

Declaration of Conformity

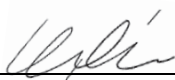
for the:

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:	Basketweave 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:	5016181BASKETWEAVE7P
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: 20/01/2026 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 12182:2012	Assistive products for persons with disability. General requirements and test methods

Appendix II – Product Listing / Schedule

Catalogue No.	UDI-DI	Device Name	EMDN	GMDN
5504/OA	05016181055048	DERBY BASKETWEAVE COMMODE - OAT	Y091203	40539

Version History

Version	Compiled by	Date	Description
1	AK	02/12/20	First issue
2	LR	20/01/26	DOC reissued to reflect updated MDR compliance and current Technical Documentation