Certificate of Conformance

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

Product Name : HOLDER ONE USE NONSTACKABLE
Catalog Number : 364815
Batch Number : 7061956

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 21CFR 807.

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

This product is non-sterile.

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
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