

EU Declaration of Conformity

Version Number: 07
Issue Date: 16th January 2023

The EU declaration of conformity shall state that the requirements specified in Regulation (EU) MDR 2017/745 for medical devices have been fulfilled in relation to the device covered within this document.

General Product Name: (as per technical file)	Disposable Pulp Hygiene and Healthcare Products
Legal Manufacturer: (Name on Label)	Vernacare Limited, Fold Road, Bolton, BL12TX, UK
Manufacturers SRN:	GB-MF-000004899
Basic UDI-DI:	5065000204C01nT004G0AQJ – Bedpans 5065000204C01nT004G0BQL – Jugs 5065000204C01nT004G0CQN - Washbowls
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Single use disposable pulp products used for the collection of human waste
MDR Classification:	Class I Rule 1 - All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies
Notified Body:	Not Applicable for Class I non-sterile
EC Certificate:	Not Applicable for Class I non-sterile
EU Authorised Representative:	Advena Limited, Tower Business Centre, 2 nd Floor, 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,

We hereby declare that the product(s) specified within this document complies with the applicable provisions of the essential principles of Regulation (EU) MDR 2017/745 Article 52 for medical devices.

The product has been subjected to the conformity assessment procedures in accordance with the Regulation (EU) MDR 2017/745 for medical devices.

This declaration of conformity is issued under the sole responsibility of legal manufacturer Vernacare Limited, Fold Road, Bolton, BL12TX, UK. All supporting documentation is retained at the premises of the manufacturer.

Name:	[REDACTED]
Position:	[REDACTED]
Signed:	[REDACTED]
Date of issue:	25/02/2023
Location of issue:	Vernacare Limited, Fold Road, Bolton, BL12TX, UK

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
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
MDR 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
BS EN ISO 20417:2021	Medical Devices - Information to be supplied by the manufacturer
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 9001:2015	Quality Management Systems
EN ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

Appendix II – Product Listing/Schedule

Product code	Description	UDI-DI	GMDN	EMDN
101AA100	Bedpan Liner	00800239011019	10335	V0402
102AA100	Male Urine Bottle	00800239011026	42891	A06030399
103AA120	Male Urine Bottle	00800239011422	42891	A06030399
104AA200	Small Bowl	00800239011385	42891	V0402
105AA260	Kidney Dish	00800239011439	42891	V0402
105AA300	Kidney Dish	08002390111617	42891	V0402
106AA300	CS Receiver	00800239011392	42891	V0402
108AA024	VernaFem Female Urinal	00800239011071	42891	A06030399
109AA100	Midi Slipper Pan Liner	00800239011095	61209	V0402
110AA100	Measuring Jug	00800239011101	42891	V0402
111AA200	Medium Bowl	00800239011118	42891	V0402
112AA100	Large Bowl	00800239011125	42891	V0402
113BA100	Specimen Collector	00800239011453	42891	V0402
114AA100	Maxi Slipper Pan Liner	00800239011149	61209	V0402
116AA200	Multi Cup	00800239011163	42891	V0402
117AA040	Maxi-Wash Bowl	00800239011569	65826	Y0933
118AA100*	Wash Bowl	00800239011446	65826	Y0933
118AA160	Wash Bowl	00800239011668	65826	Y0933
120PB050*	Male Urinal	00800239011187	42891	A06030399
121AA075	Bedpan Liner	00800239011484	10335	V0402
122AA050	Bedpan Pro Liner Disposable Support	00800239011491	10335	V0402
123AA150	Commode Pan	00800239011507	42891	V0402

* Product now discontinued

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