

## EC DECLARATION OF CONFORMITY

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

<b>General Product Name: (as per technical file)</b>	Disposable Pulp Hygiene and Healthcare products
<b>Legal Manufacturer:</b>	Vernacare Limited Folds Road Bolton BL1 2TX UK
<b>Intended Use:</b>	Single use disposable pulp products used for the collection of human waste
<b>MDD Classification:</b>	Class I non-sterile
<b>Notified Body:</b>	Not Applicable for Class I non-sterile
<b>EU Authorised Representative:</b>	Advena Ltd. Tower Business Centre, 2 <sup>nd</sup> Flr. Tower Street, Swatar, BKR4013, Malta
<b>MDD Conformity Assessment Route:</b>	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market
<b>MDD EC certificate number:</b>	Not Applicable for Class I non-sterile
<b>ISO 13485:2016 Certificate Number:</b>	Not Applicable

### Appendix I – Applicable Standards

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

<b>Standard/Document Name</b>	<b>Description</b>
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 9001:2015	Quality Management Systems

**Appendix II (Product Codes):**

Product Code	Description/Name	GMDN Code
101AA100	Bedpan Liner	10339
102AA100	Male Urine Bottle	14291
103AA120	Male Urine Bottle	14291
104AA200	Small Bowl	15561
105AA260	Kidney Bowl	15561
106AA300	CS Receiver	15561
108AA024	VernaFem Female Urinal	14291
109AA100	Midi Slipper Pan Liner	10339
110AA100	Measuring Jug	15561
111AA200	Medium Bowl	15561
112AA100	Large Bowl	15561
113BA100	Specimen Collector	15561
114AA100	Maxi Slipper Pan Liner	10339
116AA200	Multi Cup	15561
117AA040	Maxi-WashBowl	15561
118AA100	WashBowl	15561
120PB050	Male Urinal	15561
121AA075	Bedpan Liner	10339
123AA150	Commode Pan	10339

Name:	Donna Hodgers
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Signed:	
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