



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

# CERTIFICATE OF COMPLIANCE

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**Product Name** : NEEDLE ECLIPSE 21X1.25  
**Catalog Number** : 368607  
**Batch Number** : 1353090  
**Expiration Date** : 2016/12/31

This product conforms to product specification VS59831

### **GMP/MANUFACTURING**

BD medical devices are manufactured in accordance with the medical device GMP's (21CFR820). The devices are manufactured in facilities registered with the FDA and the devices are also listed with the FDA.

### **STERILITY**

BD products which are labelled as sterile have been processed and released in accordance with Company requirements. The sterilization standards used by BD (irradiation-Cobalt or EO) are based upon acceptable industry guidelines published by the Association for the Advancement of Medical Instrumentation (AAMI). Products will maintain sterility under reasonable conditions of storage and handling, provided the integrity of the packaging is maintained. For those products labelled "sterile fluid path," only the fluid path is sterile.

### **PYROGENICITY & TOXICITY**

All products which are labelled as non-pyrogenic and/or non-toxic and released for sale by BD are certified to be non-pyrogenic and have passed animal toxicity and/or cytotoxicity tests. For those products labelled "fluid path components are non-pyrogenic (or non-toxic)," only fluid path components are non-toxic or non-pyrogenic.

This certificate is produced and controlled electronically and is valid without a handwritten signature.

John Zagorski,  
QA/RA Manager