# Corning Incorporated Life Sciences

Registered ISO 9001:2008

# Certificate of Compliance

3786 Catalog Number:

**Product Description:** Collagen coated - Microcarriers: 10g vial, sterile

**Component Materials:** 

Beads Polystyrene, meets USP, Class VI requirements for plastic containers and closures.

Collagen Type A - Porcine Gelatin, 300 Bloom  $1.022-1.030 \text{ vs } \text{H}_2\text{O}$ Surface

Relative Density

#### Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of health care 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 current version of ANSI/AAMI ST 72:2002/(R)2010 Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch Results: < 0.1 EU/mL ( < 4EU/device)

# 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.

#### Surface Characterization:

The surface is coated with a proprietary concentration of Collagen Type I optimized for stem cell expansion.

#### Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of cell attachment and growth.

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: Results: Visual Attributes Pass Packaging Pass Cell Growth **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.

Judith A. Gibbs

**Quality Assurance Manager** 

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Rev No: 3