|   | Corning Incorporated<br>Life Sciences<br>Registered<br>ISO 9001:2008   |                            | Product Description |          |                                |   |                      |
|---|--|----------------------------|---------------------|----------|--------------------------------|---|----------------------|
| 0   | Catalog Number:  | 3524                       |                     |          |                                |   |                      |
| Product Description: Costar ® 24-well cell culture cluster flat bottom with lid |  |                            |                     |          |                                |   |                      |
|   | Component Materials:<br>Plate/Lid - Virgin Polystyrene, meets <i>USP, Class VI</i> requirements for plastic containers and closures. |                            |                     |          |                                |   |                      |
| Ĺ   | P <b>roduct Dimensions:</b><br>_ength of Plate<br>Width of Plate   | - 5.030 in.<br>- 3.365 in. |                     |          | r of Well @ top<br>r of Well @ | - | .640 in.<br>.615 in. |
| ٦   | Depth of Well<br>Folerances of<br>Dimensions   | 685 in.<br>- +/050 ir      |                     | Height w | ith Lid<br>Volume per well     | - | .891 in.<br>2 mL     |

# Sterilization:

The product is irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization. Sterility Assurance Level: SAL 10-3

### Pyrogens:

The product has been tested and has met the criteria established in the Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices (FDA, December, 1987).

### Surface Characterization:

Surface is characterized to be hydrophilic and negatively charged, composed of 9-17% oxygen atoms. This surface composition has been optimized for cell attachment and growth.

# Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of cell attachment and growth utilizing an attachment- dependent mammalian cell line in a serum supplemented media.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy: This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

#### Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures. Cell Culture Treatment: Wettability test using water to insure the presence of a hydrophilic

surface. Visual Attributes: Visual and microscopic examination of the product. Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

# 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.

Rev No: 10