

Declaration of Conformity



Manufacturers Name: Gordon Ellis & Co.

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

GMDN Code: 35586

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

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: 5016181PRIMAPIVOT64

Name of the Device(s): Prima Pivot Grab Bars

Product Code(s): 6701, 6702, 6703, 6704, 6705, 6706 (All White)
6716, 6717, 6718, 6719, 6720, 6721 (Aluminium)

Intended Purpose : The device is intended to assist with balance and stability when moving around the home (ie a bathroom or a doorway) 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 21856:2022 - 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: 08/02/2024

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 regulation.

