

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 9102

Product Description: Costar® 96-well cell culture cluster strip, flat bottom, with lid

Component Materials:

- Strips & Lid - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Holder - Polystyrene meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.

Product Dimensions:

- | | | | | | |
|--------------------------|---|--------------|---------------------------|---|--------------|
| Length of Plate | - | 5.025 in. | Diameter of Well @ top | - | .270 in |
| Width of Plate | - | 3.370 in. | Diameter of Well @ bottom | - | .250 in |
| Depth of Well | - | .420 in | Height with Lid | - | .650 in. |
| Tolerances of Dimensions | - | +/- .010 in. | Working Volume per well | - | 0.1 - 0.2 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 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)

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:

Strips are manufactured with animal free components.

Strip holder 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.

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.