Certificate of Conformance

BD Diagnostics
Preanalytical Systems
150 South 1st Avenue
Broken Bow NE 68822-2203 US

Product Name : KIT URIN CUP 16X100 8.0 CONI UA YEL
Catalog Number : 364989 **Manufacture Date** :2017/05/09
Batch Number : 7117984
Expiration Date : 2018/10/31

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 21CFR807.

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 10-3 SAL in accordance with current ISO 11137 guidelines.

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).

PRIMARY STERILIZIATON SITE:
BD Life Sciences Preanalytical Systems
150 South 1st Avenue
Broken Bow, NE 68822-2203
USA

LEGAL MANUFACTURER:
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885
USA

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Jennifer Jackson
Quality Assurance Manager

Creation Date: 2017/05/15 17:07:15