

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Tosoh Bioscience, Inc.**  
3600 Gantz Road  
Grove City OH 43123  
USA

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

**Manufacture and distribution of in-vitro diagnostic medical  
devices and service and repair of supporting  
analytical equipment**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2003 + AC:2009**

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

Certificate Registration No.: SX 60039654 0001

An audit was performed. Report No.: 31093797 001

This Certificate is valid until: 28.06.2016



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

Date 29.06.2011



Certification Body

  
Dr. H. Lüdemann

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Attachment to  
Registration No.: SX 60039654 0001  
Report No.: 31093797 001

Organization: Tosoh Bioscience, Inc.  
3600 Gantz Road  
Grove City OH 43123  
USA

Scope: Additional Sites:  
Tosoh Bioscience, LLC  
3600 Gantz Road  
Grove City, OH 43123

Scope: Activities related to Purchasing, Production  
and Warehousing

Tosoh Bioscience, Inc.  
6000 Shoreline Ct. Ste. 101, South San Francisco, CA 94080

Scope: Activities related to Purchasing, Technical Support,  
Review of Customer Contracts, Product Management and  
Human Resources



Date 29.06.2011



Certification Body



Dr. H. Lüdemann