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.

Digitally signed by Sarco Alexandru.
Date: 2024.09.05 11:46:24 EEST
Reason: MoldSign Signature
Location: Moldova

Report No.: 244411842-2022

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.

Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date August 08, 2023

Application for: QMS

Certificate No. : HL 2135127-1
Requirement : Directive 98/79/EC
Confirmation letter ID : DOC_2023-08-09_ HL 2135127-1
Report no. : 244508348-200

Dear Madame or Sir,

Update of information to Certificate no. HL 2135127-1, issued on 23.03.2022

The change notification received on 21.09.2022 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), Article 110(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address:	1/2/3 F, Building 1, 16 East Zhenxing Rd., Yuhang Economy Development Zone, Hangzhou, 311100 Zhejiang, P.R. China
New Manufacturer address:	Building 2 and Building 3, No.17 Jianxing Road, Taozhu street, Zhuji, 311800, Zhejiang, P.R. China

Best regards,

Herbert Zhong
Certification body

TÜV Rheinland
LGA Products GmbH

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51105 Köln
Germany

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