

BD Biosciences
Discovery Labware
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BD Biosciences Europe
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B9320 Erembodegem, Belgium



CERTIFICATE OF COMPLIANCE

Date: October 28, 2011

BD Biosciences - Discovery Labware certifies that BD Falcon™ products meet the following criteria:

BD Falcon Catalog #:

Lot #:

351058

1194749

Quality System Compliance – BD Falcon products are manufactured under the ISO 9001: 2000 Standard, and the current FDA Quality System Regulation in Chapter 1, Title 21, Section 820 of the Code of USA Federal Regulations.

Sterilization - Products are gamma irradiated. BD Biosciences – Discovery Labware products labeled sterile meet a minimum requirement of 10^{-3} SAL (Sterility Assurance Level). Contents of unopened or undamaged package guaranteed sterile.

Products Labeled 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.

Products Labeled Non-Pyrogenic – Products labeled non-pyrogenic have been validated per USP XXVI <85> Bacterial Endotoxins (LAL) testing for medical devices. The acceptance level for product is less than or equal to 0.5 EU/ml or 20 EU/device.

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.

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.

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

This product met BD Biosciences - Discovery Labware 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:

A handwritten signature in black ink, appearing to read 'Matthew Buzard', written over a light gray horizontal line.

Matthew Buzard
Director of Quality Systems & Validations