

CERTIFICATE OF QUALITY



Date: February 11, 2013

BD Reorder Number: 309604

Lot Number: 2018004

US FDA Quality System Regulation (GMP) Compliance – BD Products are manufactured in accordance with the current FDA Quality System Regulation 21CFR820.

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 21CFR807. Manufacturing sites are registered with FDA per 21CFR807. The devices satisfy FDA pre-market notification requirements per 21CFR 807.

VERIFICATION:

A handwritten signature in cursive script, reading "Jeffrey M. Silvestri".

Jeff Silvestri
WW VP, Quality Management
BD Medical - Medical Surgical Systems