



CERTIFICATE OF COMPLIANCE

BD
BD Drogheda
Donore Road
Drogheda LT IE

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Product Name : SYRINGE 10ML REG PR SALINE 10ML FILL
Catalog Number : 306546 **Manufacture Date** : 2019/11/01
Batch Number : 9325541
Expiration Date : 2022/10/31

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 21 CFR 820. Medical devices are listed with FDA per 21 CFR 807. Manufacturing sites are registered with FDA 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.

This product is sterilized via moist heat. Sterilization cycle development/validation is performed to 10⁻⁶ SAL in accordance with current ISO 17665 guidelines.

BIOCOMPATIBILITY

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 Test.

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

This product complies with the following BD Specification(s): SP100126

Creation Date: 2019/12/19 09:53:57



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PRODUCT ANALYSIS RESULTS

The following tests have been performed on representative production samples and passed the listed specification.

Test Performed (Reference) (Specification):

- Endotoxin Test (USP 85) (≤ 0.5 EU/mL-finished product)
- Particulate Test (USP 788) (≤ 6000 particles of ≥ 10 microns)(≤ 600 particles of ≥ 25 microns)
- Assay of Sodium Chloride Test (Sodium Chloride Monograph USP) (0.855-0.945% NaCl)
- Appearance and Solution Clarity Test (Sodium Chloride Monograph EP 2.2.1 and 2.2.2) (Clear and Colorless)
- Heavy Metals Test (USP 232/233)(Pass)
- Iron Test (USP 241) (< 2 ppm)
- UV/vis Test (USP 851) (< 0.40 AU at 220-360nm)
- pH Test (USP 791) (4.5-7.0)

BD MANUFACTURING SITE

BD Manufacturing Site:

BD Medical - Medical Surgical Systems
Donore Road
Drogheda
Co. Louth
Ireland

Primary Sterilization Site:

BD Medical - Medical Surgical Systems
Donore Road
Drogheda
Co. Louth
Ireland

Legal Manufacturer:

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



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A handwritten signature in black ink, appearing to read 'Diarmuid Callaghan', is written over a large, empty rectangular box.

Diarmuid Callaghan
Quality Manager, BD Drogheda