

BD Diagnostics
Preanalytical Systems
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Broken Bow, Nebraska 68822
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February 13, 2014

Product Name: CUP URIN COLLECTION BULK
Part Number: 364975
Batch Number: 3302384
Date of Manufacture: 12/2013
Expiration: 11/2015

CERTIFICATE OF COMPLIANCE

STERILITY

All products which are labeled as sterile and released for sale by BD are certified to be sterile as long as the package is unopened and undamaged. For those products labeled "Sterile fluid path", only the fluid path is sterile.

PYROGENICITY

All products which are labeled as non-pyrogenic and released for sale by BD meet BD's pyrogen testing requirements. For those products labeled "Fluid path components are non-pyrogenic" only fluid path components are non-pyrogenic.

TOXICITY

All materials which are labeled non-toxic and released for sale by BD have passed animal toxicity and/or cytotoxicity tests. For those products labeled "Fluid path components are non-toxic", only fluid path components are non-toxic.

GMP/MANUFACTURING

BD medical devices are manufactured in accordance with the medical device GMP's (21 CFR 820). The devices are manufactured in facilities registered with the FDA; the devices are also listed with the FDA. The released devices satisfy BD finished product specifications for product performance.



Michelle Miller
Plant Quality Manager