Corning Inco Life Scier ISO 9001:2	Product Description
Catalog Number:	3988
Product Description:	Corning ${ m I\!R}$ 96-well Osteo Assay plate, flat bottom, with Low Evaporation lid
Component Materials: Plate/Lid - Surface -	Virgin Polystyrene, meets <i>USP, Class VI</i> requirements for plastic containers and closures Inorganic Coating
Product Dimensions: Length of Plate Width of Plate Depth of Well Tolerances of Dimensions	<ul> <li>5.030 in.</li> <li>3.365 in.</li> <li>.420 in.</li> <li>+/ 010 in.</li> </ul> Diameter of Well @ top270 in. Diameter of Well @250 in. bottom <ul> <li>420 in.</li> <li>420 in.</li></ul>

## 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:  $\leq 0.1 \text{ EU/mL}$  ( $\leq 4 \text{EU/device}$ )

## Surface Characterization:

Surface is characterized as a propritary 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 measurement of surface coatingVisual 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: 2