

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1722196-1

Organization: Luminex Corporation
12212 Technology Blvd.
Austin TX 78727
USA

Scope: Design and 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.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 234188256-10
Effective date: 2022-07-28
Expiry date: 2024-06-21
Issue date: 2022-07-28



Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



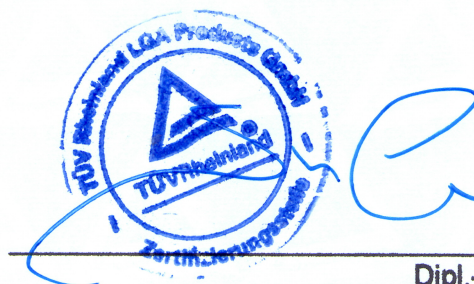
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No.	Facility	Scope
/01	Luminex Corporation 12112 Technology Blvd., Building A Austin TX 78727 USA	Activities related to design and development and administration.
/02	Luminex Corporation 12212 Technology Blvd., Building B Austin TX 78727 USA	Activities related to design and development and administration.
/03	Luminex Corporation 12201 Technology Blvd., Building C Austin TX 78727 USA	Activities related to design and development, manufacture, QC, Warehouse, Distribution and Administration.
/04	Luminex Corporation 12100 Technology Blvd., Building D Austin TX 78727 USA	Activities related to design and development and administration.

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12212 Technology Blvd.
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/05 Luminex Corporation
12301 Technology Blvd., Building E
Austin TX 78727
USA

Activities related to administration.

/06 Luminex Corporation
12306 Technology Blvd., Building G
Austin TX 78727
USA

Activities related to design and development,
manufacture, QC, Service, Warehouse,
Distribution and Administration.

/07 Luminex Corporation
1224 Deming Way
Madison WI 53717
USA

Activities related to Design and development,
manufacture, contract manufacture and
distribution.

/08 Luminex Molecular Diagnostics, Inc.
439 University Avenue
Toronto ON M5G 1Y8
Canada

Activities related to Design and development,
manufacture and distribution.

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