CERTIFICATE OF COMPLIANCE

BD Vacutainer Systems,
Preanalytical Solutions
240 Jefferson Rd
Sumter SC 29153-8786 US

Product Name : NEEDLE ECLIPSE 21X1.25
Catalog Number : 368607 **Manufacture Date** :2016/08/01
Batch Number : 6197704
Expiration Date : 2021/07/31

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 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.

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. For those products labeled #sterile fluid path#, only the fluid path is sterile.
This product is primarily sterilized via Gamma irradiation process. Sterilization cycle development/validation is performed to 10-6 SAL in accordance with current ISO11137 guidelines.

PYROGENICITY

All products which are labeled as non-pyrogenic and released for sale by BD are certified to be non-pyrogenic.

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 SPECIFIC SPECIFICATIONS

This product complies with the following BD Specifications:
VS59831

PRODUCT ATTRIBUTE RESULTS

Physical, chemical, functional characteristics:
Cannula: 304 Stainless Steel
Hub/Collar: Polystyrene
IV shield/Pivot shield: Polypropylene
NP Shield: Polyethylene
Sleeve: Synthetic rubber

Packaging:
Shelf Carton: 48 individual Eclipse Needles in a shelf pack.
Case Carton: Corrugated cardboard with 10 shelf carton

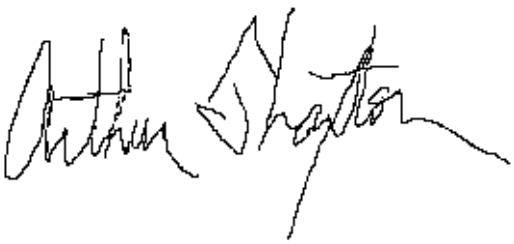
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BD MANUFACTURING SITE

BD Manufacturing Sites:
Becton Dickinson and Company
1575 Airport Road
Sumter, SC 29151
USA
Legal Manufacturer:
Becton Dickinson and Company.
1 Becton Drive
Franklin Lakes, NJ 07417
USA
Sterilization site:
Becton Dickinson and Company
1575 Airport Road
Sumter, SC 29151
USA



Arthur Thaxton
QA/RA Manager

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