

# Certificate

The Certification Body of  
TUV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Fujirebio Diagnostics, Inc.**  
**940 Crossroads Blvd.**  
**Seguin TX 78155**  
**USA**

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

**(see attachments for scope and additional sites covered by  
this registration)**

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: 2019-01-14  
Certificate Registration No.: SX 60111983 0001  
An audit was performed. Report No.: 31690308 001  
This Certificate is valid until: 2022-01-13



D-ZM-14169-01-02

Date 2019-01-14



**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**

Doc. 1/2, F 37/0



**Attachment to  
Certificate**

**Registration No.:** SX 60138673 0001  
**Report No.:** 31792771 003

**Organization:** Fujirebio Diagnostics, Inc.  
940 Crossroads Blvd.  
Seguin TX 78155  
USA

**Scope:**

Design and Development, Manufacture and Distribution of Calibrators and Controls, components and Support Reagents for In-vitro Diagnostic Test Kits used in the diagnosis/monitoring of cancer and in the monitoring of Blood Glucose, Vitamin D, Fertility and Thyroid status, and management and detection of Infectious Diseases, monitoring of Antirejection



**Date: 2019-01-14**

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



**Attachment to  
Certificate**

**Registration No.:** SX 60138673 0001  
**Report No.:** 31792771 003

**Organization:** Fujirebio Diagnostics, Inc.  
940 Crossroads Blvd.  
Seguin TX 78155  
USA

**Scope:**

Additional site included:

Fujirebio Diagnostics, Inc.  
1640 North King Street  
Seguin, TX 78155 USA

Scope: Activities related to warehousing and logistics

**Certification Body**



**Date: 2019-01-14**