

Declaration of Conformity



Manufacturers Name: Gordon Ellis & Co.

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

GMDN Code: 31059

Authorised Representative Name: UNITED KINGDOM
Gordon Ellis & Co. EUROPE
Advena Ltd

Authorised Representative Address: Trent Lane
Castle Donington
Derby
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Tower Street
Swatar
BKR 4013
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SRN (Single Registration Number): GB-MF-000012829 MT-AR-000000234

Basic UDI-DI: 5016181ASHBYRTSWE

Name of the Device(s): Ashby Raised Toilet Seats (Ashby RTS)

Product Code(s):	6202	6222	6312	63122	62182	6117
	6204	6224	6314	63144	62184	6120
	6206	6226	6316	63166	62186	
	6212	6302	6302/P	62172	62014	
	6214	6304	6304/P	62174	6101	
	6216	6306	6306/P	62176	61001	

Intended Purpose : The device is intended to raise the seat height of a toilet to assist those with limited mobility as it reduces the movement required when sitting or standing 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:

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

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

Location: Gordon Ellis & Co. Date: 18/11/2020

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.

