BD Medical
PO Box 749
Canaan CT 06018 US

CERTIFICATE OF COMPLIANCE

Product Name : SYRINGE 1ML LL
Catalog Number : 309628 **Manufacture Date :** 2013/04/14
Batch Number : 3022272
Expiration Date : 2018/01/31

REGULATORY COMPLIANCE AND QUALITY SYSTEM

BD Products comply with the regulatory requirements of the region in which these are sold and manufactured.

BD Products sold in the US comply with the current FDA Quality System Regulation 21CFR820. 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.

BD Products which are CE marked comply with Medical Devices Directive 93/42/EEC and are manufactured within production facilities that comply with the international standard ISO 13485: Quality Systems - Medical Devices - Requirements For regulatory purposes.

STERILITY

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.

This product is primarily sterilized via Gamma. Sterilization cycle development/validation is performed to 10-6 SAL in accordance with current ISO 11137 guidelines.

BIOCOMPATABILITY

This product has been evaluated in accordance with ISO 10993 "Biological Evaluation of Medical Devices", and complies with all relevant sections.

PYROGENICITY

All products which are labeled as non-pyrogenic and released for sale by BD have been tested per United States Pharmacopeia (USP) chapter 85 - Bacterial Endotoxins Test and meets limits as specified in chapter 161- Transfusion and Infusion Assemblies and Similar Medical Devices.

QUALITY CONTROL TESTING AND RELEASE

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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 released devices meet applicable BD product specifications.

PRODUCT SPECIFIC SPECIFICATIONS / STANDARDS

This product complies with the following BD Specification: SP100001

BD MANUFACTURING SITE

BD Manufacturing site: BD Medical, Route 7 and Grace Way, Canaan, CT 06018, USA

Primary Sterilization site: STERIS Isomedix Services
435 Whitney Street
Northborough, MA 01532

Legal Manufacturer: Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, USA

EU Authorized Representative: Becton Dickinson Distribution Center, Laagstraat 57 B-9140 Temse- Belgium

CE Certificate Number: 252.231

Mary Rivers

Mary Rivers
Quality Manager, BD Canaan