 2**

In Conformance with Medical Devices Regulation (EU) 2017/745

Legal Manufacturer:	Prism Medical UK Unit 1, Tir Llwyd Industrial Estate, St Asaph Avenue, Kinmel Bay, Rhyl, Conwy, LL18 5JZ, UK
SRN	GB-MF-000010634
EU Authorized Representative:	European Healthcare & Device Solutions (Ireland) Ltd Stratton House, Bishopstown Road, Cork Ireland, T12 Y9TC SRN: IE-AR-000003999

We hereby declare that the following mentioned products meet the provisions of the Council Regulation (EU) 2017/745 covering medical devices. All documentation is controlled and retained on company premises.

Product Name:	Freeway/ Mackworth TXAdv Ceiling track Hoists
Identification of the device(s) concerned:	Full List of Product Codes/Ref. to Product Range Table in appendix 1
Basic UDI-DI	50564089PMUK002RJ
Intended purpose:	Intended to be used with hoist systems for the transfer of clients from one surface to another
GMDN:	38129 - Overhead track patient lifting/transfer system A electrically-powered assembly of devices designed to enable an incapacitated patient or a person with a disability to be lifted/moved (transferred) safely and with minimal physical effort within the confines of one floor of a building, typically an institution or the person's home. It typically consists of ceiling-mounted track, and a motorized hoist and patient holding device (e.g., a sling, holder or a frame) for lifting and lowering the patient, that can be moved along the overhead track.
EMDN:	V08050302 – Electric Fixed Lifts
CND:	Y123612: Patient Lifting system – Fixed
Risk Classification:	Class I - as per Rule 13 in accordance with Annex VIII of Regulation 2017/745
Condition supplied:	Non-sterile
Conformity Assessment Route:	Annex II and III of EU Medical Device Regulation (EU) 2017/745
References to any CS:	N/A
Applied Directives	EU 2017/745 Medical device Regulation 2006/42/EC Machinery Directive 2014/35/EU Low Voltage Directive 2014/30/EU Electromagnetic Compatibility of Equipment Directive 2013/172/EU Unique Device Identification (UDI) 2011/65/EU Restriction of Hazardous Substance (RoHS) 3 2012/19/EU Waste Electrical and Electronic Equipment (WEEE)
Applied Standards	EN ISO 13485:2016 EN ISO 14971:2019 BS EN ISO 12100:2010 EN ISO 15223-1:2021 BS ISO 20417:2021 BS EN ISO 10535:2006

	IEC 60601-1-1:2012 IEC 60601-1-2:2014 IEC 60601-1-11:2010 IEC 62366-1:2015 BS EN 50419:2022
Notified Body:	N/A – Class I, self-certified devices.
Identification of the Certificate(s):	EC Quality Management System issued by NQA Certificate No. 67420, expiry date: 27 Sept 2024

This declaration of conformity is issued under the sole responsibility of the Legal Manufacturer and was written in accordance with Annex VIII of the Council Regulation (EU) 2017/745. This declaration is supported by the Quality System approval to ISO 13485 issued by NQA. It is a live document and is regularly updated. Unless an update is triggered by a change, this document will expire 5 years after it has been signed.

Identification of the person authorized to sign on behalf of Legal Manufacturer:	<p style="text-align: center;"><i>Jason Leek</i></p> <p>Signature: <u>Jason Leek (Mar 30, 2023 21:33 GMT+1)</u></p> <p>Jason Leek Chief Executive Officer, Prism Healthcare</p> <p>Place of Issue: Grange Moor, England Date: 30-Mar-2023</p>
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Appendix 1

