



# Certificate of Conformance

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

Page: 1 of 1

**Product Name** : HOLDER ONE USE NONSTACKABLE  
**Catalog Number** : 364815  
**Batch Number** : 4224866

#### 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:2014/09/22  
Name:Terri Gaedke

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

*Michelle L. Miller*

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