EU Declaration of Conformity

Portable Hoists (CP range)

Technical file Reference: PMUK_TF02-01
Revision: 3

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:	Prism/Mackworth Portable Hoist Range (CP)
Identification of the device(s) concerned:	Full List of Product Codes or Ref. to Product Range Table in appendix 1
Basic UDI-DI	50564089PMUK006RS
Intended purpose:	Intended to be used with hoist systems for the transfer of clients from one surface to another
GMDN:	30021 - Freestanding patient lifting system, electrically-powered An electrically-powered, stationary (non-mobile) assembly of devices designed to enable one person to lift and move an incapacitated patient or a person with a disability safely and with minimal physical effort within an area limited by the lifting radius of the system. Also known as a patient hoist, it typically consists of a support base (non-fixed and freestanding on the floor) with a motorized lifting mechanism, mast, boom/lifting arm(s), swivel bar, and patient holding device (e.g., a sling, holder or a frame). Repositioning of the assembly may be achieved by lifting it to a new position/location.
EMDN:	V0805030102 - Electric Mobile Lifts
CND:	Y123603 – Patient Lifting Systems, Mobile
Risk Classification:	Class I as per Rule 13 in Annex VIII of Regulation 2017/745
Condition supplied:	Devices 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 12100:2010 EN ISO 15223-1:2021 ISO 20417:2021 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:	Jason Leek Signature: Jason Leek (Mar 30, 2023 21:33 GMT+1) Jason Leek Chief Executive Officer, Prism Healthcare Place of Issue: Grange Moor, England Date: 30-Mar-2023

Appendix 1

List of Products

Brand	Product code	Description	UDI-DI
Prism	1001CP108601	Prism CP130 - TT1 Black Carry Bar (TUV)	5056408920964
	1001CP108602	Prism CP130 - TT2 Black Carry Bar (TUV)	5056408920971
	1001CP108603	Prism CP130 - TT3 Black Carry Bar (TUV)	5056408920988
	1001CP108604	Prism CP130 - TT4 Black Carry Bar (TUV)	5056408920995
	1001CP108605	Prism CP130 - TT5 Black Carry Bar (TUV)	5056408921008
	1001CP108606	Prism CP200 - TT1 Black Carry Bar (TUV)	5056408920421
	1001CP108607	Prism CP200 - TT2 Black Carry Bar (TUV)	5056408921022
	1001CP108608	Prism CP200 - TT3 Black Carry Bar (TUV)	5056408921039
	1001CP108609	Prism CP200 - TT4 Black Carry Bar (TUV)	5056408921046
	1001CP108610	Prism CP200 - TT5 Black Carry Bar (TUV)	5056408921053
	1001CP108611	Prism CP200 - FSG Black Carry Bar (TUV)	5056408921060
	1001CP108618	Prism CP130 - TT1 White Carry Bar (TUV)	5056408922371
	1001CP108619	Prism CP130 - TT2 White Carry Bar (TUV)	5056408922388
	1001CP108620	Prism CP130 - TT3 White Carry Bar (TUV)	5056408922395
	1001CP108621	Prism CP130 - TT4 White Carry Bar (TUV)	5056408922401
	1001CP108622	Prism CP130 - TT5 White Carry Bar (TUV)	5056408922418
	1001CP108623	Prism CP200 - TT1 White Carry Bar (TUV)	5056408922425
	1001CP108624	Prism CP200 - TT2 White Carry Bar (TUV)	5056408922432
	1001CP108625	Prism CP200 - TT3 White Carry Bar (TUV)	5056408922449
	1001CP108626	Prism CP200 - TT4 White Carry Bar (TUV)	5056408922456
	1001CP108627	Prism CP200 - TT5 White Carry Bar (TUV)	5056408922463
	1001CP108628	Prism CP200 - FSG White Carry Bar (TUV)	5056408922470
Mackworth	1001CP108612	MW CP440 - Track Type 1 Black Carry Bar (TUV)	5056408921077
	1001CP108613	MW CP440 - Track Type 2 Black Carry Bar (TUV)	5056408921084
	1001CP108614	MW CP440 - Track Type 3 Black Carry Bar (TUV)	5056408921091
	1001CP108615	MW CP440 - Track Type 4 Black Carry Bar (TUV)	5056408921107
	1001CP108616	MW CP440 - Track Type 5 Black Carry Bar (TUV)	5056408921114
	1001CP108617	MW CP440 - FSG Black Carry Bar (TUV)	5056408921121
	1001CP108629	MW CP440 - Track Type 1 White Carry Bar (TUV)	5056408922487
	1001CP108630	MW CP440 - Track Type 2 White Carry Bar (TUV)	5056408922494
	1001CP108631	MW CP440 - Track Type 3 White Carry Bar (TUV)	5056408922500
	1001CP108632	MW CP440 - Track Type 4 White Carry Bar (TUV)	5056408922517
	1001CP108633	MW CP440 - Track Type 5 White Carry Bar (TUV)	5056408922524
	1001CP108634	MW CP440 - FSG White Carry Bar (TUV)	5056408922531

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.	E Jones
2.0	22 June 2021	Update to typo in manufacturer address	E Jones
3.0	24 Mar 2023	Update to template, added UDI-DI, updated standards	J Henry