

**Corning Incorporated  
Life Sciences**

**Registered  
ISO 9001:2008**

# Certificate of Compliance

**Catalog Number:** 431406  
**Lot Number:** 10607001  
**Product Description:** Corning® 250 mL disposable Baffled Erlenmeyer flask, plug seal 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>

**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 Parenteral Drugs, Biological Products and Medical Devices (FDA, December, 1987)*.

Results: less than 0.1 EU/mL

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



Wendy Loitsch  
Quality Manager

Rev No: 2