CERTIFICATE OF COMPLIANCE

Becton Dickinson Caribe LTD.
BD Medical Surgical Systems
Road 31, KM 24.3
Juncos PR 00777-4010 PR

Product Name : TUBE MICRO W/MICROGARD LIHEP GN
Catalog Number : 365965 **Manufacture Date** :2019/10/05
Batch Number : 927410N
Expiration Date : 2021/03/31

REGULATORY COMPLIANCE AND QUALITY SYSTEM

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.

STERILITY

This product is non-sterile.

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).

BD Manufacturing site:
BD Caribe LTD. Rd 31, Km 24.3
Juncos, Puerto Rico 00777
USA

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

Eduardo Vega
Quality Manager

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