



**TÜV Rheinland**  
**Product Safety GmbH**  
Am Grauen Stein, D-51105 Köln

# C E R T I F I C A T E

for a

## Quality Management System

according to

**EN ISO 13485:2000**

**TÜV Rheinland Product Safety GmbH hereby certifies that the**

**Manufacturer: Corgenix, Inc.**  
**12061 Tejon Stret**  
**Westminster, CO 80234**  
**USA**

**has established and maintains a quality management system. Conformance with the requirements of the standards has been audited. The manufacturer is subject to a yearly surveillance audit.**

**Registration No.: SY 60006314 0001**

**Report No.: 02271047 002**

**Date of expiry: 06.06.2005**

**Scope: see attachment**

**Cologne, 20.11.2003**



**Certification Body**

  
**Dr. H. Lüdemann**



Doc. 1/1, Rev. 0

**TÜV Rheinland**  
**Product Safety GmbH**  
Am Grauen Stein, D-51105 Köln

**Attachment to**  
**Registration No.:** SY 60006314 0001  
**Report No.:** 02271047 002

**Manufacturer:** Corgenix, Inc.  
12061 Tejon Stret  
Westminster, CO 80234  
USA

**Scope:** Development, Manufacture and Distribution of  
in vitro diagnostic products for detection of  
Auto-Immune Diseases

Replaces Certificate, Registration No.: SY 60002539 0001

Cologne, 20.11.2003



  
Dr. H. Lüdemann