



Certificate of Conformance

Becton, Dickinson and Company
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Product Name: BD Vacutainer® Safety-Lok™ Blood Collection Set
Catalog Number: 367296
Batch Number: 2G1781
Manufacture Date: 2022-07-19
Expiration Date: 2025-07-31

REGULATORY COMPLIANCE AND QUALITY SYSTEM

BD Products are manufactured and sterilized within production facilities that meet BD requirements which comply with the US Food and Drug Administration (FDA) Quality System Regulation 21CFR820 and with International Standard ISO 13485. This product passed BD's quality standards at the time of batch/lot release.

STERILITY

All products which are labeled as "sterile" and released for sale by BD are certified to be sterile. This product is sterilized via Ethylene Oxide process. Sterilization development / validation is performed to SAL 10^{-6} in accordance with current ISO 11135 guidelines.

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 passed BD product specification(s).

PRODUCT ATTRIBUTES & SPECIFICATIONS

Color Coding: Green
Gauge Size: 21G
Needle Material: Stainless Steel
Tubing Length: 12 inches
Hub Material: Polypropylene
Sterility: Sterile (SAL 10^{-6})
Sterilization Method: Ethylene Oxide

PACKAGING & LABELLING SPECIFICATIONS

Primary: Blister Packaging with lot # and expiration date
Secondary: Cardboard with 50 individually packaged blisters
Storage: Corrugated cardboard with 4 secondary containers

Legal Manufacturer

Becton Dickinson and Company Ltd
1 Becton Drive
Franklin Lakes, NJ 07417-1885 USA

A handwritten signature in black ink, appearing to read 'R. Kalita', with a stylized flourish at the end.

Richard Kalita
BD Life Sciences - Integrated Diagnostic Solutions (IDS)
Senior Manager, Quality Management
Signature Date: 2022-07-29