## Corning Incorporated Life Sciences

Registered ISO 9001:2008

# Certificate of Compliance

Catalog Number: 431466

Lot Number: 30913003

Product Description: Corning® 175 cm² flask, angled neck, vent cap

Non-treated

**Component Materials:** 

Flask - Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and

closures

Cap - Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic

containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate. 0.2 µm microporous PTFE membrane, meets *USP*, *Class VI* requirements for plastic

containers and closures.

#### 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<sup>-6</sup>

#### Pyrogens:

The product has been tested and has met the criteria established in the *Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices (FDA, December, 1987).* 

Results: less than 0.1 EU/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:

Leak 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:**

7-22-11

Wendy Latsch

Wendy Loitsch Quality Manager

Rev No: 4