

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 13485:2016

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

Effective Date: 2017-07-27
Certificate Registration No.: SX 60121593 0001
An audit was performed. Report No.: 15093039 002
This Certificate is valid until: 2020-07-25

Certification Body



Date 2017-07-27



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60121593 0001
Report No.: 15093039 002

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: 2017-07-27

