PRODUCT TECHNICAL DATASHEET

Product Profile & Instructions for Use

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

KB250 Kidney Dish

Class I Medical Device

Dimensions	: 252 x 100 x 48mm
Volume	: 750ml
Material	: Natural Polypropylene
Case Size	: 1 x 450

Intended Use

- **Kidney dish intended to be used on one individual during a single procedure.**
- **Kidney dish shaped container used to hold and transport medical/surgical instruments and related items to facilitate a clinical procedure, or as part of a procedure pack.**
- **Used in the treatment of disease.**

Intended User

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

Product Features

- **Autoclavable.**
- **Light weight.**
- **Improved removal of residues.**
- **Smooth edges and surfaces eliminate paper rips during sterilization.**
- **Designed to maximise space for instruments and accessories.**

Packaging Information

Catalogue Number	Case Bar Code (GTIN 14)	Primary Packaging	Secondary Packaging	Case Weight
KB250	15060098133556	Polythene bag 1 x 90	Cardboard case 5 x 90	16 Kgs

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	Do not re-use
	REF	CE	MD	EC REP		LOT		NON STERILE	LATEX				

Additional Information

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

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WarwickSASCo
Moulding The Future of Medical Plastics

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enquiries@sasco.co.uk

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

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Standards

Product complies with:	**BS 5452:1977 Specification for hospital hollow-ware made of plastic material.** **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.**
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.**
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.**

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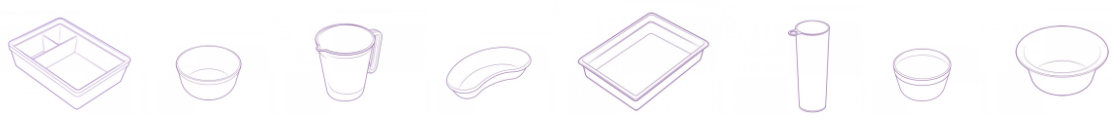

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Inspection Maintenance and Incident Reporting

- **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.**

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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