

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Lumigenex (Suzhou)  
Co., Ltd.  
Building C24  
218 Xinghu Street  
Suzhou Industrial Park  
215123 Jiangsu  
China**

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

**(see attachment for scope)**

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: 2019-09-30  
Certificate Registration No.: SX 60139875 0001  
An audit was performed. Report No.: 15084639 004  
This Certificate is valid until: 2021-12-19

Certification Body



Date 2019-09-30



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60139875 0001  
**Report No.:** 15084639 004

**Organization:** Lumigenex (Suzhou)  
Co., Ltd.  
Building C24  
218 Xinghu Street  
Suzhou Industrial Park  
215123 Jiangsu  
China

**Scope:**

Design/development, Manufacture and Distribution of  
In-vitro Diagnostic Medical Devices, including Time-Resolved  
Fluorescence Immunoanalyzers and Test Kits; Dry Chemistry  
Analyzers and Test Kits

**Certification Body**



**Date:** 2019-09-30



**Herbert Zhong**