By Royal Charter

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**

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; 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-12-14 Effective Date: 2022-02-02 Expiry Date: 2024-10-03

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™