# Corning Incorporated Life Sciences

Registered ISO 9001:2008

# Certificate of Compliance

Catalog Number: 7041

Lot Number: 17014005

Product Description: Costar ® 1 mL Stripette ®, individual, paper / plastic wrap

**Component Materials:** 

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

closures. Polystyrene also meets USP Cytotoxicity Test <87>.

Mouthpiece Plug - Polyester, meets *USP Cytotoxicity Test <87>*.

Ink - Yellow / black, meets USP Cytotoxicity Test <87>.

#### 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<sup>-6</sup>

# 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)

# RNase/DNase Testing:

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

### Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product is manufactured and packaged with animal free materials.

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure:
Visual Attributes
Volumetric Accuracy
Pass
Packaging
Pass

#### 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.

#### **Expiration Statement:**

This product has an expiration date of 3 years from the date of manufacture for the attributes contained within this certificate.

Judith A. Gibbs

Quality Assurance Manager

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