

**Corning Incorporated  
Life Sciences**

**Registered  
ISO 9001:2008**

# Certificate of Compliance

**Catalog Number:** 431221

**Lot Number:** 15614043

**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<sup>-5</sup>

**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 10<sup>7</sup> organisms per cm<sup>2</sup> 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:

<b>Test/Procedure:</b>	<b>Results:</b>
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