

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
USA

Holds Certificate No:

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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-10-23

Latest Revision Date: 2018-12-14

Effective Date: 2018-12-14

Expiry Date: 2021-10-03



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