Certificate of Compliance

Becton Dickinson de Mexico, SA de CV
BD Mexico
Km. 37.5 Autopista México-Querétaro
Cuautitlán, Izcalli MEX 54730 MX

Nombre del Producto : JERINGA HIP 3ML S/A USA C/200
Número de Cátalogo : 309657 **Fecha de producción**: 2018/08/05
Número de Lote : 8186648
Fecha de caducidad : 2023/07/31

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 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 primarily sterilized via Ethylene Oxide Method. Sterilization cycle development/validation is performed to 10-6 SAL in accordance with current ISO 11135-1 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 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 specifications.

PRODUCT SPECIFICATIONS

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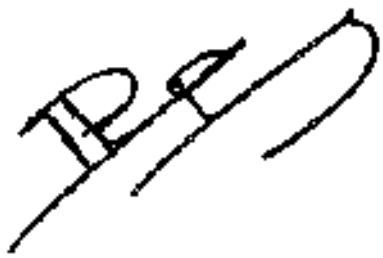
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This product complies with the following BD Specification: EP-IS-01-01 current version.

BD SITE

- BD Manufacturing site: Becton Dickinson de México, S.A. de C.V., Highway Mexico-Queretaro Km.37.5, Industrial Complex Cuamatla, C.P. 54730, Cuautitlan Izcalli, Mexico State.
- Primary Sterilization sites:
  1. Sterigenics S. de R.L. de C.V., James Watt No. 22. Parque Industrial Cuamatla Cuautitlan Izcalli Estado de Mexico CP 54730.
  2. Procesos Para Esterilización S.A de C.V. Paseo de Constitución S/N San Isidro Mexico 54730.
- Legal Manufacturer: Becton Dickinson de México, S.A. de C.V., Highway Mexico-Queretaro Km. 37.5, Industrial Complex Cuamatla, C.P. 54730, Cuautitlan Izcalli, Mexico State.

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QFB. JOSE JUAN PACHECO JIMENEZ
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