

Corning Incorporated – Life Sciences

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www.corning.com/lifesciences

Refer to website for regional contact information

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Date: June 5, 2014

Corning Incorporated - Life Sciences certifies that Falcon® products meet the following criteria:

Falcon Catalog #:	Lot #:	Manufacturing Date:	Expiration Date:
353935	2174533	2012/06/25	Not Established

Quality System Compliance - Falcon® products are manufactured under the ISO 9001 Standard and the current FDA Quality System Regulation in Chapter 1, Title 21, Section 820 of the Code of USA Federal Regulations.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and signed off by qualified personnel for product release.

Cytotoxicity - Testing is conducted to qualify all material resins using USP and/or ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

Tissue Culture Treated - Products labeled tissue culture treated have representative samples subjected to an actual performance test for growth with MRC-5 (human fetal lung fibroblast cells). Cells are plated to be confluent within 72 hours. A minimum of 90% confluency is required for lot acceptance.


Non-Pyrogenic - Products labeled non-pyrogenic have been validated per FDA guidelines on LAL (Limulus Amebocyte Lysate) testing for medical devices and Company guidelines. The acceptance level for product is less than 0.1 EU/ml or 5 EU/device.

Sterilization - Product labeled as sterile is irradiated and dosimetrically released upon US Association for the Advancement of Medical Instrumentation (AAMI) recommended practices in effect at the time of validation. Sterilization records are reviewed and signed off by qualified personnel for product release. Falcon products labeled sterile meet a minimum requirement of 10^{-3} SAL (Sterility Assurance Level).

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

This product met Corning Incorporated - Life Sciences stringent quality standards at the time of batch/lot release. Any test results reported on this certificate were obtained at the time of release.

VERIFICATION:



Tara Rogers
Quality Manager