CERTIFICATE OF COMPLIANCE

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

Product Name : NEEDLE ECLIPSE 22X1.25 CE
Catalog Number : 368610 **Manufacture Date**: 2024/04/01
Batch Number : 4095814
Expiration Date : 2029/03/31

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 are manufactured in ISO 13485: certified facilities. In addition, BD facilities are registered with the United States Food and Drug Administration (FDA) and are regulated by the FDA's Quality System Regulations (QSRs). This product met BD's stringent quality standards at the time of batch/lot release.

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 29153, USA

Primary Sterilization Site:
Steris-Isomedix, 2072
Southport Rd.

Creation Date: 2024/04/24 15:30:07

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Spartanburg, SC 29306, USA

Legal Manufacturer:
Becton Dickinson and Company.
1 Becton Drive
Franklin Lakes, NJ 07417, USA



Jason Appel
Quality Manager