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:	Bath Seat
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:	5016181BATHSEATS2B
Variants:	As per Appendix II (this document) – Product Listing / Schedule
Intended Purpose:	The device is intended as a seat for use in the bath to assist those with limited strength and mobility as it reduces the height movement required when lowering into and rising from the bath 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, 2nd 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: 22/01/2026 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 21856:2022	Assistive products. General requirements and test methods

Appendix II – Product Listing / Schedule

Catalogue No.	UDI-DI	Device Name	EMDN	GMDN
6006/W	05016181000154	Derby In Bath Seat 6 Inch - White	Y093303	42809
6008/W	05016181060080	Derby In Bath Seat 8 Inch - White	Y093303	42809
6408	05016181064088	Cosby 8 Inch 20 cm In Bath Seat	Y093303	42809

Version History

Version	Compiled by	Date	Description
1	AK	12/01/21	First issue
2	LR	22/01/26	DOC reissued to reflect updated MDR compliance and current Technical Documentation