

Declaration of Conformity

Manufacturers Name: Gordon Ellis & Co.

Manufacturers Address: Trent Lane
Castle Donington
Derby
DE74 2AT
United Kingdom



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
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Swatar
BKR 4013
Malta

SRN (Single Registration Number): GB-MF-000012829 MT-AR-000000234

Basic UDI-DI: 5016181PRIMATOILETAIDWU

Name of the Device(s): Prima Toilet Aid
Prima Commode

Product Code(s):	68000	68020/H	6832	6839
	68001/FP	68021/H/FP	6833	6840/H/FP
	68003/FP	68023/H/FP	6834	68011/FP/B
	68005	68025/H	6835/FP	68011/FP/R
	68010	68004	6837/H	68011/FP/WA

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 21856:2022 - 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.

Update Information: 02/12/2020 1st Issue for MDR 2017/745
16/02/2022 The Classic Frame has been reduced in width by 40mm & the foot changed from PVC to TPE.
18/07/2022 Two new product codes have been added.
02/09/2024 New width adjustable frame added.

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: 02/09/2024

Name: Lee Rice Function: Product Development Manager

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

