

**Corning Incorporated
Life Sciences**

**Registered
ISO 9001:2008**

Certificate of Compliance

Catalog Number: 431221

Lot Number: 07914023

Product Description: Corning® syringe filter, surfactant free cellulose acetate (SFCA) membrane, 0.80 µm pore size, 28 mm diameter, individually packaged

Component Materials:

- Housing - Acrylic Copolymer, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.
- Membrane - Surfactant Free Cellulose Acetate (SFCA), 0.80 µm pore size, meets *USP, Class VI* requirements for plastic containers and closures.

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 10⁻⁵

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: less than 0.1EU/mL

Bacterial Challenge:

This lot has been tested and determined to be quantitatively retentive when challenged with a concentration of 10⁷ organisms per cm² using *Brevundimonas diminuta*.
Results: Pass

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:	Results:
Membrane Bubble Point Integrity	Pass
Housing Burst Pressure Test	Pass
Pressure Hold Test	Pass
Visual Attributes	Pass
Packaging	Pass

Expiration Statement:

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

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date of manufacture; Next 2 digits - Year of manufacture; Last 3 digits - Run number for that year.



Wendy Loitsch
Quality Manager

Rev No: 4