

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

TAG-015 YELLOW Tray Tag

Not a medical device

Dimensions : 105 x 40 mm
Material : Yellow Nylon
Pack Size : 1 x 100



Intended Use

- Tray tag for use in sterile services and decontamination, for identification and traceability.
- To show barcode, QR or written label, with information of tray and contents.
- Reusable product.

Intended User

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

Product Features

- Autoclavable.
- Can be securely attached to instrument trays and containers to track and trace through the decontamination process.
- Guaranteed 1000 cycles for steam sterilization.
- Clear and easy identification of sets during processing.
- Available in different colours to aid segregation of instrument sets.
- Can be written on with a permanent pen.
- Can be used with an autoclave proof label.
- Lightweight, strong, and durable.
- Smooth edges and surfaces eliminate paper rips during sterilization.

Packaging Information

Catalogue Number	Case Bar Code (GTIN 14)	Primary Packaging	Secondary Packaging	Pack Weight
TAG-015	15060098131668	Polythene bag 1 x 100	n/a	1.20 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
	REF		LOT						

Additional Information

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



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Manufacturer



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

Distributor/Importer



Standards

- **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 to medical devices.
BS EN ISO 15223-1:2021 Medical Devices. Symbols to be used with information to be supplied by the manufacturer. Part 1: General requirements.
BS ISO 17664-2:2021 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices. Part 2: Non-critical medical devices.
BS EN ISO 20417:2021 Medical devices. Information to be supplied by the manufacturer.
- **Referenced standards:** **BS EN ISO 15883 Washer disinfectors. Requirements.**
BS EN ISO 11135 Sterilization of health care products. Ethylene oxide.
BS EN ISO 17665-1 Sterilization of health care products. Moist heat.
BS ISO 22441 Sterilization of health care products. Low temperature vaporized hydrogen peroxide.

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 can be used in conjunction with

- **TR30 Stainless steel attachment ring.**

Cleaning and Disinfection

- **Position products individually, avoiding contact with other items.**
- **Position products to allow water penetration and drainage.**



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- **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 nylon 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 and Maintenance

- **Visually inspect product to identify damage.**
- **Discard damaged product.**

Wrapping

- **Sterilization wrapping sheets and pouches must be compatible with nylon 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 17665-1, ISO 22441, 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 for steam sterilization.**
- **Do not exceed 8 minutes hold time for steam sterilization.**
- **Do not exceed 10 cycles for H2O2 sterilization.**

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**

