



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

Holds Certificate Number: FM 620151

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

Design, Development, Manufacturing, and Distribution of In-Vitro Diagnostic Medical Devices used in the Diagnostics and Management of Blood Analytes, Blood Components, Coagulation, and Urine Chemistry Reagents for Professional Laboratory use and for Point of Care (POC) Testing.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2014-10-23 Effective Date: 2021-10-04 Latest Revision Date: 2022-07-19 Expiry Date: 2024-10-03

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...making excellence a habit."

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Certificate No:

FM 620151

Location

Registered Activities

Testing.

Fisher Diagnostics

A division of Fisher Scientific Company,

LLC

A part of Thermo Fisher Scientific, Inc.

8365 Valley Pike Middletown Virginia

22645-1905

USA

Fisher Diagnostics

A division of Fisher Scientific Company

210 Prospect Dr.

Winchester

Virginia

22603

USA

Receiving, warehousing, and shipping



Design, Development, Manufacturing, Distribution used in the Diagnostics and Management of Blood Analytes, Blood

Components, Coagulation, and Urine Chemistry Reagents for

Professional Laboratory use and for Point of Care (POC)

Original Registration Date: 2014-10-23 Latest Revision Date: 2022-07-19

Effective Date: 2021-10-04 Expiry Date: 2024-10-03

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