## Corning Incorporated Life Sciences

Registered ISO 9001:2008

# **Product Description**

Catalog Number: 3987

Product Description: Corning ® 24-well Osteo Assay plate, flat bottom, with lid

**Component Materials:** 

Plate/Lid - Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and

closures

Surface - Inorganic Coating

**Product Dimensions:** 

Length of Plate - 5.030 in. Diameter of Well @ top - .640 in. Width of Plate - 3.365 in. Diameter of Well @ - .615 in.

bottom

Depth of Well - .685 in. Height with Lid - .891 in. Tolerances of - +/-. 050 in. Growth Area - 1.9 cm<sup>2</sup>

**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>-6</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)

#### Surface Characterization:

Surface is characterized as a proprietary inorganic coating. This surface composition has been optimized for Osteoclast pit formation.

## **Surface Function:**

This product has been tested for the attribute of Osteoclast pit formation.

## Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Surface Uniformity: Optical density of surface coating

Visual Attributes: Visual and microscopic examination of the product.

Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct

product configuration.

# 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: 3