

Declaration of Conformity

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

European Representative: Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA,
the Hague, Netherlands.
Tel: +31644168999
E-mail: peter@lotusnl.com

Product Name / Model: VivaChek™ Ino X Blood Glucose Monitoring System / VGM49
VivaChek™ Ino X Blood Glucose Meter / VGM49
VivaChek™ Ino Blood Glucose Test Strips / VGS01
VivaChek™ Ino Blood Glucose Control Solution / VGC01

Classification (Annex II, 98/79/EC) : List B
Conformity Assessment procedure: Annex IV, 98/79/EC

We hereby declare that the above mentioned products meet the COUNCIL DIRECTIVE 98/79/EC and applicable Standards. All supporting documentations are retained in the manufacturer and EU representative.

Notified Body: TÜV Rheinland LGA Products GmbH
Address: Tillystraße 2, 90431, Nürnberg, Germany
Identification number: 0197

EC Certificate Registration No. HL 2135127-1
Issue date: 23-March-2022
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Hangzhou, China, 25 March, 2022
Place, Date of issue


Simon Ma
Regulatory Affairs Department
VivaChek Biotech (Hangzhou) Co., Ltd.