List of Products

Product Code	Product Description	UDI-DI
1001TXADV122600	FW TX132Adv-TT1, Manual Powered Turntable 130kg	5056408920957
1001TXADV122601	FW TX132Adv-Track Type 1 Manual-Const Charge 130kg	5056408920964
1001TXADV122602	FW TX132Adv-TT1, Driven 130kg	5056408920971
1001TXADV122603	FW TX132Adv-TT1, Driven Powered Turntable 130kg	5056408920988
1001TXADV122604	FW TX132Adv-TT1, Driven Constant Charge 130kg	5056408920995
1001TXADV122605	FW TX202Adv-TT1, Manual Powered Turntable 200kg	5056408921008
1001TXADV122606	FW TX202Adv-TT1, Manual Constant Charge 200kg	5056408921015
1001TXADV122607	FW TX202Adv-TT1, Driven 200kg	5056408921022
1001TXADV122608	FW TX202Adv-TT1, Driven Powered Turntable 200kg	5056408921039
1001TXADV122609	FW TX202Adv-TT1, Driven Constant Charge 200kg	5056408921046
1001TXADV122610	FW TX272Adv-TT1, Manual Powered Turntable 272kg	5056408921053
1001TXADV122611	FW TX272Adv-TT1, Manual Constant Charge 272kg	5056408921060
1001TXADV122612	FW TX272Adv-TT1, Driven 272kg	5056408921077
1001TXADV122613	FW TX272Adv-TT1, Driven Powered Turntable 272kg	5056408921084
1001TXADV122614	FW TX272Adv-TT1, Driven Constant Charge 272kg	5056408921091
1001TXADV122615	MW TX440Adv-TT1 Manual Powered Turntable 200kg	5056408921107
1001TXADV122616	MW TX440Adv-TT1, Manual Constant Charge 200kg	5056408921114
1001TXADV122617	MW TX440Adv-TT1 Driven 200kg	5056408921121
1001TXADV122618	MW TX440Adv-TT1 Driven Powered Turntable 200kg	5056408921138
1001TXADV122619	MW TX440Adv-TT1, Driven Constant Charge 200kg	5056408921145
1001TXADV122620	MW TX600Adv-TT1, Manual Powered Turntable 272kg	5056408920476
1001TXADV122621	MW TX600Adv-TT1, Manual Constant Charge 272kg	5056408921169
1001TXADV122622	MW TX600Adv-TT1, Driven 272kg	5056408921176
1001TXADV122623	MW TX600Adv-TT1, Driven Powered Turntable 272kg	5056408921152
1001TXADV122624	MW TX600Adv-TT1, Driven Constant Charge 272kg	5056408920490
1001TXADV122625	FW TX132Adv- TT2, Manual Constant Charge 130kg	5056408921183
1001TXADV122626	FW TX132Adv-TT3, Driven 130kg	5056408921190
1001TXADV122627	FW TX132Adv-TT3, Manual Constant Charge 130kg	5056408921206
1001TXADV122628	FW TX132Adv-TT3, Driven Constant Charge 130kg	5056408921213
1001TXADV122629	FW TX132Adv-TT4, Driven 130kg	5056408921220
1001TXADV122630	FW TX132Adv-TT4, Driven Constant Charge 130kg	5056408921237
1001TXADV122631	FW TX132Adv-TT4, Manual Constant Charge 130kg	5056408921244
1001TXADV122632	FW TX132Adv-TT5, Driven 130kg	5056408921251
1001TXADV122633	FW TX132Adv-TT5, Driven Constant Charge 130kg	5056408921268
1001TXADV122634	FW TX132Adv-TT5, Manual Constant Charge 130kg	5056408921275
1001TXADV122635	FW TX202Adv-TT2, Manual Constant Charge 200kg	5056408921282
1001TXADV122636	FW TX202Adv-Track Type 3 Driven 200kg	5056408921299
1001TXADV122637	FW TX202Adv-TT3, Driven Constant Charge 200kg	5056408921305
1001TXADV122638	FW TX202Adv-TT3, Manual Constant Charge 200kg	5056408921312
1001TXADV122639	FW TX202Adv-TT4, Driven 200kg	5056408921329
1001TXADV122640	FW TX202Adv-TT4, Driven Constant Charge 200kg	5056408921336
1001TXADV122641	FW TX202Adv-TT4, Manual Constant Charge 200kg	5056408921343
1001TXADV122642	FW TX202Adv-TT5, Driven 200kg	5056408921350
1001TXADV122643	FW TX202Adv-TT5, Driven Constant Charge 200kg	5056408921367
1001TXADV122644	FW TX202Adv-TT5, Manual Constant Charge 200kg	5056408921374
1001TXADV122645	FW TX272Adv-TT2, Manual Constant Charge 272kg	5056408921381
1001TXADV122646	FW TX272Adv-TT3, Driven 272kg	5056408921398
1001TXADV122647	FW TX272Adv-TT3, Driven Constant Charge 272kg	5056408921404

