

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: 40539

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: 5016181WOODENCOMMODEUB

Name of the Device(s): Royale Commode Chair, Wide Royale Commode Chair
Deluxe Commode Chair

Product Code(s): 5505/A, 5505/F,
55059/BL, 55059/BL/F, 55059/BR, 55059/BR/F, 55059/GR, 55059/GR/F
5501, 5501/F, 55019/BL, 55019/BR, 55019/GR
55100/BR, 55100/CN, 55100/FB
6250, 62299, 6229, 62501, 6125, 6125/BL, 6125/BR, 6125/GR,
6128, 6128/BR, 61223/BR

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.

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: 30/11/2020

Name:

Function:

Ashley Kidd

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.

