

**Corning Incorporated  
Life Sciences**

Registered  
ISO 9001:2008

# Certificate of Compliance

**Catalog Number:** 431406

**Product Description:** Corning® 250 mL disposable Baffled Erlenmeyer flask, flat cap

**Component Materials:**

- Flask - Virgin Polycarbonate, meets *USP, Class VI* requirements for plastic containers and closures.
- Cap - Virgin Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.

**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>

**Sterile Fluid Path:**

Product labeled Sterile Fluid Path has been designed to ensure sterility of the portion of the product intended for contact with fluids.

**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.

**RNase/DNase Testing:**

This product has been tested and is free of any detectable RNase/DNase contamination.

**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 medicinal 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:

<b>Test/Procedure:</b>	<b>Results:</b>
Leak 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 - Run number for that year.

**Revision Date:**

07-01-14



Wendy Loitsch  
Quality Manager

Rev No: 10