

PRODUCT TECHNICAL DATASHEET

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

Product Profile & Instructions for Use

GPS60 Gallipot

Not a Medical Device

Dimensions : 62 x 30mm
Volume : 60ml
Material : Natural Polypropylene
Case Size : 1 x 2000



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
GPS60	15060098133457	Polythene bag 40 x 50	Cardboard case 1 x 2000	9 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							

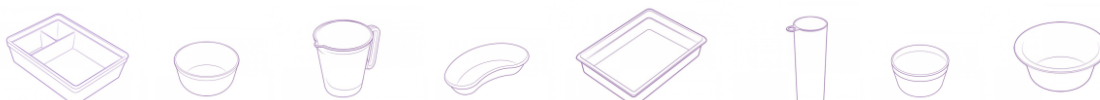
Additional Information

- 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



PRODUCT TECHNICAL DATASHEET

Product Profile & Instructions for Use

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

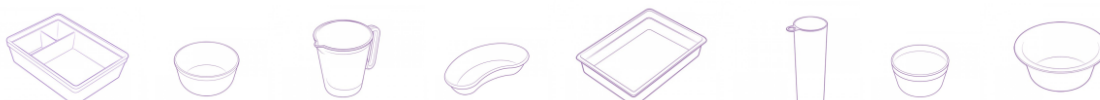
- Product supplied clean ready for packing and sterilisation.
- Cleaning and Disinfection not permitted.

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.

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

