# Corning Incorporated Life Sciences

Registered ISO 9001:2008

# Certificate of Compliance

Catalog Number: 3201

Lot Number: 30604014

Product Description: Corning ® CellCube ® Culture Module, 25 Layer

## Fluid Path Components Materials:

Middle Plates - Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and

closures.

End Plates - Polycarbonate, meets *USP, Class VI* requirements for plastic containers and closures.

Encapsulate - Polycarbonate and white concentrate blend, both meet USP, Class VI requirements for

plastic containers and closures.

Hose Barb Adapter - Polycarbonate, meets *USP*, *Class VI* requirements for plastic containers and closures. Polycarbonate, meets *USP*, *Class VI* requirements for plastic containers and closures.

Tubing - Silicone, meets USP, Class VI requirements for plastic containers and closures.

#### Sterilization:

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

## Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest version of EMEA 410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary 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:

Test/Procedure:

Leak Test
Visual Attributes
Cell Culture Treatment
Pass
Packaging
Pass

### Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacture; 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** 

Judith A. Libbs

Rev No: 14