

Declaration of Conformity

Manufacturers Name: Gordon Ellis & Co.

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

GMDN Code: 43093

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

SRN (Single Registration Number): GB-MF-000012829

MT-AR-000000234

Basic UDI-DI: 5016181MULTIFRAME8E

Name of the Device(s): Prima Multi Frames

Product Code(s): 65233 65233/B
65240 65240/B
65244 61531
61530 61233

Intended Purpose : The device is intended as a toilet surround frame with arms for those with limited mobility as It can be used as a support when sitting or standing.

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.

Update Information: 24/11/2020 1st Issue for MDR 2017/745
04/07/2022 The foot has changed from PVC to TPE.
03/09/2024 IFU + Label update, removed parts.

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: 03/09/2024

Name:

Function:

Lee Rice

Product Development Manager

Signing of this declaration of conformity authorises the manufacturer to affix the CE Mark to the product in accordance with the above directive.

