

PRODUCT TECHNICAL DATASHEET

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Product Profile & Instructions for Use

GP130 Gallipot

Not a Medical Device

Dimensions : 130 x 66mm
Volume : 500ml
Material : Natural Polypropylene
Case Size : 1 x 735



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
GP130	15060098133518	Polythene bag (7 x 100) + (1 x 35)	Cardboard case 1 x 735	13.5 Kgs

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							

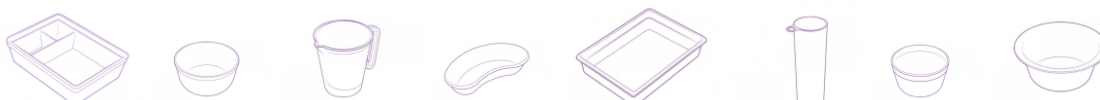
Additional Information

- 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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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

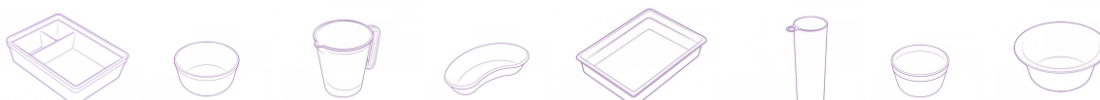
- > **Product supplied non-sterile.**
- > **Inspect products before processing.**
- > **Withdraw damaged products and report to manager.**
- > **Product not used in conjunction with any other device.**

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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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**

