



CERTIFICATE OF COMPLIANCE

Becton, Dickinson and Company
BD Medical Surgical Systems
Periferico Luis Donald Colosio # 579
Nogales SON 84048 MX

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Product Name : SYRINGE 30ML LL TIP CONV PAK
Catalog Number : 305618 **Manufacture Date** : 2019/10/02
Batch Number : 9297121
Expiration Date : 2024/09/30

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 21 CFR 820. Medical devices are listed with FDA per 21C FR 807. Manufacturing sites are registered withFDA per 21 CFR 807. The devices satisfy FDA pre-market notification requirements per 21 CFR 807.

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- Medical Devices-Bacterial Endotoxin and Pyrogen Tests.

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 specification(s).

PRODUCT SPECIFIC SPECIFICATIONS / STANDARDS

This product complies with the following BD Specification(s):



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SP100056 SYRINGE CONVENIENCE PAK PRODUCT SPECIFICATION

BD MANUFACTURING SITE

BD Manufacturing site:
Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V.
Periferico Luis Donaldo Colosio 579, Colonia Obrera 84048
Nogales Sonora Mexico

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

Legal Manufacturer:
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, New Jersey 07417

EU Authorized Representative: N/A

CE Certificate Number: N/A

Manuel Plazola
Quality Manager, Nogales