Declaration of Conformity

Manufacturers Name:	Gordon Ellis & Co.		
Manufacturers Address:	Trent Lane Castle Donington Derby DE74 2AT United Kingdom		
SRN (Single Registration Number):			
GMDN Code:	31059		
Authorised Representative Name:	UNITED KINGDOM Gordon Ellis & Co.	EUROPE Advena Ltd	
Authorised Representative Address:	Trent Lane Castle Donington Derby DE74 2AT UNITED KINGDOM	Tower Business Centre, 2nd Floor Tower Street Swatar BKR 4013 Malta	
Basic UDI-DI:	5016181PRIMATOILETAIDWU		
Name of the Device(s):	Prima Toilet Aid Prima Commode		
Product Code(s):	68000 68001/FP 68003/FP 68005 68010	68020/H 68021/H/FP 68023/H/FP 68025/H 68004	6832 6833 6834 6835/FP 6837/H	6839 6840/H/FP
Intended Purpose :	The device is intended to raise the seat height of a toilet whilst offering the added security of a support frame with arms for those with limited mobility as it reduces the movement required when sitting or standing, but also offers additional arm support, and is used as an aid to daily living. A bracket & potty can be added to convert to a commode.		
Classification:	Class I		
Conformity Assessment Route:	Gordon Ellis & Co. uses the requirements for the CE-labelling of their products according the Regulations MDR 2017/745 - Article 19 Annex II and Annex III. Gordon Ellis & Co. test their products in accordance with BS EN 12182:2012 - Assistive Products for Persons with Disability - General Requirements and Test Methods and Risk Assess to BS EN ISO 14971:2019 - Application of Risk Management to Medical Devices.		

This declaration of conformity is issued under the sole responsibility of Gordon Ellis & Co. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Place and Date (DD/MM/YYYY) of Issue:

Location: Gordon Ellis & Co. Date: 02/12/2020

Name: Ashley Kidd

Function: QHSE Manager

Signing of this declaration of conformity authorises the manufacturer to affix the CE Mark to the product in accordance with the above directive.

CE