# Corning Incorporated Life Sciences

Registered ISO 9001:2008

# **Product Description**

Catalog Number: 3656

Product Description: Costar ® 384-well plate, polypropylene, sterile

**Component Materials:** 

Plate - Virgin Polypropylene, meets *USP, Class VI* requirements for plastic containers and

closures.

**Product Dimensions:** 

Plate Height - .560 in. Height of well - .455 in.
Plate length @ bottom - 5.030 in. Opening @ top of well - .143 in.sq.
Plate width @ bottom - 3.365 in. Distance from well center - .177 in.

to center

Tolerance of length & - +/- .010 in. Tolerances of other - +/- .010 in.

width 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>

#### **Surface Characterization:**

Surface is characterized to be hydrophobic and non-charged.

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)

### RNase/DNase Testing:

This product has been tested and is free of any detectable RNase/DNase contamination.

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.

## 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.

#### 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.

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