Corning Incor Life Scier ISO 9001:2	Product Description
Catalog Number:	7007
Product Description:	Costar ® 96-well Ultra Low Attachment, round bottom, with Low Evaporation lid
Component Materials: Plate/Lid - Surface -	Virgin Polystyrene, meets <i>USP, Class VI</i> requirements for plastic containers and closures. Proprietary hydrogel.
Product Dimensions: Length of Plate Width of Plate Depth of Well Tolerances of Dimensions	<ul> <li>5.030 in.</li> <li>3.365 in.</li> <li>.445 in.</li> <li>+/ 010 in.</li> </ul> Diameter of Well @ top270 in. <ul> <li>Diameter of Well @250 in.</li> <li>bottom</li> <li>Height with Lid650 in.</li> <li>Working Volume per well360μL</li> </ul>

## 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<sup>-3</sup>

#### 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:  $\leq 0.1 \text{ EU/mL}$  ( $\leq 4 \text{EU/device}$ )

## 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. This 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  $\geq$  98% as compared to a standard tissue culture treated surface.

# Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product does not contain materials of animal origin.

#### Performance Testing:

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

Cell Attachment Inhibition:	Verification of cell attachment inhibition utilizing an attachment-dependent
	mammalian cell line in a serum supplemented media.
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.

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