

Product Description

Catalog Number: 9016

Product Description: Costar® 2 mL Aspirating Pipette, Individual, Paper/plastic Wrap

Component Materials:

- Polystyrene meets *USP, Class VI requirements for plastic containers and closures.*
- Polystyrene, *meets USP Cytotoxicity Test <87>*

Product Dimensions:

- | | | | | | |
|-----------------------|---|------------------------|---------------|---|----------|
| Overall Length | - | 11.13 in. +/- .050 in. | Mouthpiece OD | - | .247 in. |
| Pipette OD | - | .247 in. | Tip ID | - | .064 in. |
| Tolerances of ID & OD | - | +/- .015 in. | | | |

Regulatory Compliance - Product manufactured in a facility that is registered to the current version of ISO 9001 or ISO 13485

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization.*

Sterility Assurance Level: SAL 10⁻³

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 *Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing*, Results: < 0.1 EU/mL (< 4EU/device)

BSE/TSE:

This product is deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Visual Attributes: Visual examination of the product.

Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Lot Number Designation:

8 Digit Lot Number: First 3 digits – Julian date, start of manufacturing; Next 2 digits – Year of manufacture; Last 3 digits – Batch identification.

or

7 Digit Lot Number: First digit – Last number of year of manufacture, Next 3 digits – Julian date, start of manufacturing, Last 3 digits – Batch identification