

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: 5016181PRIMAGRABBARDG

Name of the Device(s): Prima Grab Bars (Straight and Angled)

Product Code(s):	6507 - 6512	Inclusive	6553/DR03 - 6556/DR03	Inclusive
	6519 - 6524	Inclusive	6558/DR03	
	6529 - 6539	Inclusive	61501/W	
	6547 - 6560	Inclusive	61501/M	
	6562 - 6564	Inclusive	61501/B	
	6577 - 6594	Inclusive		

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 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 regulation.

