

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**VivaChek Biotech (Hangzhou)
Co., Ltd.**
Level 2, Block 2
146 East Chaofeng Rd.
Yuhang Economy Development Zone
Hangzhou
311100 Zhejiang
China

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

**Design and Development, Manufacture and Distribution of
Medical Devices**
(see attachment for products and additional site included)

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: 2019-09-05
Certificate Registration No.: SX 60139342 0001
An audit was performed. Report No.: 15077757 014
This Certificate is valid until: 2021-03-02

Certification Body



Date 2019-09-05



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

Doc. 1/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60139342 0001
Report No.: 15077757 014

Organization: VivaChek Biotech (Hangzhou)
Co., Ltd.
Level 2, Block 2
146 East Chaofeng Rd.
Yuhang Economy Development Zone
Hangzhou
311100 Zhejiang
China

Scope:

Products:
Blood Glucose Monitoring Systems (Blood Glucose Meters, Blood Glucose Test Strips and Blood Glucose Control Solutions), In Vitro Diagnostic Tests Kits used in the detection of Cardiac Markers, Tumor Markers, Infection, Inflammation, Renal Function, Diabetes, Hormone, Drug of Abuse, Anemia and Vitamins based on fluorescence immunochromatography; Multi-function Monitoring Systems (including Multi-function Meters; Blood Ketone Test Strips, Blood Ketone Control Solutions, Uric Acid Test Strips, Uric Acid Control Solutions, Blood Glucose Test Strips, and Blood Glucose Control Solutions)

Certification Body



Date: 2019-09-05



Herbert Zhong

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60139342 0001
Report No.: 15077757 014

Organization: VivaChek Biotech (Hangzhou)
Co., Ltd.
Level 2, Block 2
146 East Chaofeng Rd.
Yuhang Economy Development Zone
Hangzhou
311100 Zhejiang
China

Scope: Site included:

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy
Development Zone, Hangzhou, 311100 Zhejiang, China

Design and Development, Manufacture of Blood Glucose Test
Strips, Blood Glucose Control Solutions, In Vitro Diagnostic
Test Kits used in the detection of Cardiac Markers, Tumor
Markers, Infection, Inflammation, Renal Function, Diabetes,
Hormone, Drug of Abuse, Anemia and Vitamins based on
fluorescence immunochemistry, Blood Ketone Test Strips,
Blood Ketone Control Solutions, Uric Acid Test Strips and
Uric Acid Control Solutions

Certification Body



Date: 2019-09-05



Herbert Zhong

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60139342 0001
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Organization: VivaChek Biotech (Hangzhou)
Co., Ltd.
Level 2, Block 2
146 East Chaofeng Rd.
Yuhang Economy Development Zone
Hangzhou
311100 Zhejiang
China

Scope:

Site included:

1/2/3 F, Building 1, 16 East Zhenxing Rd., Yuhang Economy
Development Zone, Hangzhou, 311100 Zhejiang, China

Design and Development, Manufacture of Blood Glucose Meters,
Multi-function Meters

Distribution of Blood Glucose Monitoring Systems (Blood
Glucose Meters, Blood Glucose Test Strips and Blood Glucose
Control Solutions); In Vitro Diagnostic Test Kits used in
the detection of Cardiac Markers, Tumor Markers, Infection,
Inflammation, Renal Function, Diabetes, Hormone, Drug of
Abuse, Anemia and Vitamins based on fluorescence
immunochemistry; Multi-function Monitoring Systems
(including Multi-function Meters, Blood Ketone Test Strips,
Blood Ketone Control Solutions, Uric Acid Test Strips,
Uric Acid Control Solutions, Blood Glucose Test Strips,
and Blood Glucose Control Solutions)

Certification Body



Date: 2019-09-05



Herbert Zhong