

Declaration of Conformity



Manufacturers Name: Gordon Ellis & Co.

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

GMDN Code: 42809

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: 5016181PRIMABATHSTEPHA

Name of the Device(s): Prima Bath Step

Product Code(s): 62920, 66925, 61920, 61922, 61923

Intended Purpose : This device is intended as a step to reduce the height between the floor and a bath or shower to assist those with limited mobility 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: 01/12/2020

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.

