

**Catalog Number:** 431212

**Product Description:** Corning® syringe filter, regenerated cellulose (RC) membrane, 0.20 µM pore size, 4 mm diameter, individually packaged

**Component Materials:**

- Housing - Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures.
- Membrane - Regenerated Cellulose (RC), 0.20 µM pore size, meets *USP, Class VI* requirements for plastic containers and closures.

**Product Dimensions:**

- |                           |   |                      |                |   |                       |
|---------------------------|---|----------------------|----------------|---|-----------------------|
| Diameter of unit          | - | 0.47 in. (12 mm)     | Length of unit | - | 0.79 in. (20 mm)      |
| Diameter of membrane      | - | 0.16 in. (4 mm)      | Tolerances     | - | +/- 0.05 in. (1.3 mm) |
| Effective filtration area | - | 0.07 cm <sup>2</sup> |                |   |                       |

**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.

**HPLC Certified:**

The product has been tested to ensure there are no extraneous peaks in the UV range.

**Membrane Bubble Point:**

The product has been tested according to an established procedure to determine the water bubble point of the product. The product meets the established criteria of >3.5 bar.

**Housing Burst Pressure Test:**

The product has been tested according to an established procedure to determine the housing burst pressure. The product meets the established criteria of >6 bar (approx. 87 psi).

**Flow Rate Test:**

The product has been tested according to an established procedure to determine the flow rate. The product meets the established criteria of >3.5 mL/min/bar.

**Bacterial Challenge:**

The product 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*.

**Performance Testing:**

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Pressure Hold Test:

Forward pressurization of the unit to 1.5 bar.

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 of manufacture; Next 2 digits - Year of manufacture; Last 3 digits - Run number for that year.

**Revision Date:**

01-24-19