# 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

DUNS Number: 07-846-7603

Holds certificate No: **MDSAP 682960**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1- SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

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: 2018-12-14 Effective Date: 2018-12-14 Expiry date: 2021-10-03



BSI Group America Inc. is an MDSAP authorized auditing organization

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