Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description

Catalog Number:		3765				
Product Description:		Corning ® 384-well, white with clear bottom plate, low flange, tissue culture treated, with lid				
Component Materials:						
Plate walls	-	Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and closures. White concentrate.				
Plate bottom	-	Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and closures.				
Lid	-	Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and closures.				
Product Dimensions:						
Length of Plate	-	5.030 in.	Width of Square Well@ Top	-	.143 in.	
Width of Plate	-	3.365 in.	Width of Square Well @ Bottom	-	.111 in.	
Depth of Well	-	.455 in.	Height with lid	-	.660 in.	
Tolerances of			Working volume per well	-	20 μL to 75 μL	
Dimensions	-	+/010 in.				

BSE/TSE - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

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

Sterility - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products – Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10³.

Tissue Culture - Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. A minimum of 95% confluency is required for acceptance.

Surface Characterization - Surface is characterized to be hydrophilic and negatively charged, composed of 9-17% oxygen atoms. This surface composition has been optimized for cell attachment and growth.

Optical Characteristics - The product is made of opaque white polystyrene walls to minimize well to well crosstalk and background fluorescence and / or luminescence. The bottom is made of clear polystyrene to permit direct microscopic viewing.

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	Treatme	ent Verification	- Pass

- This product met Corning Incorporated – Life Sciences' high standards of guality at the time of batch/lot release.

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: 1