



# CERTIFICATE OF COMPLIANCE

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

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**Product Name** : NEEDLE ECLIPSE 21X1.25  
**Catalog Number** : 368607 **Manufacture Date** : 2016/01/02  
**Batch Number** : 5351808  
**Expiration Date** : 2020/12/31

## 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<sup>-6</sup> 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