Declaration of Conformity

| Manufacturers Name: | Gordon Ellis & Co. | | |
|---|--|---|------------|
| Manufacturers Address: | Trent Lane Castle Donington Derby DE74 2AT United Kingdom | | 8 |
| SRN (Single Registration Number): | | | GORDON |
| GMDN Code: | 35586 | | |
| Authorised Representative Name: | UNITED KINGDOM Gordon Ellis & Co. | EUROPE Advena Ltd | <u> </u> |
| 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: | 5016181ASHBYGRABBAR2J | | |
| Name of the Device(s): | Ashby Grab Bar, Ashby Grab Rail, Ashby Shower Rail Kit | | |
| Product Code(s): | 6218/B, 6219/B, 6220/B, 6257/B 6268/B, 6269/B, 6270/B 6278/B, 6279/B, 6280/B 6260 | | |
| 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: | | |
| Œ | 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. | | | |