Certificate of Conformance

BD Medical
Diabetes Care
1329 West Highway #6
Holdrege NE 68949-3126 US

Product Name : SYRINGE 0.5ML 29G 12.7MM 10BAG 500 EU
Catalog Number : 324824 **Manufacture Date** :2023/07/02
Batch Number : 3156425
Expiration Date : 2028/06/30

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 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.

All components are manufactured and have passed testing (including heavy metals and pH) as defined and required by ISO 8537:2007.

STERILITY

All products labeled "Sterile" and released for sale by Becton Dickinson and Company are certified to be sterile per EN 556-1 Sterilization of Medical Devices provided the packages or seals are not opened or damaged. The sterilization cycle is validated and controlled per AAMI TIR 13004 and/or ISO 11137 (Cobalt 60 - Irradiation).

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.

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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): SP700117

BD MANUFACTURING SITE

BD Manufacturing site: BD Medical Diabetes Care - 1329 West Hwy 6, Holdrege, NE 68949-0860 USA

Primary Sterilization site: BD Medical Diabetes Care 1329 West Hwy 6, Holdrege, NE 68949-0860 USA

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

EU Authorized Representative: BD Medical - Diabetes Care
Becton Dickinson France S.A.S.11 rue Aristide Bergès - BP4 38801 Le Pont de Claix Cedex France

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Shelley Hendricksen

Quality Representative: Shelley Hendricksen