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**: 2018/04/01
Batch Number : 8088898
Expiration Date : 2023/03/31

REGULATORY COMPLIANCE AND QUALITY SYSTEM

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.

STERILITY

All products which are labeled as "sterile" and released for sale by BD are certified to be sterile. For those products labeled "sterile fluid path", only the fluid path is sterile.

This product is sterilized via Gamma irradiation process.
Sterilization cycle development/validation is performed to 10-6 SAL in accordance with current ISO11137 guidelines.

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 non-toxic. For those products labelled "fluid path components are non-pyrogenic (or non-toxic)", only fluid path components are non-toxic or 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 specification(s).

BD Manufacturing site:
Becton Dickinson and Company
1575 Airport Road
Sumter, SC 29151, USA

Creation Date: 2018/04/12 11:19:11

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Primary Sterilization Site:
Steris-Isomedix, 2072
Southport Rd.
Spartanburg, SC 29306, USA
Legal Manufacturer:
Becton Dickinson and Company.
1 Becton Drive
Franklin Lakes, NJ 07417, USA

Sandra D Vining
Quality Manager

Creation Date: 2018/04/12 11:19:11