By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LGC Clinical Diagnostics, Inc.
37 Birch Street
Milford
Massachusetts
01757
USA

Facility ID Number: F000389

Holds Certificate No: **MDSAP 689354**

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; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-02-07 Effective Date: 2021-10-03 Expiry Date: 2024-10-02

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

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 689354**

Registered Scope:

The design, development, manufacture and distribution of research and in vitro diagnostic reagents.

The design, development, manufacture and distribution of in vitro diagnostic reagents and kits, quality control products, and clinical services used in the diagnosis and management of blood analytes, blood components, cancer, disease status, donor screening, endocrine disorders, genetic testing, immune status, prenatal screening, protein metabolism, sexually transmissible agents and transmissible agents. The design development, manufacture and distribution of bulk serum and plasma, specialty biologics, and detection system products used in the research and diagnostic industries.

The distribution of human and animal powders and solutions used in the research and diagnostic industries.

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Certificate No: **MDSAP 689354**

Location	Registered Activities
LGC Clinical Diagnostics, Inc. 25 Birch Street Milford Massachusetts 01757 USA Facility ID Number: F000389	The design, development, manufacture and distribution of research and in vitro diagnostic reagents. The design, development, manufacture and distribution of in vitro diagnostic reagents and kits, quality control products, and clinical services used in the diagnosis and management of blood analytes, blood components, cancer, disease status, donor screening, endocrine disorders, genetic testing, immune status, prenatal screening, protein metabolism, sexually transmissible agents and transmissible agents. The design development, manufacture and distribution of bulk serum and plasma, specialty biologics, and detection system products used in the research and diagnostic industries. The repackaging, relabeling and distribution of human and animal powders and solutions used in the research and diagnostic industries.
LGC Clinical Diagnostics, Inc. 37 Birch Street Milford Massachusetts 01757 USA Facility ID Number: F000389	The design, development, manufacture and distribution of research and in vitro diagnostic reagents. The design, development, manufacture and distribution of in vitro diagnostic reagents and kits, quality control products, and clinical services used in the diagnosis and management of blood analytes, blood components, cancer, disease status, donor screening, endocrine disorders, genetic testing, immune status, prenatal screening, protein metabolism, sexually transmissible agents and transmissible agents. The design development, manufacture and distribution of bulk serum and plasma, specialty biologics, and detection system products used in the research and diagnostic industries. The repackaging, relabeling and distribution of human and animal powders and solutions used in the research and diagnostic industries.

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