

Catalog Number: 9186

Product Description: 2 mL non-printed pipette, individual, plastic wrap

Component Materials:

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

Product Dimensions:

Overall Length	-	10.97 in. +/- .050 in.	Mouthpiece OD	-	.255 in.
Pipette OD	-	.255 in.	Tip ID	-	.082 in.
Tolerances of ID & OD	-	+/- .015 in.			

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.

Rev 7