



MAKING CARE EASIER

prismmedicaluk  
a prismhealthcare company



## EU Declaration of Conformity

### Powered Assistive Aids

**Technical file Reference: PMUK\_TF05-01**

**Revision: 3**

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

Legal Manufacturer:	<b>Prism Medical UK</b> Unit 1, Tir Llwyd Industrial Estate, St Asaph Avenue, Kinmel Bay, Rhyl, Conwy, LL18 5JZ, UK
SRN	GB-MF-000010634
EU Authorized Representative:	<b>European Healthcare &amp; Device Solutions (Ireland) Ltd</b> 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:	Mackworth, Freeway & Harvest Stand aids
Identification of the device(s) concerned:	Full List of Product Codes or Ref. to Product Range Table in appendix 1
Basic UDI-DI	50564089PMUK004RN
Intended purpose:	Stand aids are intended to assist in movement of a person with a disability from seated to standing and to move in a standing position.
GMDN:	37937: Standing transfer platform, electric An electrically-powered device designed to assist a healthcare provider in the physical moving (transfer) of a patient with a disability in an upright (standing) position over a short distance on a horizontal plane. It consists of a wheeled platform with a low centre of gravity and a surrounding framework with body securing devices (e.g., belts, foot plates, knee pads) to hold the patient being transferred in the standing position, and includes a powered mechanism to, e.g., to adjust the platform to assist standing. It is neither intended to maintain the patient in a prolonged standing position (i.e., not a stander) nor intended to lift and suspend the patient (i.e., not a patient lift).
EMDN:	V0805 - Patient Transfer Equipment
CND:	Y123009 – Standing up Devices
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

	BS EN ISO 12182:2012 ISO 10535:2006 IEC 60601-1-1:2006 IEC 60601-1-2:2015 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><i>Jason Leek</i></p> <p>Signature: <u>Jason Leek (Mar 30, 2023 21:34 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

Brand	Product code	Description	UDI-DI
Mackworth	1301SA-ESS180	Mackworth Essentials SA180 Stand Aid	5056408920315
	1301SA-ESS180EU	Mackworth Essentials SA180 Stand Aid (EU)	
	1301SA-SA180	Mackworth SA180 Stand Aid	5056408920179
	1301SA-SA400	Mackworth SA400 Stand Aid	5056408920186
Freeway	1301SA-SA180C	Freeway SA180 Compact Stand Aid	5056408920100
	1301SA-SA180CEU	Freeway SA180 Compact Stand Aid (EU)	
Harvest	1301SA-HH180CM	Harvest Ascent 180 (Clip) With Manual Legs	5056408920353
	1301SA-HH180CP	Harvest Ascent 180 (Clip) With Powered Legs	5056408920070
	1301SA-HH180LM	Harvest Ascent 180 (Loop) With Manual Legs	5056408920346
	1301SA-HH180LP	Harvest Ascent 180 (Loop) With Powered Legs	5056408920063

**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, addition of UDI-DI	J Henry