

## **Certificate of Conformance**

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

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| Product Name   | : | HOLDER  | ONE | USE | NONSTACKABLE |
|----------------|---|---------|-----|-----|--------------|
| Catalog Number | : | 364815  |     |     |              |
| Batch Number   | : | 3008172 | 2   |     |              |

## 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: 2013/02/25 Name: Terri Gaedke

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

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