

# Certificate

The Certification Body of  
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

**Cylex, Inc.**  
**8980-I Old Annapolis Road**  
**Columbia, MD, 21045**  
**USA**

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 products related to  
immune function testing**

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 60022439 0001

An audit was performed. Report No.: 30890939 002

This Certificate is valid until: 09.09.2013



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

Cologne, 10.09.2008



Certification Body

  
Dr. H. Lüdemann