

Certificate



TUV Rheinland of North America, Inc., a CMDCAS
recognized registrar, certifies that

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


has established and maintained a
Quality Management System
according to
ISO 13485:2003

Audit Report No.: 31690308 001
Certificate Registration No.: 74 500 4905
Expiry Date: December 31, 2018

for the 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

(See attachment for additional site(s) included)




Certification Officer: Jürgen Welte
TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: July 23, 2016
Issue Date: July 22, 2016

Attachment
Quality Management System
according to ISO 13485:2003

for

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

The scope of the registration includes the following sites:

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

Scope

Activities associated with Warehousing and Logistics

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Certification Officer: Juergen Welte

TUV Rheinland of North America, Inc.
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