


EU Declaration of Conformity

Freeway Transative Xtra

Technical Documentation Reference: PMUK MDR 001

This Declaration of Conformity is issued under the sole responsibility of the Prism medical UK. We hereby declare that the mentioned product/ attached list of product comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745

Legal Manufacturer:	Prism Medical UK Unit 1 Tir Llwyd Industrial Estate, St Asaph Avenue, Kinmel Bay, Rhyl, Conwy, LL18 5JZ	
SRN	GB-MF-000010634	
Authorized Representative:	European Healthcare & Device Solutions (Ireland) Ltd Stratton House, Bishopstown Road, Cork Ireland T12 Y9TC SRN: IE-AR-000003999	
Product Name:	Freeway Transactive XtraCeiling track Hoists	
GMDN Code and Title:	38129 - Overhead track patient lifting/transfer system	
CND nomenclature	123612 – Patient Lifting Systems Fixed	
Basic UDI-DI	50564089PMUK012RM	
Identification of the device(s) concerned:	Full List of Product Codes or Ref. to Product Range Table in appendix 1	
Catalogue Number:	Full List of Product Codes or Ref. to Product Range Table in appendix 1	
Intended purpose:	Intended to be used with hoist systems for the transfer of clients from one surface to another	
Risk Classification:	Class 1 as per Rule 13 in Annex VIII	
Conformity Assessment Route:	Annex II and III of EU Medical Device Regulation (EU) 2017/745	
Relevant Harmonized Standards	EN ISO 13485:2016 ISO 14971:2012 EN ISO 10535: 2006	EN ISO 15223-1:2016 EN 60601-1: 2006
References to any CS:	N/A	
Identification of Notified Body:	N/A	
Identification of the Certificate(s):	EC Quality Management System Certificate No. 67420 issued by NQA	
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Paul Morton Signature:  Chief Executive Officer Place of Issue: Grange Moor, England, Date: 30 Sept 2021	

List of Products

Code	Product Description
134000	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 1 - Euro Plug
134001	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 2 - Euro Plug
134002	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 3 - Euro Plug
134003	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 4 - Euro Plug
134004	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 5 - Euro Plug
134005	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 6 - Euro Plug
134006	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 7 - Euro Plug
134007	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 8 - Euro Plug
134008	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 9 - Euro Plug
134009	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 10 - Euro Plug
134010	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 11 - Euro Plug
134012	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 13 - Euro Plug
134013	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 14 - Euro Plug
134014	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 1 - Euro Plug - QRT
134015	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 5 - Euro Plug - QRT
134016	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 12 - Euro Plug - QRT
134017	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 13 - Euro Plug - QRT
134018	Freeway Transactive Xtra - 130kg - 2 Way - Manual - Track Type 14 - Euro Plug - QRT
134020	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 1 - Euro Plug
134021	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 2 - Euro Plug
134022	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 3 - Euro Plug
134023	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 4 - Euro Plug
134025	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 6 - Euro Plug
134026	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 7 - Euro Plug
134027	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 8 - Euro Plug
134028	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 9 - Euro Plug
134029	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 10 - Euro Plug
134030	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 11 - Euro Plug
134032	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 13 - Euro Plug
134033	Freeway Transactive Xtra - 130kg - 4 Way - Driven - Track Type 14 - Euro Plug
134040	Freeway Transactive Xtra - 130kg - 6 Way - Driven - Track Type 1 - Euro Plug
134100	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 1 - Euro Plug

134101	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 2 - Euro Plug
134102	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 3 - Euro Plug
134103	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 4 - Euro Plug
134104	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 5 - Euro Plug
134105	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 6 - Euro Plug
134106	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 7 - Euro Plug
134107	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 8 - Euro Plug
134108	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 9 - Euro Plug
134109	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 10 - Euro Plug
134110	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 11 - Euro Plug
134112	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 13 - Euro Plug
134113	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 14 - Euro Plug
134114	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 1 - Euro Plug - QRT
134115	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 5 - Euro Plug - QRT
134116	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 12 - Euro Plug - QRT
134117	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 13 - Euro Plug - QRT
134118	Freeway Transactive Xtra - 160kg - 2 Way - Manual - Track Type 14 - Euro Plug - QRT
134120	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 1 - Euro Plug
134121	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 2 - Euro Plug
134122	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 3 - Euro Plug
134123	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 4 - Euro Plug
134125	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 6 - Euro Plug
134126	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 7 - Euro Plug
134127	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 8 - Euro Plug
134128	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 9 - Euro Plug
134129	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 10 - Euro Plug
134130	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 11 - Euro Plug
134132	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 13 - Euro Plug
134133	Freeway Transactive Xtra - 160kg - 4 Way - Driven - Track Type 14 - Euro Plug
134140	Freeway Transactive Xtra - 160kg - 6 Way - Driven - Track Type 1 - Euro Plug
134200	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 1 - Euro Plug
134201	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 2 - Euro Plug
134202	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 3 - Euro Plug
134203	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 4 - Euro Plug

