

Declaration of Conformity

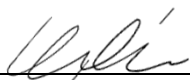
for the:

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:	TIMBERRY KURVE COMMODE
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:	5016181TIMBERRYKURVEXE
Variants:	As per Appendix II (this document) – Product Listing / Schedule
Intended Purpose:	The device is intended to be used for toileting around the home to assist those who find it difficult getting to the bathroom and is used 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: 09/03/2026 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
55500	05016181651738	TIMBERRY KURVE COMMODOE CHAIR - FRAME PACK	Y091203	40539
56551	05016181651691	TIMBERRY KURVE COMMODOE CHAIR - GREY	Y091203	40539
56552	05016181651707	TIMBERRY KURVE COMMODOE CHAIR - BLUE	Y091203	40539
56553	05016181651714	TIMBERRY KURVE COMMODOE CHAIR - BEIGE	Y091203	40539
56554	05016181651721	TIMBERRY KURVE COMMODOE CHAIR - GREEN	Y091203	40539
56555	05016181651752	TIMBERRY KURVE COMMODOE CHAIR - ORANGE	Y091203	40539
56556	05016181651769	TIMBERRY KURVE COMMODOE CHAIR - YELLOW	Y091203	40539
56557	05016181651776	TIMBERRY KURVE COMMODOE CHAIR - PURPLE	Y091203	40539
56558	05016181651783	TIMBERRY KURVE COMMODOE CHAIR - PINK	Y091203	40539
56559	05016181651790	TIMBERRY KURVE COMMODOE CHAIR - RED	Y091203	40539
56560	05016181651806	TIMBERRY KURVE COMMODOE CHAIR - TEAL	Y091203	40539

Version History

Version	Compiled by	Date	Description
1	AK	23/05/2023	First issue
2	LR	09/03/2026	Updated DoC