

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2135127-1

Certificate Holder: 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), Hemoglobin Testing System (Hemoglobin Meters, Hemoglobin Test Strips and Hemoglobin Control Strips)

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.: 244589733-200

Effective date: 2024-03-11

Expiry date: 2027-03-02

Issue date: 2024-03-11

Replaces certificate SX 2135127-1 issued 2023-08-09

This certificate can be validated on <https://www.certipedia.com>



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

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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 sites:

No.	Facility	Scope
/01	c/o VivaChek Biotech (Hangzhou) Co., Ltd. Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou, 311100 Zhejiang P.R. China	Manufacture of Blood Glucose Test Strips, Blood Glucose Control Solutions, Blood Ketone Test Strips and Blood Ketone Control Solutions
/02	c/o VivaChek Biotech (Hangzhou) Co., Ltd. Building 2 and Building 3, No.17 Jianxing Road, Taozhu street, Zhujia, 311800 Zhejiang P.R. China	Manufacture 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 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), Hemoglobin Testing System (Hemoglobin Meters, Hemoglobin Test Strips and Hemoglobin Control Strips)

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East Chaofeng Rd., Yuhang Economy Development Zone,
Hangzhou,
311100 Zhejiang
P.R. China

The scope of certification also covers the following sites:

/03	c/o VivaChek Biotech (Hangzhou) Co., Ltd. Room 801, 8F, Jian Space 502 Linping Avenue, Yuhang Economy Development Zone, Hangzhou, 311100 Zhejiang P.R. China	Design and Development, 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), Hemoglobin Testing System (Hemoglobin Meters, Hemoglobin Test Strips and Hemoglobin Control Strips)
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