



BD Medical Systems  
Medical Surgical  
2153 12th Avenue  
Columbus, NE, USA 68602

# CERTIFICATE OF COMPLIANCE

Page: 1 of 2

**Product Name** : Syringe 60ml LL Tip 1ml 2 oz in 1/4 oz  
**Catalog Number** : 309653 **Manufacture Date** : 2013/08/01  
**Batch Number** : 3198203  
**Expiration Date** : 2018/07/31

## **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. For those products labeled "sterile fluid path", only the fluid path is sterile.

This product is primarily sterilized via Gamma radiation. Sterilization cycle development/validation is performed to 10<sup>-6</sup> 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**

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.

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## PRODUCT SPECIFIC SPECIFICATIONS

This product complies with the following BD Specifications:  
SP100001 - Syringe, Single Use

## BD MANUFACTURING SITE

**BD Manufacturing Site:** BD Medical - Medical Surgical Systems  
2153 12th Avenue  
Columbus, NE 68602  
USA

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

**Primary Sterilization site:** BD Medical - Medical Surgical Systems  
2153 12th Avenue  
Columbus, NE 68602  
USA

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

**CE Certificate Number:** 252.231

Allen Lang,  
Quality Manager