

# 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: 41159

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: 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.

