PRODUCT TECHNICAL DATASHEET

Product Profile & Instructions for Use

WarwickSASCo
Moulding The Future of Medical Plastics

Warwick House, Heathcote Way, Warwick
CV34 6TE, United Kingdom
T: 0044 (0)1926 422427 www.sasco.co.uk
enquiries@sasco.co.uk

UML1000 Male Urinal with Handle

Class I Medical Device
Volume : 1000 ml
Material : Urinal Natural Polyethylene
: Cap Green Polyethylene
Pack Size : 1 x 50

Intended Use

- **Hand-held urinal with handle, male, reusable.**
- **Used in the treatment of disease, and for the alleviation of or compensation for injury or disability.**

Intended User

- **Product to be used by injured, disabled, or infirm patients, nursing, and healthcare professionals.**

Product Features

- **Strong and durable.**
- **Secure fitting attached cap to prevent spills, reduce unpleasant odours, and risk of cross infection.**
- **Easy grip handle – suitable for patients with limited hand movements.**
- **Smooth material surfaces and hollow handle, ensure ease of cleaning.**
- **Guaranteed 1000 cycles.**
- **Can be cleaned in automatic washer disinfectors or hand washed.**
- **Graduated.**

Packaging Information

Catalogue Number	Case Bar Code (GTIN 14)	Primary Packaging	Secondary Packaging	Case Weight
UML1000	15060098135406	Cardboard case 1 x 50	n/a	7.8 kg

Product Symbols

Manufacturer	Catalogue number	EU Compliance	Medical Device	Authorized EC representative	Caution	Batch code	Use-by date	Non-sterile	Absence of natural rubber latex	Do not use if package is damaged	Keep dry	Keep away from sunlight
												

Additional Information

- **Harmonised System – Product Tariff / Commodity Export Code 39.26.9097.**
- **Country of Origin United Kingdom.**

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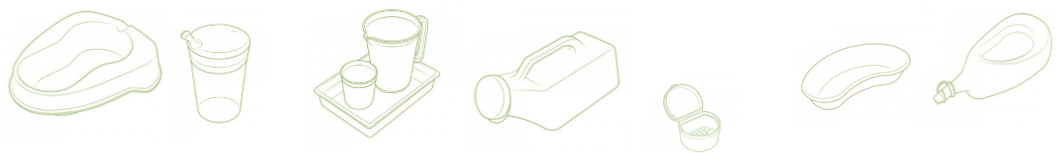

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Manufacturer

- **Warwick SASCo Ltd. Warwick House, Heathcote Way, CV34 6TE, United Kingdom.**
- **Telephone: 0044 (0)1926 422427 E-mail: enquiries@sasco.co.uk**

European Representative

EC REP

- **Medical Device Management Ltd. Block B, The Crescent Building, Santry, Dublin, D09 C6X8, Eire.**
- **Telephone: +353(0)18934143 E-mail: EU-REP@medicaldevicemanagement.com**

Distributor/Importer

-

Standards

- **Product complies with:** **BS 3215:1995 Reusable Portable Urinals.**
  BS EN ISO 20417:2021 Medical devices. Information to be supplied by the manufacturer.
  BS EN ISO 15223-1:2016 Medical Devices. Symbols to be used with medical device labels, labelling and information to be provided
- **Company compliant to:** **BS EN ISO 13485:2016 Medical Devices. Quality management systems. Requirements for regulatory purposes.**
  BS EN ISO 14971:2019 Medical Devices. Application of risk management.
  BS EN ISO 17664-1:2021 Processing of health care products – Information to be provided by the medical device manufacturer.
- **Referenced standards:** **BS EN ISO 15883 Washer disinfectors. Requirements.**

Instructions for Use

Storage and Handling

- **Do not drop.**
- **Store in original packaging.**
- **Store in clean and dry conditions.**
- **Store off the floor on a shelf or pallet.**
- **Shelf life 36 months.**

Preparation

- **Product supplied non-sterile.**
- **Inspect products before processing.**
- **Withdraw damaged products and report to manager.**
- **Rinse with warm water to remove any packaging residues.**

Product supplied as a kit comprising of

- **Urinal and attached cap.**

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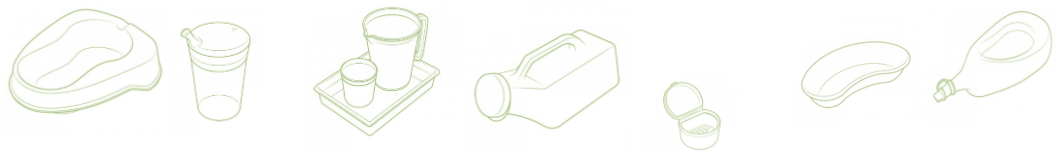

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Product can be used in conjunction with

- **UBH2002 Bottle holder.**

Cleaning and Disinfection

- **Position products individually, avoiding contact with other items.**
- **Position products to allow water penetration and drainage.**
- **Machine clean in washer disinfectors compliant with ISO 15883.**
- **Wash cycle at 80°C. Disinfection at 90°C.**
- **Use approved detergents, enzymatic or biocide cleaners, suitable for cleaning medical devices.**
- **Use detergents and disinfectants with a range between 2pH and 13pH.**
- **Manual cleaning is permissible.**
- **Rinse with clean water.**

Inspection Maintenance and Incident Reporting

- **Visually inspect product to identify damage.**
- **Discard damaged product.**
- **Any serious incident that has occurred during the use of this product should be reported to the manufacturer, and the Competent Authority of the territory in which the user is established.**

Disposal

- **End of life is determined by wear and tear, visual inspection, or damage to product.**
- **If product is contaminated treat as clinical waste and dispose of in accordance with clinical waste procedures.**

Warnings ⚠

- **Do not use abrasive powders or metal brushes as they may cause surface damage.**
- **Do not exceed 100°C.**

Important Information for Processing

- **The information provided by Warwick SASCo is the company's official instructions for this product.**
- **It is the responsibility of the processor to ensure processing is performed in accordance with this information and that personnel, machines and equipment comply with relevant standards for processing.**
- **Any deviation from this information requires evaluation for the effectiveness and potential adverse consequences.**

- **Additional information available on request contact: enquiries@sasco.co.uk**

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