

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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EN ISO 13485:2016

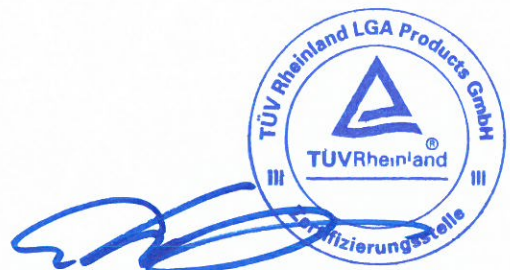
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Level 2, Block 2, 146
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Hangzhou,
311100 Zhejiang
P.R. China

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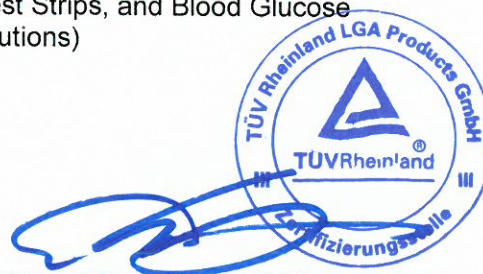
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Level 2, Block 2, 146
East Chaofeng Rd., Yuhang Economy Development Zone,
Hangzhou,
311100 Zhejiang
P.R. China

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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