Corning Incorporated Life Sciences

Registered ISO 13485

Product Description

Catalog Number: 3005

Product Description: Corning ® Spatula, round end/spoon

Component Materials:

Spatula - Polystyrene and color concentrate blend

Product Dimensions:

Overall Length - 9.73 in. Spoon Width - 0.49 in.

Maximum Working End - 0.35 in.

Width

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137:2013 Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization. Sterility Assurance Level: SAL 10⁻³

BSE/TSE:

Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

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 72:2011 Bacterial endotoxins-Test methods, routine monitoring, and alternatives to batch testing and USP <85> Bacterial Endotoxin Test. 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 - Batch identification. The entire lot is sterilized as one unit.

Rev No: 6