

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
P.R. 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: 2020-07-16
Certificate Registration No.: SX 60149280 0001
An audit was performed. Report No.: 16803295 010
This Certificate is valid until: 2023-07-15

Certification Body



Date 2020-07-06



Jing Zhang

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 60149280 0001
Report No.: 16803295 010

Organization: AccuBioTech Co., Ltd.
Building 10, No.28, Yuhua Road
101300 Beijing
P.R. 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: 2020-07-06

Jing Zhang