CERTIFICATE OF COMPLIANCE

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

Product Name : NEEDLE ECLIPSE 21X1.25
Catalog Number : 368607
Batch Number : 5064990
Expiration Date : 2020/02/29

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.

Creation Date: 2015/03/18 19:14:08

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This product conforms to product specification VS59831



Howie Cullum,
QA/RA Manager

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