

# Certificate of Analysis

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Becton Dickinson Infusion Therapy System 9450 South State Street Sandy UT 84070-3213 US

Product Name : E-Z SCRUB POVI IODINE

Catalog Number : 372053 Manufacture Date :2017/03/31

Batch Number : 7146996 Expiration Date : 2019/03/31

Color Test = Pass

Color Test Specification = Dark reddish brown

Microbial Limits Test = Pass

Microbial Limits Test Specification = No Staphylococcus aureus, Candida albicans or gram-negative rods. Other microorganism limits of not more than 25 CFU/mL (colony forming units per mL)

Characteristic	Unit	Value	Lower Limit	Upper Limit
Percent Iodine not less than 1.1% PH 3.9 - 6.5	%C	1.3 4.9	1.1	6.5

## REGULATORY COMPLIANCE AND QUALITY SYSTEM

BD Products comply with the regulatory requirements of the region in which these are sold and manufactured.

BD Products were produced under the U.S. Food and Drug Administration (FDA) current Good Manufacturing Practice (cGMP) including 21 CFR 210 and 211.

### **OUALITY 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 in the Quality Control Unit for product release. The released product meets applicable BD specification(s).

# PRODUCT SPECIFIC SPECIFICATIONS

This product complies with the following BD Specification(s): PPS-064

### BD MANUFACTURING SITE

BD Manufacturing site:

BD Becton Dickinson Infusion Therapy Systems Inc.

9450 South State Street, Sandy, UT 84070, USA

Legal Manufacturer:

BD Becton Dickinson Infusion Therapy Systems Inc.

9450 South State Street, Sandy, UT 84070, USA

Creation Date: 2017/06/23 13:55:56



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Stephanie Linke

Manager Quality Assurance

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