CERTIFICATE OF COMPLIANCE

BD Medical
Medical Surgical Systems
1852 10th Avenue
Columbus NE 68601-3617 US

Product Name : Syringe 60ml LL Tip 1ml
Catalog Number : 309653 **Manufacture Date** :2018/04/01
Batch Number : 8086607
Expiration Date : 2023/03/31

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^{-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

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 68601
USA

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

CE Certificate Number: 252.231



Jason Appel
Quality Manager

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