

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Luminex Corporation
12212 Technology Blvd.
Austin
Texas
78727
USA

Facility ID Number: F007165

Holds Certificate No: **MDSAP 800618**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and development of microsphere-based and PCR-based systems used in the detection, diagnosis and/or management of nucleic acids related to hereditary diseases, drug metabolism and infectious diseases including software, hardware and reagents.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-12-19

Effective Date: 2026-03-10

Expiry Date: 2027-06-21



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 800618**

Location	Registered Activities
Luminex Corporation 12212 Technology Blvd. Building A Austin Texas 78727 USA Facility ID Number: F007165	Design and development of microsphere-based and PCR-based systems used in the detection, diagnosis and/or management of nucleic acids related to hereditary diseases, drug metabolism and infectious diseases including software, hardware and reagents.
Luminex Corporation 12212 Technology Blvd. Building B Austin Texas 78727 USA Facility ID Number: F007165	Design and development of microsphere-based and PCR-based systems used in the detection, diagnosis and/or management of nucleic acids related to hereditary diseases, drug metabolism and infectious diseases including software, hardware and reagents.
Luminex Corporation 12201 Technology Blvd. Building C Austin Texas 78727 USA Facility ID Number: F007165	Manufacture and distribution of microsphere-based and PCR-based systems used in the detection, diagnosis and/or management of nucleic acids related to hereditary diseases, drug metabolism and infectious diseases including software, hardware and reagents. Contract manufacturer of custom primer mixes for in vitro diagnostic use.
Luminex Corporation 12100 Technology Blvd. Building D Austin Texas 78727 USA Facility ID Number: F007165	Clinical Affairs and Distribution and of microsphere-based and PCR-based systems used in the detection, diagnosis and/or management of nucleic acids related to hereditary diseases, drug metabolism and infectious diseases including software, hardware and reagents.
Luminex Corporation 12306 Technology Blvd. Building G Austin Texas 78727 USA Facility ID Number: F007165	Activities related to Manufacture, QC, Incoming Inspection, Service, Installation, Warehouse, Distribution and Administration.

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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](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.
A Member of the BSI Group of Companies.