## Corning Incorporated Life Sciences

Registered ISO 9001:2008

# Certificate of Compliance

 Catalog Number:
 431155

 Lot Number:
 27414004

Product Description: Corning® 150 mL filter system, cellulose acetate membrane, 0.45 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

Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.

Connector & Plug Seal Cap

- Cellulose Acetate, 0.45 µm pore size

Gasket - Polyethylene Foam liner

Adapter Plug - Cellulose Acetate

#### Sterilization:

Membrane

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<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.

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.

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:

Membrane Integrity Test
Visual Attributes
Pass
Packaging

Results:
Pass
Pass
Pass
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 Lotsch

Wendy Loitsch Quality Manager

Rev No: 8