


Declaration of Conformity

for the:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	PRIMA PIVOT GRAB BARS
Legal Manufacturer: (Name on Label)	Gordon Ellis & Co., Trent Lane, Castle Donington, Derby. DE74 2AT United Kingdom
Manufacturers SRN:	GB-MF-000012829
Basic UDI-DI:	5016181PRIMAPIVOT64
Variants:	As per Appendix II (this document) – Product Listing / Schedule
Intended Purpose:	The device is intended to assist with balance and stability when moving around the home (ie a bathroom or a doorway) as an aid to daily living.
MDR Classification:	Class 1, [Rule 1]
Notified Body:	Not applicable
EC Certificate:	Not applicable
EU Authorised Representative:	Advena Limited., Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name: Lee Rice Position: Product Development Manager
 Signed:  Date: 06/03/2026 Place: Derby

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard / CS / Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 21856:2022	Assistive products. General requirements and test methods

Appendix II – Product Listing / Schedule

Catalogue No.	UDI-DI	Device Name	EMDN	GMDN
6701	05016181621908	PRIMA PIVOT GRAB BAR 8IN -8IN 20CM-20CM ALL WHITE	Y181803	35586
6702	05016181621946	PRIMA PIVOT GRAB BAR 8IN - 16IN 20CM -40CM ALL WHITE	Y181803	35586
6703	05016181622011	PRIMA PIVOT GRAB BAR 8IN - 24IN - 20CM -60CM ALL WHITE	Y181803	35586
6704	05016181622004	PRIMA PIVOT GRAB BAR 16IN - 16IN 40CM -40CM ALL WHITE	Y181803	35586
6705	05016181621991	PRIMA PIVOT GRAB BAR 16IN - 24IN 40CM -60CM ALL WHITE	Y181803	35586
6706	05016181621984	PRIMA PIVOT GRAB BAR 24IN - 24IN 60CM -60CM ALL WHITE	Y181803	35586
6716	05016181621977	PRIMA PIVOT GRAB BAR 8IN - 8IN- 20CM -20CM ALUMINIUM	Y181803	35586
6717	05016181621960	PRIMA PIVOT GRAB BAR 16IN - 16IN - 40CM - 40CM ALUMINIUM	Y181803	35586
6718	05016181621953	PRIMA PIVOT GRAB BAR 24IN - 24IN - 60CM - 60CM ALUMINIUM	Y181803	35586
6719	05016181647946	PRIMA PIVOT GRAB BAR 8IN-16IN - 20CM-40CM ALUMINIUM	Y181803	35586
6720	05016181647953	PRIMA PIVOT GRAB BAR 8IN - 24IN - 20CM-60CM ALUMINIUM	Y181803	35586
6721	05016181647939	PRIMA PIVOT GRAB BAR 16IN - 24IN - 40CM -60CM ALUMINIUM	Y181803	35586

Version History

Version	Compiled by	Date	Description
1	AK	08/02/2024	First issue
2	LR	06/03/2026	Updated DOC