

EU Declaration of Conformity

Transfer Aids

Technical Documentation Reference: PMUK MDRTD 005

This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer. 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	TBD
Authorized Representative:	European Healthcare & Device Solutions (Ireland) Ltd Stratton House, Bishopstown Road, Cork Ireland T12 Y9TC
Product Name:	Mackworth, Freeway, Harvest transfer aids
GMDN Code and Title:	37953: Standing transfer platform, Manual
CND nomenclature	Y123009 – Standing up Devices
Basic UDI-DI	50564089PMUK004RN
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:	Transfer Aids are intended to assist in movement of a person with a disability from seated to standing and to move in a standing position.
Risk Classification:	Class 1 as per Rule 1 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
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

<p>Identification of the person authorized to sign on behalf of Legal Manufacturer:</p>	<p>Name: Paul Morton Signature:</p>  <p>Chief Commercial Officer Place of Issue: Grange Moor, England, Date: 22 June 2021</p>
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List of Products

ICC code / Part Number	Description
1301TA-MWESSTURN	<i>Mackworth Patient Turner</i>
1301TA-FWTA180	Freeway TA180
107475	Harvest Olympic Mover 180
1301TA-MWRAIS-1	Mackworth Raiser - (Single Kneepad)
1301TA-MWRAIS-2	Mackworth Raiser – (Dual Kneepad)
370300	Harvest Olympic Turner - (Single Kneepad)
370350	Harvest Olympic Turner – (Dual Kneepad)

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 manufacturer address	EJ