Certificate of Conformance

Becton, Dickinson and Company,
Belliver Industrial Estate, Belliver Way,
Roborough,
Plymouth DV PL6 7BP GB

Product Name : TUBE EDTA PLH 13X75 4.0 PLBLCE LAV
Catalog Number : 368861 **Manufacture Date** :2024/05/01
Batch Number : 4122823
Expiration Date : 2025/08/31

REGULATORY COMPLIANCE AND QUALITY SYSTEM

BD Products are manufactured within production facilities that comply with the current FDA Quality System Regulation 21CFR820 and with the International Standard ISO 13485.

BD products are manufactured in ISO 13485 Registered 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 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 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.

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).

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

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



Glenn Pengelly
Associate Director, Quality Management