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 STOOL
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:	5016181PRIMASTOOLSXE
Variants:	As per Appendix II (this document) – Product Listing / Schedule
Intended Purpose:	The device is intended to support the user in a semi standing or seated position, adjustable in height the device will offer improved mobility for those with limited strength when performing tasks in the kitchen or shower 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

Appendix II – Product Listing / Schedule

Catalogue No.	UDI-DI	Device Name	EMDN	GMDN
66153	05016181001380	Prima Modular Perching Chair - Steel	Y180999	41159
66173	05016181001465	Prima Modular Shower Chair - Aluminium	Y093303	41159

Version History

Version	Compiled by	Date	Description
1	AK	24/11/20	First issue
2	AK	04/07/22	The foot has changed from Rubber to TPE
3	LR	22/01/26	DOC reissued to reflect updated MDR compliance and current Technical Documentation