Product Code	Product Description	UDI-DI
1001TXADV122648	FW TX272Adv-TT3, Manual Constant Charge 272kg	5056408921411
1001TXADV122649	FW TX272Adv-TT4, Driven 272kg	5056408921428
1001TXADV122650	FW TX272Adv-TT4, Driven Constant Charge 272kg	5056408921435
1001TXADV122651	FW TX272Adv-TT4, Manual Constant Charge 272kg	5056408921442
1001TXADV122652	FW TX272Adv-TT5, Driven 272kg	5056408921459
1001TXADV122653	FW TX272Adv-TT5, Driven Constant Charge 272kg	5056408921466
1001TXADV122654	FW TX272Adv-TT5, Manual Constant Charge 272kg	5056408921473
1001TXADV122655	MW TX440Adv-TT2, Manual Constant Charge 200kg	5056408921480
1001TXADV122656	MW TX440Adv-TT3, Driven 200kg	5056408921497
1001TXADV122657	MW TX440Adv-TT3, Driven Constant Charge 200kg	5056408921503
1001TXADV122658	MW TX440Adv-TT3, Manual Constant Charge 200kg	5056408921510
1001TXADV122659	MW TX440Adv-TT4, Driven 200kg	5056408921527
1001TXADV122660	MW TX440Adv-TT4, Driven Constant Charge 200kg	5056408921534
1001TXADV122661	MW TX440Adv-TT4, Manual Constant Charge 200kg	5056408921541
1001TXADV122662	MW TX440Adv-TT5, Driven 200kg	5056408921558
1001TXADV122663	MW TX440Adv-TT5, Driven Constant Charge 200kg	5056408921565
1001TXADV122664	MW TX440Adv-TT5, Manual Constant Charge 200kg	5056408921572
1001TXADV122665	MW TX600Adv-TT2, Manual Constant Charge 272kg	5056408921589
1001TXADV122666	MW TX600Adv-TT3, Driven 272kg	5056408921596
1001TXADV122667	MW TX600Adv-TT3, Driven Constant Charge 272kg	5056408921602
1001TXADV122668	MW TX600Adv-Track Type 3 Manual-Const Charge 272kg	5056408921619
1001TXADV122669	MW TX600Adv-Track Type 4 Driven 272kg	5056408921626
1001TXADV122670	MW TX600Adv-Track Type 4 Driven-Const Charge 272kg	5056408921633
1001TXADV122671	MW TX600Adv-Track Type 4 Manual-Const Charge 272kg	5056408921640
1001TXADV122672	MW TX600Adv-Track Type 5 Driven 272kg	5056408921657
1001TXADV122673	MW TX600Adv-Track Type 5 Driven-Const Charge 272kg	5056408921664
1001TXADV122674	MW TX600Adv-Track Type 5 Manual-Const Charge 272kg	5056408921671
1001TXADV122675	FW TX132Adv-Track Type 1 Manual QRT 130kg	5056408921688
1001TXADV122676	FW TX202Adv-Track Type 1 Manual QRT 200kg	5056408921695
1001TXADV122677	FW TX272Adv-Track Type 1 Manual QRT 272kg	5056408921701
1001TXADV122678	MW TX440Adv-TT1, Manual QRT 200kg	5056408921718
1001TXADV122679	MW TX600Adv-TT1, Manual QRT 272kg	5056408920506
1001TXADV122685	FW TX132Adv-Track Type 3 Manual QRT 130kg	5056408921770
1001TXADV122686	FW TX202Adv-Track Type 3 Manual QRT 200kg	5056408921787
1001TXADV122687	FW TX272Adv-Track Type 3 Manual QRT 272kg	5056408921794
1001TXADV122688	MW TX440Adv-TT3, Manual QRT 200kg	5056408921800
1001TXADV122689	MW TX600Adv-TT3, Manual QRT 272kg	5056408921817
1001TXADV122690	FW TX132Adv-Track Type 4 Manual QRT 130kg	5056408921824
1001TXADV122691	FW TX202Adv-Track Type 4 Manual QRT 200kg	5056408921831
1001TXADV122692	FW TX272Adv-Track Type 4 Manual QRT 272kg	5056408921848
1001TXADV122693	MW TX440Adv-TT4 Manual QRT 200kg	5056408921855
1001TXADV122694	MW TX600Adv-TT4, Manual QRT 272kg	5056408921862
1001TXADV122695	FW TX132Adv-Track Type 5 Manual QRT 130kg	5056408921879
1001TXADV122696	FW TX202Adv-Track Type 5 Manual QRT 200kg	5056408921886
1001TXADV122697	FW TX272Adv-Track Type 5 Manual QRT 272kg	5056408921893
1001TXADV122698	MW TX440Adv-TT5, Manual QRT 200kg	5056408921909
1001TXADV122699	MW TX600Adv-TT5, Manual QRT 272kg	5056408921916
1001TXADV122700	FW TX132Adv-Track Type 1 Driven RTC 130kg	5056408921923
1001TXADV122701	FW TX202Adv-Track Type 1 Driven RTC 200kg	5056408921930
1001TXADV122702	FW TX272Adv-Track Type 1 Driven RTC 272kg	5056408921947
1001TXADV122703	MW TX440Adv-TT1, Driven RTC 200kg	5056408921954
1001TXADV122704	MW TX600Adv-TT1, Driven RTC 272kg	5056408920483

