# 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

## GP100 Gallipot

**Not a Medical Device**

| | |
|---|---|
| **Dimensions** | **: 100 x 53mm** |
| **Volume** | **: 250ml** |
| **Material** | **: Natural Polypropylene** |
| **Case Size** | **: 1 x 1050** |

### Intended Use

- **Gallipot intended to be used on one individual during a single procedure.**
- **Used to contain medicinal products, disinfectants, and antiseptic fluids.**

### Intended User

- **Product to be used by clinical professionals and decontamination technicians.**

### Product Features

- **Autoclavable.**
- **Light weight.**
- **Smooth edges and surfaces eliminate paper rips during sterilization.**

### Packaging Information

| Catalogue Number | Case Bar Code (GTIN 14) | Primary Packaging | Secondary Packaging | Case Weight |
|---|---|---|---|---|
| **GP100** | **15060098133501** | **Polythene bag 15 x 70** | **Cardboard case 1 x 1050** | **10 Kg** |

### Product Symbols

| Manufacturer | Catalogue number | 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 | Do not re-use |
|---|---|---|---|---|---|---|---|---|---|---|
| | REF | | LOT | | NON STERILE | LATEX | | | | |

### Additional Information

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

### Manufacturer

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



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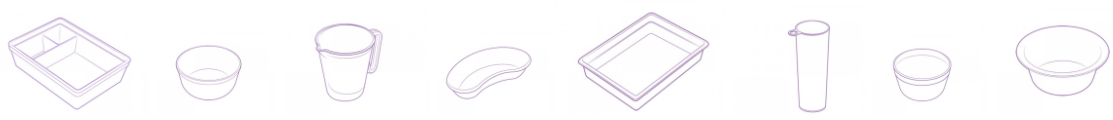

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### Distributor/Importer

- 

### Standards

- **Company compliant to:** **BS EN ISO 17664:2017 Processing of health care products – Information to be provided by the medical device manufacturer.**
  **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.**
  **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.**
- **Referenced standards:** **BS EN ISO 17665 Sterilization of health care products. Moist heat.**
  **BS EN ISO 25424 Sterilization of health care products. Low temperature steam and formaldehyde.**
  **BS EN ISO 11135 Sterilization of health care products. Ethylene oxide.**

## 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.**
- **Product not used in conjunction with any other device.**

### Cleaning and Disinfection

- **Product supplied clean ready for packing and sterilisation.**
- **Cleaning and Disinfection not permitted.**

### 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.**



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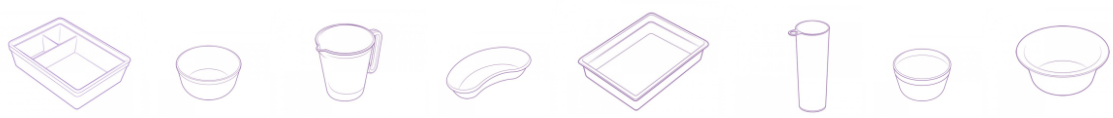

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### Wrapping

- **Sterilization wrapping sheets and pouches must be compatible with polypropylene material and suitable for the chosen method of sterilization.**
- **Be aware that some wrapping sheets and pouches shrink during sterilization.**
- **Pouches must be large enough to contain the product without stressing the seals.**
- **We advise using a pouch or bag that is 25% larger than the product.**

### Sterilization

- **Moist Heat sterilization (Autoclave) at 134.6°C (+2°C) for a minimum of 2 minutes.**
- **EO Ethylene Oxide "Gas" sterilization at maximum temperature of 65°C.**
- **H2O2 Hydrogen Peroxide "Plasma" sterilization at maximum temperature of 65°C.**
- **Sterilization procedures and machines to comply with ISO 17655, ISO 25424, and ISO 11135.**
- **Position tray away from other products to avoid distortion during sterilization.**

### Disposal

- **If product is contaminated treat as clinical waste, and dispose of in accordance with clinical waste procedures.**

### Warnings ⚠

- **Do not re-use.**
- **Do not exceed 137°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 the 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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