APOSTILLE

(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961)

- 1. COUNTRY: UNITED STATES OF AMERICA
- 2. THIS PUBLIC DOCUMENT HAS BEEN SIGNED BY: RESHMA SHAIK
- 3. ACTING IN THE CAPACITY OF:
 NOTARY PUBLIC OF NEW JERSEY
- 4. BEARS THE SEAL/STAMP OF: RESHMA SHAIK, NOTARY

CERTIFIED

- 5. AT TRENTON, NEW JERSEY
- 6. THE 1ST DAY OF NOVEMBER 2024
- 7. BY: Elizabeth Maher Muoio State Treasurer
- 8. NO: 100068916
- 9. SEAL/STAMP:

10. SIGNATURE



Elizabeth Maher Muoio State Treasurer

Shipper Meren

Certificate Number: 8507331648

Verify this certificate at https://www.njportal.com/DOR/businessrecords/Validate.aspx



Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070 USA bd.com

Cover Letter

Becton Dickinson Infusion Therapy Systems Inc., located at 9450 South State Street, Sandy, Utah 84070 USA, as Legal Manufacturer, hereby declare that the attached Quality Management System- ISO 13485:2016 with certificate number **MD 748928** is true and accurate copy.

Sincerely,

Victoria Morrow

Sr. Manager, International Regulatory Affairs Becton Dickinson Infusion Therapy Systems, Inc. 10/38/34

Date

SHMA S ARY PU SO2250 SO2250 SO2250

Reshma Shaik NOTARY PUBLIC State of New Jersey ID # 50225979 My Commission Expires September 20, 2029

10/28/2024





Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street

Sandy Utah

84070 USA

Holds Certificate Number:

MD 748928

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of vascular introducers, peripheral intravascular catheters and cannulas, venous blood collection devices, connectors and extension sets, insertion procedure trays, and catheter injection ports for the area of vascular access and surgical scrub brushes for the area of preoperative cleaning of healthcare personnel arms and hands. On- site ethylene oxide sterilization for medical devices (ISO 11135).

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-07-23 Latest Revision Date: 2024-10-24

Expiry Date: 2027-10-28

Effective Date: 2024-10-29

Page: 1 of 1

bsi.



...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online.

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.