

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Luminex Corporation
12212 Technology Blvd.
Building A
Austin
Texas
78727
USA

Holds Certificate Number:

MD 800613

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture, distribution, installation and service 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-01-24

Latest Revision Date: 2026-01-05

Effective Date: 2024-06-22

Expiry Date: 2027-06-21



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...making excellence a habit.™

Certificate No: MD 800613

Location	Registered Activities
Luminex Corporation 12212 Technology Blvd. Building A Austin Texas 78727 USA	Design, development, installation and service 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	Design, development, installation and service 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	Manufacture, distribution, installation and service 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	Distribution and service 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	Manufacture, distribution, installation and service 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.

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An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.

A Member of the BSI Group of Companies.

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Location	Registered Activities
Luminex Corporation 1224 Deming Way Madison Wisconsin 53717 USA	Design and development of microsphere-based and PCR-based reagents and assays used in the detection, diagnosis and/or management of nucleic acids related to hereditary diseases, drug metabolism and infectious diseases.
Luminex Molecular Diagnostics, Inc. 439 University Avenue Toronto Ontario M5G 1Y8 Canada	Design, development, manufacture and distribution of microsphere-based and PCR-based reagents and assays used in the detection, diagnosis and/or management of nucleic acids related to hereditary diseases, drug metabolism and infectious diseases. Contract manufacturer of custom primer mixes for in vitro diagnostic use.
Luminex Corporation 4088 Commercial Ave. Northbrook Illinois 60062 USA	Manufacture and distribution of PCR-based systems used in the detection, diagnosis and/or management of nucleic acids related to infectious diseases.

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