

**Corning Incorporated  
Life Sciences**

**Registered  
ISO 9001:2008**

# Certificate of Compliance

**Catalog Number:** 3578

**Product Description:** Corning ® Spinner Flask, Disposable, 500ml, with vent caps

**Component Materials:**

- Vessel - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures, "complies with International Organization for Standardization (ISO) 10993-18, Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Materials (2005)."
- Caps - High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures.
- Filter - .2µm/polyester non-woven membrane, meets *USP, Class VI* requirements for plastic containers and closures.
- Flange Base - Acrylonitrile Butadiene Styrene
- Magnet - Polystyrene encapsulated ALNICO magnet, 12800 Gauss induction

**Sterilization:**

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR 33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization*. Sterility Assurance Level: SAL 10<sup>-6</sup>

**Pyrogens:**

This vessel has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 *Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing*. Results: ≤ 0.1 EU/mL ( ≤ 4EU/device)

**Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:**

This product is manufactured and packaged with animal free materials.

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:

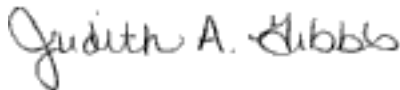
<b>Test/Procedure:</b>	<b>Results:</b>
Visual Attributes	Pass
Packaging	Pass

**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.

**Expiration Statement:**

This product has an expiration date of 3 years from the date of manufacture for the attributes contained within this certificate.



Judith A. Gibbs  
Quality Assurance Manager

Rev No: 4