

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Getein Biotech, Inc.**  
**No. 9 Bofu Road**  
**Luhe District**  
**211505 Nanjing**  
**China**

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

**(see attachment for scope)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012**  
**EN ISO 13485:2012/AC:2012**

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

Effective Date: 2016-07-26  
Certificate Registration No.: SX 60109576 0001  
An audit was performed. Report No.: 15093039 001  
This Certificate is valid until: 2019-07-25

Certification Body



Date 2016-05-30



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

**Attachment to  
Certificate**

**Registration No.:** SX 60109576 0001  
**Report No.:** 15093039 001

**Organization:** Getein Biotech, Inc.  
No. 9 Bofu Road  
Luhe District  
211505 Nanjing  
China

**Scope:** Manufacture and distribution of in-vitro diagnostic test kits in use of Clinical Chemistry and Immunochemistry, Analyzers in use of Quantitative Immunoassay and Immunofluorescence-Assay, Automatic Chemiluminescence Immunoassay Analyzers

**Certification Body**



**Date:** 2016-05-30

