

Certificate

Quality Management System EN ISO 13485:2016

Registration No.:

SX 2187098-1

Organization:

AccuBioTech Co., Ltd.

Building 4, Maohua Industry Park, No. 1, CAIDA Third Street, Nancai Town,

Shunyi District, 101399 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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: Effective date:

2022-03-25

190136080 110

Expiry date:

2023-07-15

Issue date:

2022-03-25



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