

Declaration of Conformity



Manufacturers Name: Gordon Ellis & Co.

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

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

SRN (Single Registration Number): GB-MF-000012829

MT-AR-000000234

Basic UDI-DI: 5016181TIMBERRYKURVEXE

Name of the Device(s): Timberry Kurve Commode

Product Code(s): 55500, 56551, 56552, 56553, 56554, 56555, 56556, 56557, 56558, 56559, 56560

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 21856:2022 - Assistive Products - General Requirements and Test Methods and Risk Assess to BS EN ISO 14971:2019 - Application of Risk Management to Medical Devices.

Update Information: 23/05/2023 1st Issue for MDR 2017/745

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:

A handwritten signature in black ink, appearing to read 'Ashley Kidd', is written over a horizontal line.

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

Location: Gordon Ellis & Co. Date: 20/11/2023

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.

