

EC Certificate

**Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)**

Registration No.: HL 2135127-1

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

Products: Blood Glucose Monitoring Systems (Blood Glucose Meters, Blood Glucose Test Strips, Blood Glucose Control Solutions); 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)

Replaces Approval, Registration No.: HL 60145622 0001


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The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 244411842-200
Effective date: 2022-03-23
Expiry date: 2025-05-26
Issue date: 2022-03-23



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

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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Annex IV excluding (4, 6)

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Hangzhou,
311100 Zhejiang
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location
/01	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



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