



Certificate of Conformance

Becton Dickinson UK Limited
Plymouth location
Belliver Industrial Estate
Plymouth DV PL6 7BP GB

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Product Name : NEEDLE CNV 21X1 MLTSMP CE
Catalog Number : 360212 **Manufacture Date** : 2019/06/02
Batch Number : 9149878
Expiration Date : 2024/05/31

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,
Belliver Industrial Estate, Belliver Way, Roborough,
Plymouth, PL6 7BP, United Kingdom

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Primary Sterilization site:
Becton, Dickinson and Company,
Belliver Industrial Estate, Belliver Way, Roborough,
Plymouth, PL6 7BP, United Kingdom

Legal Manufacturer:
Becton, Dickinson and Company,
Belliver Industrial Estate, Belliver Way, Roborough,
Plymouth, PL6 7BP, United Kingdom

Lisa Davey
Associate Director, Quality Management