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 Tower Street Swatar BKR 4013 Malta
SRN (Single Registration Number):	GB-MF-000012829	MT-AR-000000234
Basic UDI-DI:	5016181SERENITYRTSWH	
Name of the Device(s):	Serenity Raised Toilet Seat	

Product Code(s):

64602	64612	64622/AL	64624/AL/WI03
64604	64614	64624/AL	64624/AL/WI18
64606	64616	64626/AL	

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:

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

Location: Gordon Ellis & Co.   Date: 07/01/2021

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.

CE