

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Luminex Corporation
12212 Technology Blvd.
Austin TX 78727
USA

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, manufacture, distribution,
installation and service of microsphere-based and PCR-based
multiplexing systems for in-vitro-diagnostic purposes
including software, hardware and reagents.**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-06-22
Certificate Registration No.: SX 60130255 0001
An audit was performed. Report No.: 31890247 002
This Certificate is valid until: 2021-06-21

Certification Body



Date 2018-06-22



S. Hoffmann
Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60130255 0001
Report No.: 31890247 002

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

Scope: Additional sites included:

- Luminex Corporation
12112 Technology Blvd., Building A
Austin, TX 78727 USA

Scope: Activities related to design and development and
administration

- Luminex Corporation
12212 Technology Blvd., Building B
Austin, TX 78727 USA

Scope: Activities related to design and development
and administration

Certification Body



Date: 2018-06-22


Dipl.-Ing. Sven Hoffmann

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60130255 0001
Report No.: 31890247 002

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

Scope: Additional sites included:

- Luminex Corporation
12201 Technology Blvd., Building C
Austin, TX 78727 USA

Scope: Activities related to design and development,
manufacture, installation, service, distribution
and administration

- Luminex Corporation
12100 Technology Blvd., Building D
Austin, TX 78727 USA

Scope: Activities related to design and development
and administration

Certification Body



Date: 2018-06-22


Dipl.-Ing. Sven Hoffmann

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60130255 0001
Report No.: 31890247 001

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

Scope: Additional site included:


- Luminex Corporation
12301 Technology Blvd., Building E
Austin, TX 78727 USA

Scope: Activities related to administration

Certification Body



Date: 2018-06-22



S. Hoffmann
Dipl.-Ing. Sven Hoffmann