

# Certificate

Technical University of Rhineland

## Quality management system ISO 13485:2016

Number: sx 2135127-1

registration: VivaChek Biotech (Hangzhou) Co. Ltd.  
Level 2, block 2, 146.  
East Chaofeng Rd. Yuhang Economic Development Zone,  
Hangzhou,  
Organization: 311100 Zhejiang  
People's Republic of China

Scope: Design and development, manufacture and sale of blood glucose monitoring systems (glucometers, test strips and glucose control solutions), in vitro test kits and diagnostic analyzers used to detect cardiac markers, markers of cancer, infections, inflammation, renal function, diabetes, hormones, drugs, anemia and vitamins by fluorescence immunochromatography; Multifunctional control systems (including multifunction counters, blood ketone test strips, blood ketone control strips, uric acid test strips, uric acid control strips, blood glucose test strips and blood glucose control solutions).

The certification body TOV Rheinland LGA Products GmbH confirms that the organization has implemented and applies a quality management system for medical devices. demonstrates that the requirements set out in the standard management system

fulfilled. The quality

These data are subject to annual monitoring.

Message number: 244312018-200  
Entry into force: 2021-03-12

Date: A 2024-03-02  
expiration date : 2021-03-12

Release  
The date:



Fuxiu Sheng  
TOV Rheinland LGA Products GmbH  
Tillystraße 2 - 90431 Nürnberg -  
Germany

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The scope of certification includes the following aspects:

Ne after already arc ajt and m / 01	<b>Case:</b>  VivaChek Biotech (Hangzhou) Co., Lt d.  Level 2, Block 2, Floor 146 East Chaofeng Rd. Yuhang Economic Development Zone, Hangzhou, 311100 Zhejiang People's Republic of China
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### Area of application

Design, development and manufacture of blood glucose test strips, blood glucose control solutions, in vitro diagnostic test kits used for fluorescent immunochromatographic detection of cardiac markers, markers of cancer, infections, inflammation, renal function, diabetes, hormones, drugs, anemia and vitamins, blood ketone test strips, blood ketone control solutions, uric acid test strips, uric acid control solutions .

Message number:	244312018-200
Date of entry into force:	2021-03-12
Date	2024-03-02
End date	2021-03-12

validity:  
(Renewal system)

The date: Accreditation body  
D-ZM- 14 169-01-02



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Design and development of glucometers, multifunctional glucometers, in vitro diagnostic analyzers, production of cardiological markers, cancer markers , distribution of blood glucose monitoring systems (glucometers, test strips and blood glucose monitoring solutions) based on fluorescence immunochromatography for infections, inflammation, renal function, diabetes, hormones, drugs, anemia and vitamins; In vitro diagnostic test kits and analyzers for the detection of cardiac markers, markers of cancer, infections, inflammation, renal function, diabetes, hormones, drug abuse, anemia and vitamins; in vitro diagnostic test kits and analyzers based on fluorescence immunochromatography; multifunction monitoring systems (including multifunction counters, blood ketone test strips, blood ketone monitoring solutions, uric acid

test strips, uric acid control solutions , test strips and blood glucose control solutions; ... ::, 0 ---- Control Solutions ) -" - "GA

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