

**Corning Incorporated  
Life Sciences**

**Registered  
ISO 9001:2008**

# Certificate of Compliance

**Catalog Number:** 3321  
**Lot Number:** 05514004  
**Product Description:** Corning® CellSTACK®- 40 Chamber with Corning® CellBIND® surface

**Component Materials:**

- Top Plate - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures
- Middle Plate - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures
- Bottom Plate - Virgin Polystyrene, 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.
- Adhesive - Proprietary Acrylate, meets ISO-10993, Biocompatibility requirements and does not contain any animal products.

**Sterilization:**

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.*  
Sterility Assurance Level: SAL 10<sup>-6</sup>

**Pyrogens:**

The CellStack 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:

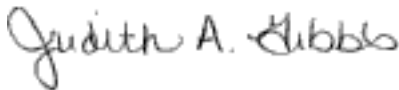
<b>Test/Procedure:</b>	<b>Results:</b>
Leak Test	Pass
Visual Attributes	Pass
Cell Culture Treatment	Pass
Packaging	Pass

**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: 13