

**BD Biosciences**  
**Discovery Labware**  
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## CERTIFICATE OF COMPLIANCE

Date: March 28, 2008

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

**BD Falcon Catalog #:**

**Lot #:**

**357575**

**7572**

**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.

**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 or equal to 0.5 EU/ml or 20 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. All BD Biosciences - Discovery Labware products labeled sterile meet a minimum requirement of  $10^{-3}$  SAL (Sterility Assurance Level).

**Products Labeled for In Vitro Fertilization – (353652, 353653, 353654)**

- Have been tested for embryotoxicity using the mouse 1-cell embryotoxicity assay. At least 75% of both test and control embryos must reach the hatched and/or expanded blastocyst stage in order for test product to be deemed non-embryotoxic. Non-embryotoxicity records are reviewed and signed off by qualified personnel for product release.
- 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. These products meet a  $10^{-6}$  SAL (Sterility Assurance Level).

VERIFICATION:

Heather Donovan  
Quality Systems & Compliance Manager