

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
AccuBioTech Co., Ltd.
Building 10, No.28, Yuhua Road
101300 Beijing
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: 2018-12-07
Certificate Registration No.: SX 60130818 0001
An audit was performed. Report No.: 16803295 006
This Certificate is valid until: 2020-07-15

Certification Body



Date 2018-12-07



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60130818 0001
Report No.: 16803295 006

Organization: AccuBioTech Co., Ltd.
Building 10, No.28, Yuhua Road
101300 Beijing
China

Scope: Design and development, manufacture and distribution of in-vitro diagnostic analyzers, in-vitro diagnostic test kits used in the detection of cancer, cardiac markers, disease status, drugs of abuse, fertility testing, pregnancy testing including home use in-vitro diagnostic devices

Certification Body



Date: 2018-12-07

