EU Declaration of Conformity

Free Standing Gantry

Technical file Reference: PMUK_TF02-06
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:	Free Standing Gantry (FSG)
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 2013/172/EU Unique Device Identification (UDI) 2011/65/EU Restriction of Hazardous Substance (RoHS) 3
Applied Standards	EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 15223-1:2021 ISO 20417:2021 ISO 10535:2006 BS EN ISO 12182:2012 IEC 62366-1:2015
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:	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	1102PH-FSG200	FSG 200KG	5056408920445
Mackworth	1102PH-FSG440	Mackworth FSG 440KG	5056408922364
Activlift	1102PH149000	Activlift 200 FSG ASSY	5056408925310

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 of template, addition of Activlift Branded Product	J Henry