



Certificate of Compliance

BD Biosciences - Discovery Labware
One Becton Circle
Durham NC 27712 US

Page: 1 of 1

Product Name : Tube 5mL 12x75mm R-btm PS 125pac 1000cas
Catalog Number : 352054 **Manufacture Date** : 2013/01/11
Batch Number : 3010841
Expiration Date : 2018/01/31

Quality System Compliance - BD FalconTM products are manufactured under the ISO 9001:2008 Standard, and the current FDA Quality System Regulation in Chapter 1, Title 21, Section 820 of the Code of USA Federal Regulations.

Sterilization - Product labeled as sterile is irradiated and dosimetrically released upon U.S. 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. BD Biosciences - Discovery Labware products labeled sterile meet a minimum requirement of 10^{-3} SAL (Sterility Assurance Level).

Products Labeled 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.

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.

Tara Rogers
Quality Manager