

Declaration of Conformity


for the:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

| | |
|---|---|
| General Product Name: | SERENITY HOME TOILET SEAT |
| Legal Manufacturer: (Name on Label) | Gordon Ellis & Co., Trent Lane, Castle Donington, Derby. DE74 2AT United Kingdom |
| Manufacturers SRN: | GB-MF-000012829 |
| Basic UDI-DI: | 5016181SERENITYHOMERTSLM |
| Variants: | As per Appendix II (this document) – Product Listing / Schedule |
| Intended Purpose: | The device is intended to raise the seat height of a toilet to assist those with limited mobility as it reduces the movement required when sitting or standing and is used as an aid to daily living. |
| MDR Classification: | Class 1, [Rule 1] |
| Notified Body: | Not applicable |
| EC Certificate: | Not applicable |
| EU Authorised Representative: | Advena Limited., Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta. |
| EU Authorised Representative SRN: | MT-AR-000000234 |
| Medical Device Regulation Assessment Route: | Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745. |

Name: Lee Rice Position: Product Development Manager

Signed:  Date: 06/03/2026 Place: Derby

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

| Standard / CS / Document Name | Description |
|-------------------------------|---|
| 2017/745 | Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices |
| EN ISO 13485:2016+A11:2021 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2019+A11:2021 | Medical Devices – Application of Risk Management to Medical Devices |
| EN ISO 15223-1:2021 | Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements |
| EN ISO 20417:2021 | Medical devices. Information to be supplied by the manufacturer |
| EN ISO 12182:2012 | Assistive Products for Persons with Disability - General Requirements and Test Methods |

Appendix II – Product Listing / Schedule

| Catalogue No. | UDI-DI | Device Name | EMDN | GMDN |
|---------------|----------------|---|---------|-------|
| 64702 | 05016181649506 | SERENITY HOME TOILET SEAT 2IN - 5CM | Y091215 | 31059 |
| 64704 | 05016181649513 | SERENITY HOME TOILET SEAT 4IN - 10CM | Y091215 | 31059 |
| 64706 | 05016181649520 | SERENITY HOME TOILET SEAT 6IN - 15CM | Y091215 | 31059 |
| 64712 | 05016181650021 | SERENITY HOME TOILET SEAT 2IN - 5CM - MULTIPACK x8 | Y091215 | 31059 |
| 64714 | 05016181650038 | SERENITY HOME TOILET SEAT 4IN - 10CM - MULTIPACK x5 | Y091215 | 31059 |
| 64716 | 05016181650045 | SERENITY HOME TOILET SEAT 6IN - 15CM - MULTIPACK x4 | Y091215 | 31059 |
| 64722 | 05016181650052 | SERENITY HOME TOILET SEAT 2IN - 5CM WITH LID | Y091215 | 31059 |
| 64724 | 05016181650076 | SERENITY HOME TOILET SEAT 4IN - 10CM WITH LID | Y091215 | 31059 |
| 64726 | 05016181650069 | SERENITY HOME TOILET SEAT 6IN - 15CM WITH LID | Y091215 | 31059 |

Version History

| Version | Compiled by | Date | Description |
|---------|-------------|------------|-------------|
| 1 | AK | 19/04/2023 | First issue |
| 2 | LR | 06/03/2026 | Updated DoC |