



Certificate of Quality

Becton, Dickinson and Company
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes NJ 07417-1815 US

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Product Name : SHARPS COLL 2GAL PEARL
Catalog Number : 305422
Batch Number : 6048905

US FDA Quality System Regulation (GMP) Compliance - BD Products are manufactured in accordance with the current FDA Quality System Regulation 21 CFR 820.

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.

Toxicity - All materials which are labeled not-toxic and released for sale by BD have passed animal toxicity and/or cytotoxicity in accordance with ISO 10993 Biocompatibility Testing Guidelines for Medical Devices.

Products Labeled Non-Pyrogenic - All products which are labeled as non-pyrogenic and released for sale by BD meet BD pyrogen testing requirements.

Sterilization - All products which are labeled as sterile and released for sale by BD are certified to be sterile as long as the package is unopened and undamaged. For those products labeled "sterile fluid path", only the fluid path is sterile. Sterilization cycle development/validation is performed in accordance with current ANSI/AAMI/ISO guidelines.

Device Listing/Manufacturing Site Registration/Pre-Market Notification: Medical devices are listed with FDA per 21 CFR 807. Manufacturing sites are registered with FDA per 21 CFR 807. The devices satisfy FDA pre-market notification requirements per 21 CFR 807.

VERIFICATION:

WW VP, Quality Management
BD Medical - Medication Delivery Solutions