Product Code	Product Description	UDI-DI
1001TXADV122705	FW TX132Adv-Track Type 3 Driven RTC 130kg	5056408921961
1001TXADV122706	FW TX202Adv-Track Type 3 Driven RTC 200kg	5056408921978
1001TXADV122707	FW TX272Adv-Track Type 3 Driven RTC 272kg	5056408921985
1001TXADV122708	MW TX440Adv-Track Type 3 Driven-RTC 200kg	5056408921992
1001TXADV122709	MW TX600Adv-Track Type 3 Driven-RTC 272kg	5056408922005
1001TXADV122710	FW TX132Adv-Track Type 4 Driven RTC 130kg	5056408922012
1001TXADV122711	FW TX202Adv-Track Type 4 Driven RTC 200kg	5056408922029
1001TXADV122712	FW TX272Adv-Track Type 4 Driven RTC 272kg	5056408922036
1001TXADV122713	MW TX440Adv-Track Type 4 Driven-RTC 200kg	5056408922043
1001TXADV122714	MW TX600Adv-Track Type 4 Driven-RTC 272kg	5056408922050
1001TXADV122715	FW TX132Adv-Track Type 5 Driven RTC 130kg	5056408922067
1001TXADV122716	FW TX202Adv-Track Type 5 Driven RTC 200kg	5056408922074
1001TXADV122717	FW TX272Adv-Track Type 5 Driven RTC 272kg	5056408922081
1001TXADV122718	MW TX440Adv-Track Type 5 Driven-RTC 200kg	5056408922098
1001TXADV122719	MW TX600Adv-Track Type 5 Driven-RTC 272kg	5056408922104

Revision History

Rev Number	Date	Comment	Author
1.0	30 Sept 2021	Initial issue of CE Certificate under EU Medical Device Regulation (EU) 2017/745.	E Jones
2.0	24 Mar 2023	Template changed and document control number added. GTIN for products and DoC statement added	J Henry