Corning Incorporated Life Sciences Registered ISO 9001

Product Description

Catalog Number: 4676

Product Description: Corning®, 1536 well, tissue culture treated, black plate with

clear flat bottom, high web, without lid, with barcode labels

Component Materials:

Plate walls - Cyclic Olefin Co-Polymer, meets USP, Class VI requirements for

plastic containers and closures. Black cyclic olefin co-polymer

concentrate.

- Cyclic Olefin Co-Polymer, meets USP, Class VI requirements for Plate bottom

plastic containers and closures.

Barcode Label - White polypropylene base, acrylic adhesive.

Special Feature:

Barcode label (format 128) on A1 short side, H12 short side both centered.

Product Dimensions:

Length of Plate 5.030 in. Width of Square Well @ Top -.070 in. Width of Plate 3.365 in. Tolerances of Dimensions for length + .010 in. / -.015 in Depth of Well .244 in. Diameter Well @ Bottom .059 in. Tolerance of Dimensions +/- 0.10 in. Recommended working Height without Lid .315 in.

Maximum well volume volume per well 15µL 10µL

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.

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. The bottom is made of clear cyclic olefin co-polymer to permit direct microscopic viewing.

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 10⁻³.

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.

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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.

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.

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 2