

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

Fujirebio Diagnostics AB
Elof Lindälvs gata 13
SE-414 55 Göteborg
Sweden

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

**Design and Development, Manufacture and Distribution of
in-vitro diagnostic test kits used for the determination of
cancer and other disease state biomarkers for diagnosis and
management of patients with cancer and other disease states**

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 60027313 0001

An audit was performed. Report No.: 21143523 002

This Certificate is valid until: 18.10.2014

Certification Body



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



Cologne, 19.10.2009


Dr. H. Lüdemann

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