

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Becton, Dickinson and Company (BD)**  
7 Loveton Circle  
Sparks  
Maryland  
21152  
USA

Facility ID Number: F000076

Holds Certificate No: **MDSAP 688599**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

\_\_\_\_\_  
Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-11-14

Effective Date: 2024-10-11

Expiry Date: 2027-10-10



BSI Group America Inc. is an MDSAP recognised auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 688599**

## Registered Scope:

The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents prepared media products, dehydrated culture media, collection and transport, antimicrobial susceptibility tests, sample preparation, cytology devices, cytopathology auto-imaging devices with computerized microscopy, telepathology devices, lab automation, ancillary devices and instrument software for use in the screening and diagnosis of diseases, transmissible and sexually transmissible agents, and autoimmune status.



Original Registration Date: 2018-11-14      Effective Date: 2024-10-11

Expiry Date: 2027-10-10

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 688599**

Location	Registered Activities
Becton, Dickinson and Company (BD) 7 Loveton Circle Sparks Maryland 21152 USA Facility ID Number: F000076	The design, development, manufacture, service and distribution of in- vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in- vitro diagnostic test kits and reagents, collection and transport, antimicrobial susceptibility tests, sample preparation, devices with computerized microscopy, telepathology devices, ancillary devices and instrument software for use in the screening and diagnosis of diseases, transmissible and sexually transmissible agents, and autoimmune status.
Becton Dickinson and Company (BD) BD Diagnostic Systems 52/54 Loveton Circle Sparks Maryland 21152 USA Facility ID Number: F000076	The design, development, manufacture, service and distribution of in- vitro diagnostic medical devices and microbiological products. These devices and products include in vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, sample preparation.
Becton Dickinson and Company (BD) BD Diagnostic Systems 39 Loveton Circle Sparks Maryland 21152 USA Facility ID Number: F000076	The manufacture, and distribution of in- vitro diagnostic medical devices and microbiological products. These devices and products include in- vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, dehydrated culture media, sample preparation.
Becton Dickinson and Company (BD) BD Diagnostic Systems 250 Schilling Circle Cockeysville Maryland 21030 USA Facility ID Number: F000076	The manufacture and distribution of in- vitro diagnostic medical devices and microbiological products. These devices and products include in- vitro diagnostic test kits and reagents used in the diagnosis of diseases, and prepared media products.

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