CERTIFICATE OF COMPLIANCE

Becton, Dickinson and Company
BD Medical Surgical Systems
Route 7 and Grace Way
Canaan CT 06018-2415 US

Product Name : SYRINGE 5ML LL SP125
Catalog Number : 309646 **Manufacture Date** :2017/01/17
Batch Number : 7001999
Expiration Date : 2021/12/31

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 E-beam. 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.
PRODUCT SPECIFIC SPECIFICATIONS
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: BD Medical, Route 7 and Grace Way, Canaan, CT 06018, USA
Legal Manufacturer: Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, USA
File name Z1003_CLST_IS_CN6 Revision Date 09/11/2015

Creation Date: 2017/01/17 19:14:11

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Paul Strzepa
Quality Manager, BD Canaan

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