

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:

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: 2014-10-23

Latest Revision Date: 2024-10-02

Effective Date: 2024-10-04

Expiry Date: 2027-10-03

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BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Americas Headquarters: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA

Certificate No: FM 620151

Location	Registered Activities
Fisher Diagnostics A division of Fisher Scientific Company, LLC A part of Thermo Fisher Scientific, Inc. 8365 Valley Pike Middletown Virginia 22645-1905 USA	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	Receiving, warehousing, and shipping

Original Registration Date: 2014-10-23
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