

Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 3964

Product Description: Costar® 384-well Assay Block, polypropylene, sterile

Component Materials:

Assay Block - Virgin Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures.

Product Dimensions:

Block height	-	1.095 in.	Height of well	-	.989 in.
Block length @ bottom	-	5.030 in.	Opening @ top of well	-	.143 in.sq.
Block width @ bottom	-	3.365 in.	Distance from well center to center	-	.177 in.
Tolerances of Dimensions	-	+/- .010 in.			

Sterilization:

This lot has been 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

Surface Characterization:

Surface is characterized to be hydrophobic and non-charged.

Pyrogens:

The product has been tested and has met the criteria established in the *Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices (FDA, December, 1987)*.

RNase/DNase Testing:

This product has been tested and is free of any detectable RNase/DNase contamination.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine 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.

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.

Rev No: 10