

# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 2135127-1

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

Scope: Design and Development, Manufacture and Distribution of Blood Glucose Monitoring Systems (Blood Glucose Meters, Blood Glucose Test Strips and Blood Glucose Control Solutions), In Vitro Diagnostic Test Kits and Analyzers 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)

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.: 244312018-200  
Effective date: 2021-03-12  
Expiry date: 2024-03-02  
Issue date: 2021-03-12



Fuxiu Sheng  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following:

No.	Facility	Scope
/01	VivaChek Biotech (Hangzhou) Co., Ltd. Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou, 311100 Zhejiang P.R. 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, Uric Acid Control Solutions

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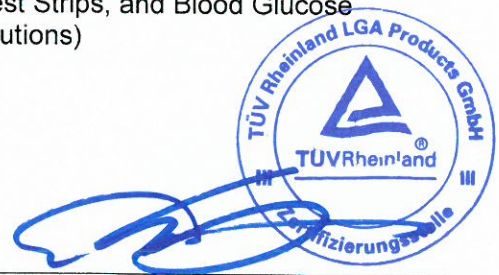
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Hangzhou,  
311100 Zhejiang  
P.R. China

The scope of certification also covers the following:

- /02 VivaChek Biotech (Hangzhou) Co., Ltd.  
1/2/3 F, Building 1,  
16 East Zhenxing Rd., Yuhang Economy  
Development Zone,  
Hangzhou,  
311100 Zhejiang  
P.R. China
- Design and Development, Manufacture of  
Blood Glucose Meters, Multi-function Meters,  
In Vitro Diagnostic Analyzers 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  
Distribution of Blood Glucose Monitoring  
Systems (Blood Glucose Meters, Blood  
Glucose Test Strips and Blood Glucose  
Control Solutions); In Vitro Diagnostic Test  
Kits and Analyzers 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)

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