Corning Incor Life Scier <sub>Registere</sub>	nces	duct Descri	intion
ISO 9001:2	008		
Catalog Number:	4566		
Product Description:	Corning ® 1536-well, tissu with barcode labels	e culture treated, solid blac	k plate, flat bottom, without lid,
Component Materials: Plate -			
Barcode Label: -	White polypropylene base, acrylic adhesive		
Product Dimensions: Length of Plate	- 5.030 in.	Width of Square Well @ Top	067 in.
Tolerances of Dimensions for Length	- + .010 in. /015 in.	Width of Plate	- 3.365 in.
Width of Square Well @	- 0.60 in.	Depth of Well	195 in.
Bottom Height without Lid	409 in.	Tolerances of	- +/010 in.
Working Volume	- 8μL	Dimensions Maximum well volume	- 13µL

#### **Special Feature:**

Barcode Label (format 128) on A1 longside and H12 longside

#### 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<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 negatively charged. The negatively charged, carboxyl surface composition, has been optimized for cell attachment and growth.

## Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line in a serum supplemented media.

### 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.

#### **Optical Characteristics:**

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

#### Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures. Visual Attributes: Packaging: Cell Culture Treatment: Visual examination of the product. Cell Culture Treatment: Visual examination of the product. Inspection for seal and barrier integrity, accurate labeling and correct product configuration. Vettability test using water to insure the presence of a hydrophilic surface.

#### 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.

# Corning Incorporated Life Sciences Registered ISO 9001:2008



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Rev No: 3