

Declaration of Conformity



Manufacturers Name: Gordon Ellis & Co.

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

GMDN code: 41159

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

Authorised Representative Address: Trent Lane
Castle Donington
Derby
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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: 5016181PRIMASTOOLSXE

Name of the Device(s): Prima Modular Perching Stool / Shower Stool

Product Code(s):	66153	66104	66108	61610
	66173	66105	66109	61611
	66173/XCN	66106	66110	61612
	66142	66107		61613

Intended Purpose : The device is intended to support the user in a semi standing or seated position, adjustable in height the device will offer improved mobility for those with limited strength when performing tasks in the kitchen or shower 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 to 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: 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.

