Declaration of Conformity

Manufacturers Name: Gordon Ellis & Co. Manufacturers Address: Trent Lane **Castle Donington** Derby **DE74 2AT United Kingdom** EMDN Code: Y091203 **Authorised Representative** UNITED KINGDOM EUROPE Gordon Ellis & Co. Advena Ltd **Authorised Representative** Trent Lane Tower Business Centre, 2nd Floor Address: Castle Donington **Tower Street** Derby Swatar **DE74 2AT** BKR 4013 UNITED KINGDOM Malta MT-AR-000000234 GB-MF-000012829 SRN (Single Registration Number): 5016181BIGJOHNCOMMODEXP Basic UDI-DI: Name of the Device(s): Big John Commode Big John Commode - Frame & Pan Product Code(s): 66250/SET 66250 Intended Purpose: The Big John commode is intended to be used for toileting around the home, for those who find it difficult getting to the bathrooom whilst the extra width seat provides more stability for those who find a standard toilet seat uncomfortable. Classification: Class I Gordon Ellis & Co. uses the requirements for the CE-labelling of their products according the Regulations MDR Conformity Assessment Route: 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: Gordon Ellis & Co. 22/11/2021 Location: Date: Function: Name: 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.

