

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Fisher Diagnostics  
A division of Fisher Scientific Company,  
LLC  
A part of Thermo Fisher Scientific, Inc.  
8365 Valley Pike  
Middletown  
Virginia  
22645-1905  
USA

Facility ID Number: F000186

Holds Certificate No:

**MDSAP 682960**

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

The design, development, manufacture, and distribution of invitro diagnostic medical device reagents, controls, and kits used in the diagnosis and management of blood analytes, blood components, coagulation, urine chemistry, prenatal screening, and therapeutic drug monitoring for professional laboratory use.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-12-14

Effective Date: 2024-10-04

Expiry Date: 2027-10-03



BSI Group America Inc. is an MDSAP recognised auditing organization

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Location

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Middletown  
Virginia  
22645-1905  
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Facility ID Number: F000186

Registered Activities

The design, development, manufacture, and distribution of invitro diagnostic medical device reagents, controls, and kits used in the diagnosis and management of blood analytes, blood components, coagulation, urine chemistry, prenatal screening, and therapeutic drug monitoring for professional laboratory use.

Fisher Diagnostics  
A division of Fisher Scientific Company  
LLC,  
A part of Thermo Fisher Scientific, Inc.  
201 Prospect Dr.  
Winchester  
Virginia  
22603  
USA  
Facility ID Number: F000186

Receiving, warehousing, and shipping.



Original Registration Date: 2018-12-14

Effective Date: 2024-10-04

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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](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://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.