Product Profile & Instructions for Use

TAG-030 RED Tray Tag

| Not a medical device | | | |
|----------------------|---------------|--|--|
| Dimensions | : 105 x 40 mm | | |
| Material | : Red Nylon | | |
| Pack Size | : 1 x 100 | | |

WarwickSASCo Moulding The Future of Medical Plastics

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



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 | Case Bar Code | Primary | Secondary | Pack Weight |
|-----------|----------------|--------------------------|-----------|-------------|
| Number | (GTIN 14) | Packaging | Packaging | |
| TAG-030 | 15060098131682 | 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 | \triangle | LOT | \sum | NON | LATER | | Ĵ | * |

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. |
| \succ | 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 \Lambda

- > 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

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