## Corning Incorporated Life Sciences

Registered ISO 9001:2008

## Certificate of Compliance

Catalog Number: 3321

Lot Number: 31313004

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 ČellStack 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:

Test/Procedure:

Leak Test
Visual Attributes
Cell Culture Treatment
Pass
Packaging
Pass
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** 

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