

PRODUCT TECHNICAL DATASHEET

Product Profile & Instructions for Use

Warwick House, Heathcote Way, Warwick
CV34 6TE, United Kingdom
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GPLB60 Gallipot – Flat base

Not a Medical Device

Dimensions : 60mm x 40mm
Volume : 50ml
Material : Blue Polypropylene
Case Size : 1 x 400



Intended Use

- Gallipot, reusable.
- Used to contain medicinal products, disinfectants, and antiseptic fluids.

Intended User

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

Product Features

- Autoclavable.
- Strong and durable.
- Guaranteed 1000 cycles.
- Light weight – “about 50% lighter than stainless steel”.
- Smooth edges and surfaces eliminate paper rips during sterilization.

Packaging Information

Catalogue Number	Case Bar Code (GTIN 14)	Primary Packaging	Secondary Packaging	Case Weight
GPLB60	15060098133006	Polythene bag 1 x 400	Cardboard case 1 x 400	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

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 17664-1:2021 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 15883 Washer disinfectors. Requirements.**
 - 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.**
- **Rinse with warm water to remove any packaging residues.**
- **Product not used in conjunction with any other device.**

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.**
- **Use approved detergents, enzymatic or biocide cleaners, suitable for cleaning medical devices and surgical instruments which are compatible with polypropylene material (see detergent manufacturers' guide).**
- **Use detergents and disinfectants with a range between 2pH and 13pH.**
- **Ultrasonic cleaning is permissible.**
- **Manual cleaning is permissible – separate product components and clean individually.**
- **Rinse with clean water.**
- **Dry with unwoven towels.**



- **Do not use abrasive materials.**

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.**

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 137°C.**
- **Do not exceed 8 minutes.**

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

