### Corning Incorporated Life Sciences

Registered ISO 9001:2008

# **Product Description**

Catalog Number: 3542

Product Description: Corning ® 384-well, low volume, tissue culture treated, black plate with clear flat

bottom, with lid

**Component Materials:** 

Plate walls - Virgin Polystyrene, meets USP. Class VI requirements for plastic containers and

closures. Black 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. Diameter of Well @ top - .130 in. Width of Plate - 3.365 in. Diameter of Well @ - .079 in.

bottom

Depth of Well - .370 in. Height with Lid - .573 in. Tolerances of - +/- .010 in. Total well volume - 50 μL

Dimensions

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: < 0.1 EU/mL ( < 4EU/device)

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.

#### 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.

#### Cell Attachment and Growth Characteristics:

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

## **Optical Characteristics:**

The product is made of opaque black 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.

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.

Cell Culture Treatment: Wettability 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.

Rev No: 5