## Corning Incorporated Life Sciences Registered ISO 9001

# **Product Description**

Catalog Number:		4515				
Product Description:		Corning ® Spheroid Microplate, 96-well, black clear round bottom, ultra low attachment, with lid				
Component Materials:						
Plate walls	-	Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and closures. Black concentrate.				
Plate bottom	-	Polystyrene, meets USP, Class VI requirements for plastic containers and closures.				
Lid	-	Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and closures.				
Surface	-	Proprietary hydrogel.				
Product Dimensions:						
Length of Plate	-	5.030 in.	Diameter @ top of well	-	0.270 in.	
Width of Plate	-	3.365 in.	Well bottom radius	-	0.100 in.	
Depth of Well	-	.494 in.	Well bottom elevation	-	0.073 in	
Tolerances of			Height with lid	-	0.650 in.	
Dimensions	-	+/010 in.	-			
Working volume per well	-	75 μL to 300 μL				

## 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 10<sup>-3</sup>

## **Animal Content:**

Product does not contain materials of animal origin.

## 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" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is  $\leq 0.10 \text{ EU/mL}$  or  $\leq 4 \text{ EU/device}$ .

## **Optical Characteristics:**

The product is made of opaque black polystyrene walls to minimize well-to-well crosstalk and background fluorescence. The bottom is made of clear thin polystyrene to permit direct microscopic viewing.

## 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 had been optimized for cell attachment inhibition.

## **Tissue Culture:**

Tested for the ability to promote the growth and formation of 3D cellular spheroids of mammalian suspension cells in culture. Spheroid formation in  $\ge$  95% of the wells required for acceptance.

## **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 Attributes	-	Pass
Packaging	-	Pass
Well Bottom Elevation	-	Pass

- This product met Corning Incorporated – Life Sciences' high standards of quality 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.