Corning Incorporated Life Sciences

Registered ISO 9001

Product Description

Catalog Number: 430157

Product Description: Corning® 16 x 125 mm culture tube, plug seal cap

Component Materials:

Tube - Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and

closures.

Cap - Virgin Low Density Polyethylene. Heavy metal free (meets CONEG reg.) color

concentrate.

Product Dimensions:

Length w/cap - 4.90 in. O.D. (cap) - 0.84 in. Length w/o cap - 4.86 in. Tolerances - +/-0.05 in.

Width (tube) - 0.58 in.

Sterilization:

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

Sterility Assurance Level: SAL 10⁻⁵

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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: less than 0.1EU/mL.

Performance Testing:

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

Integrity Testing: Forward pressurization of the product to 40 inches of water column.

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.

Revision Date:

10-31-18

Rev No: 5