



# Certificate of Conformance

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

Page: 1 of 2

**Product Name** : CUP URIN COLLECTION BULK  
**Catalog Number** : 364975 **Manufacture Date:** 2018/01/31  
**Batch Number** : 8004805  
**Expiration Date** : 2020/01/31

## 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<sup>-3</sup> 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 STERILIZATION 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