Corning Incorporated Life Sciences

> Registered ISO 9001:2008

**Product Description** 

Catalog Number: 4705

Dreduct Dimensioner

Product Description:	Corning ${f @}$ 1536-well, tissue culture treated, solid black plate, flat bottom, without lid, w/Barcode labels
Component Materials: Plate -	Cyclic Olefin Co-polymer, meets USP Class VI requirements for plastic containers and closures. Black cyclic olefin co-polymer concentrate
Barcode Label - Special Feature - Barcode I	White polypropylene base, acrylic adhesive abel (format 128) on A1 short side and H12 short side both centered.

Product Dimensions:				
Length of Plate -	5.030 in.	Width of Square Well @ Top	-	.067 in.
Width of Plate -	3.365 in.	Width of Square Well @ Bottom	-	.060 in.
Tolerance of Dimensions -	+.010 in. /015 in.	Depth of Well	-	.195 in.
For Length		Height without Lid	-	.409 in.
Tolerance of Dimensions -	+/010 in.	Maximum well volume	-	13µL
Working volume -	8µL			

**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 materials having been processed per specific conditions of section 6.4 of EMA/410/01.

**Surface Characteristic** – Surface is characterized to be hydrophilic and negatively charged. The negatively charged, carboxyl surface composition, has been optimized for cell attachment and growth.

**Optical Characteristic –** The product is made of opaque black cyclic olefin co-polymer walls to minimize well to well crosstalk and background fluorescence and / or luminescence.

**Tissue Culture –** Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. Cell attachment within 24 hours is required for acceptance.

**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  $\leq 0.10$  EU/ml or  $\leq 4$  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 10<sup>-3</sup>.

**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 Treatment Verification – Pass

## 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 1