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

Certificate of Conformance

Product Name : KIT URIN TRANSTR 16X100 8.0 CONI UA YEL
Catalog Number : 364991
Batch Number : 1306885
Expiration Date : 2013/05/31

CERTIFICATE OF STERILITY

STERILITY CLAIM:

All products which are labeled as either "Sterile" or "Sterile Interior" and released for sale by BD Diagnostics Preanalytical Systems are certified to be sterile as long as the product package or product is unopened and undamaged. For those products labeled "Sterile Interior" only the product interior is sterile.

MANUFACTURING CLAIM:

BD Diagnostics Preanalytical Systems products are manufactured in accordance with the medical device regulations (21CFR820) and comply with Medical Device Reporting (MDR) Regulations (21CFR803). All products and manufacturing facilities comply with FDA registration and listing requirements (21CFR807). The released products satisfy BD Diagnostics Preanalytical Systems finished product specifications. The Broken Bow facility is also ISO 13485:2003 certified.

Broken Bow Quality Assurance
Release date: 2011/12/15
Name: ERLINDA LARSEN

This certificate is produced and controlled electronically and is valid without handwritten signature.

Michelle D. Miller

"Michelle L. Miller,
Plant Quality Assurance Manager."