

Certificate

The Certification Body of
TÜV Rheinland Product Safety 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:

**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, Fertility and Thyroid Status**

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2007

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

Certificate Registration No.: SX 60026503 0001

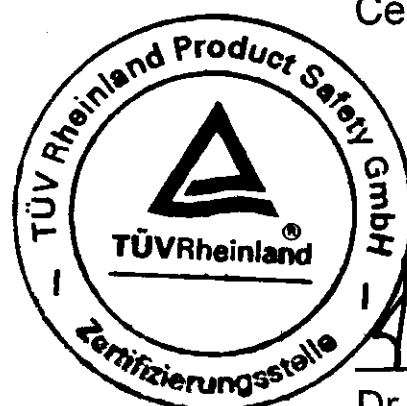
An audit was performed. Report No.: 30792831 003

This Certificate is valid until: 08.08.2013



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Cologne, 10.12.2009



Certification Body


Dr. H. Lüdemann

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