

# Certificate

The Certification Body of  
TÜV 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 13485:2012**  
**EN ISO 13485:2012/AC:2012**

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

Effective Date: 2016-07-23  
Certificate Registration No.: SX 60111983 0001  
An audit was performed. Report No.: 31690308 001  
This Certificate is valid until: 2019-07-05

Certification Body



Date 2016-07-22



**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 60111983 0001  
**Report No.:** 31690308 001

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

**Scope:** Design and Development, Manufacture and Distribution of  
Calibrators and Controls 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

**Certification Body**



**Date:** 2016-07-23

  
**Jürgen Welte**

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

**Attachment to  
Certificate**

**Registration No.:** SX 60111983 0001  
**Report No.:** 31690308 001

**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:** 2016-07-23



**Jürgen Welte**