## Corning Incorporated Life Sciences

Registered ISO 9001:2008

# **Product Description**

Catalog Number: 431386

Product Description: Corning ® 2 mL cryogenic vial, internally threaded, round bottom, self standing

**Component Materials:** 

Vial - Virgin Polypropylene, meets USP, Class VI requirements for plastic containers and

closures.

Cap - Virgin Polypropylene, meets USP, Class VI requirements for plastic containers and

closures. Heavy metal free (meets *CONEG* req.) color concentrate.

Washer - Silicone, meets USP, Class VI requirements for plastic containers and closures.

**Product Dimensions:** 

Length of vial w/cap - 1.91 in. Diameter of cap - 0.47 in.

Diameter of vial - 0.50 in. Tolerances - +/- 0.05 in.

## Sterilization:

This lot has been irradiated and dosimetrically released based on the *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.* 

Sterility Assurance Level: SAL 10<sup>-5</sup>

## RNase/DNase Testing:

This product has been tested and is free of any detectable RNase/DNase contamination.

#### Pyrogens:

The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing. Results: less than 0.1 EU/mL

## 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 - Run number for that year.

Rev No: 2