

Catalog Number: 3814

Product Description: Corning® Ultra Low Attachment, 75cm² cell culture flask, canted neck, u-shape, vent cap

Component Materials:

- Flask - Virgin Polystyrene, meets *USP Class VI* requirements for plastic containers and closures.
- Cap - Virgin High Density Polyethylene, meets *USP Class VI* requirements for plastic containers and closures. Heavy metal free (meets CONEG requirements) color concentrate.
0.2µm microporous PTFE membrane, meets *USP Class VI* requirements for plastic containers and closures.
- Surface - Proprietary hydrogel, meets ISO-10993, Biocompatibility requirements.

Product Dimensions:

- | | | | | | |
|--------------|---|----------|----------------|---|--------------|
| Length w/Cap | - | 6.39 in. | Height (depth) | - | 1.56 in. |
| Width | - | 3.52 | Tolerances | - | +/- 0.05 in. |

Sterilization - Product has been sterilized and dosimetrically released per the requirements ANSI/AAMI/ISO 11137 "Sterilization of health care products- Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10⁻³.

Non-Pyrogenic - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

Animal Content - Product does not contain materials of animal origin.

Surface Characterization - Surface is characterized to be hydrophilic and neutrally charged, composed of a covalently bound hydrogel layer that is biologically inert and non-degradable. This surface composition has been optimized for cell attachment inhibition.

Tissue Culture - Tested for the attribute of cell attachment inhibition utilizing an attachment-dependent mammalian cell line. A minimum of 98% cell attachment inhibition is required for acceptance.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Visual Inspection - Pass

Packaging Inspection - Pass

Cell Attachment & Growth Treatment Verification – Pass

Leak Test – Forward pressurization of the product to 10 inches of water column - 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.

Rev 8