

**Corning Incorporated
Life Sciences**

**Registered
ISO 9001:2008**

Certificate of Compliance

Catalog Number: 431475

Product Description: Corning® 500 mL filter system, polyethersulfone (PES) membrane, 0.1 µm pore size

Component Materials:

- Funnel, Funnel Lid & Receiver/Storage Bottle - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Funnel Adapter, Hose Connector & Plug Seal Cap - Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.
- Membrane - Polyethersulfone (PES), 0.1 µm pore size
- Gasket - Polyethylene Foam liner
- Adapter Plug - Cellulose Acetate

Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *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.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Membrane Bacterial Retention:

The product has been tested as per the HIMA guidelines and determined to be quantitatively retentive at a concentration of 10⁷ organisms per cm² using *Brevundimonas diminuta*.
Results: Sterile

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 Integrity Test | Pass |
| Visual Attributes | Pass |
| Packaging | Pass |

Expiration Statement:

This product 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, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Revision Date:

03-01-14



Wendy Loitsch
Quality Manager

Rev No: 4