

**Corning Incorporated  
Life Sciences**

Registered  
ISO 9001:2008

**Product Description**

**Catalog Number:** 3303

**Product Description:** Corning® Ultra Low Attachment CellSTACK® - 1 Chamber

**Component Materials:**

- Top Plate - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Bottom Plate - 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* req.) color concentrate.
- Filter - .2µm/polyester non-woven membrane, meets *USP, Class VI* requirements for plastic containers and closures.
- Adhesive Surface - Proprietary Acrylate, meets ISO-10993, Biocompatibility requirements.
- Proprietary hydrogel, meets ISO-10993, Biocompatibility requirements.

**Product Dimensions:**

- |                         |   |                  |                         |   |                     |
|-------------------------|---|------------------|-------------------------|---|---------------------|
| Overall Length          | - | 13.2 in. (335mm) | Overall Width           | - | 8.1 in. (206mm)     |
| Overall Height with cap | - | 2.0 in. (51mm)   | Tolerances              | - | +/- 0.1 in. (2.5mm) |
| Neck ID                 | - | 1.0 in. (26mm)   | Neck O.D. incl. Threads | - | 1.3 in. (32mm)      |
| Distance between plates | - | 0.67 in. (17mm)  |                         |   |                     |

**Total Cell Growth Area:**

636 cm<sup>2</sup>

**Recommended Working Volume:**

130 - 200 ml

**Sterilization:**

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization*.  
Sterility Assurance Level: SAL 10<sup>-6</sup>

**Pyrogens:**

The CellStack 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 neutrally charged, composed of a covalently bound hydrogel layer that is biologically inert and non-degradable. The surface composition has been optimized for cell attachment inhibition.

**Cell Attachment and Growth Characteristics:**

The product has been tested for the attribute of cell attachment inhibition utilizing an attachment-dependent mammalian cell line in a serum supplemented media. Cell attachment inhibition must be ≥ 95% as compared to a standard tissue culture treated surface.

**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.

**Performance Testing:**

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Integrity Testing: Forward pressurization of the product to 1.5 psi.

Visual Attributes: Visual 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.

**Corning Incorporated  
Life Sciences**

**Registered  
ISO 9001:2008**

## Product Description

**Catalog Number:** 3303

**Product Description:** Corning® Ultra Low Attachment CellSTACK® - 1 Chamber

**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.

**Serial Number Designation:**

12 Digit Serial Number: First 8 digits - Lot number (see lot number designation above); Next 3 digits CellSTACK serial number; Last digit - Stack designation.

Rev No: 8

DOMINIQUE DUTSCHER SAS