

**Corning Incorporated  
Life Sciences**

Registered  
ISO 9001:2008

**Product Description**

**Catalog Number:** 10034

**Product Description:** Corning® HYPERFlask® M Cell Culture Vessel, solid cap, CellBIND® surface

**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.
- Liner - Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures.
- Film - Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.

**Product Dimensions:**

- |                |   |              |                |   |                      |
|----------------|---|--------------|----------------|---|----------------------|
| Length         | - | 8.009 in.    | I.D. (neck)    | - | 1.02 in.             |
| Width          | - | 4.809 in.    | O.D. (cap)     | - | 1.40 in.             |
| Height (depth) | - | 2.091 in.    | Growth surface | - | 1720 cm <sup>2</sup> |
| Tolerances     | - | +/- .005 in. |                |   |                      |

**Sterilization:**

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR 33) *Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization*  
Sterility Assurance Level: SAL 10<sup>-6</sup>

**Pyrogens:**

This 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 ≥ 20% 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 is manufactured and packaged with animal free materials.

**Performance Testing:**

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

Integrity Testing: Forward pressurization of the product to 0.5 psi.  
Cell Culture Treatment: Wettability test using water to insure the presence of a hydrophilic surface.

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.

**Serial Number Designation:**

11 Digit Serial Number: First 8 digits - Lot Number (see lot number designation above); Last 3 digits - HYPERFlask M Vessel Serial Number.

Rev No: 7