Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description

Catalog Number: 9099

Product Description: 5 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 - 13.65 in. +/- .15 in. Mouthpiece OD - .315 in. Pipette OD - .315 in. Tip ID - .073 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: Bacterial Endotoxins - Test methodologies, routine testing, 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.

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