Corning Incorporated Life Sciences

Registered ISO 9001

Product Description

Catalog Number: 3809

Product Description: Corning ® 96-well, Corning ® CellBIND® surface, white plate with clear flat bottom,

with low evaporation 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 - 0.270 in.

Width of Plate - 3.365 in. Diameter of Well @

Bottom - 0.250 in.

Depth of Well - 0.420 in. Height with Lid - 0.650 in. Tolerances of - +/-0.010 in. Volume per Well - 0.36 mL

Dimensions

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

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.

Surface Characterization – Surface is characterized to be hydrophilic and negatively charged, composed of ≥20% oxygen atoms. This surface composition has been developed for cell attachment and growth.

Tissue Culture - 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.

BSE/TSE - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising 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.

Optical Characteristics - The product is made of opaque white 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

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 and Growth Treatment Verification - 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.

Rev. 1