134204	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 5 - Euro Plug
134205	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 6 - Euro Plug
134206	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 7 - Euro Plug
134207	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 8 - Euro Plug
134208	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 9 - Euro Plug
134209	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 10 - Euro Plug
134210	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 11 - Euro Plug
134212	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 13 - Euro Plug
134213	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 14 - Euro Plug
134214	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 1 - Euro Plug - QRT
134215	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 5 - Euro Plug - QRT
134216	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 12 - Euro Plug - QRT
134217	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 13 - Euro Plug - QRT
134218	Freeway Transactive Xtra - 200kg - 2 Way - Manual - Track Type 14 - Euro Plug - QRT
134220	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 1 - Euro Plug
134221	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 2 - Euro Plug
134222	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 3 - Euro Plug
134223	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 4 - Euro Plug
134225	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 6 - Euro Plug
134226	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 7 - Euro Plug
134227	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 8 - Euro Plug
134228	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 9 - Euro Plug
134229	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 10 - Euro Plug
134230	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 11 - Euro Plug
134232	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 13 - Euro Plug
134233	Freeway Transactive Xtra - 200kg - 4 Way - Driven - Track Type 14 - Euro Plug
134240	Freeway Transactive Xtra - 200kg - 6 Way - Driven - Track Type 1 - Euro Plug
134260	Freeway Transactive Xtra - 200kg - 4 Way - Manual - Track Type 1 - Euro Plug - Powered Pivot Carry Bar
134261	Freeway Transactive Xtra - 200kg - 4 Way - Manual - Track Type 1 - Euro Plug - QRT - Powered Pivot Carry Bar
134270	Freeway Transactive Xtra - 200kg - 6 Way - Manual - Track Type 1 - Euro Plug - Powered Pivot Carry Bar
134271	Freeway Transactive Xtra - 200kg - 6 Way - Manual - Track Type 1 - Euro Plug - QRT - Powered Pivot Carry Bar
134280	Freeway Transactive Xtra - 200kg - 6 Way - Driven - Track Type 1 - Euro Plug - Powered Pivot Carry Bar
134300	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 1 - Euro Plug
134301	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 2 - Euro Plug

134302	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 3 - Euro Plug
134303	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 4 - Euro Plug
134304	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 5 - Euro Plug
134305	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 6 - Euro Plug
134306	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 7 - Euro Plug
134307	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 8 - Euro Plug
134308	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 9 - Euro Plug
134309	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 10 - Euro Plug
134310	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 11 - Euro Plug
134312	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 13 - Euro Plug
134313	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 14 - Euro Plug
134314	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 1 - Euro Plug - QRT
134315	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 5 - Euro Plug - QRT
134316	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 12 - Euro Plug - QRT
134317	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 13 - Euro Plug - QRT
134318	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 14 - Euro Plug - QRT
134320	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 1 - Euro Plug
134321	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 2 - Euro Plug
134322	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 3 - Euro Plug
134323	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 4 - Euro Plug
134325	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 6 - Euro Plug
134326	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 7 - Euro Plug
134327	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 8 - Euro Plug
134328	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 9 - Euro Plug
134329	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 10 - Euro Plug
134330	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 11 - Euro Plug
134332	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 13 - Euro Plug
134333	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 14 - Euro Plug
134340	Freeway Transactive Xtra - 270kg - 6 Way - Driven - Track Type 1 - Euro Plug
134342A	Freeway Transactive Xtra - 270kg - 2 Way - Manual - Track Type 1 - Constant Charge
134343A-	Freeway Transactive Xtra - 270kg - 4 Way - Driven - Track Type 1 - Constant Charge

Revision History

Rev Number	Date	Comment	Author
1.0	26 May 2021	Initial issue of CE Certificate under EU Medical Device Regulation (EU) 2017/745.	EJ
2.0	22 June 2021	Update to Typo in Manufacturers address	EJ
3.0	30 Sep 2021	Constant charge variations added, SRN number Added	EJ