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

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

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

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

Report No.: 244411842-200

Effective date: 2022-03-23

Expiry date: 2025-05-26

Issue date: 2022-03-23

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.