

EU DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/746 on in vitro diagnostic Medical Devices

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

Trademark:  VivaDiag™

SRN: CN-MF-000012160

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

SRN: NL-AR-000000121

Trade name: VivaDiag™ POCT Multifunction Meter

Product name: POCT Multifunction Meter

Model: VIM220H

Basic UDI-DI: 697022176VIM220H001KM

Classification acc. to IVDR Class A, rule 5
Ax. VIII:

Conformity assessment procedure: Annex IX, Chapter I

CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on in vitro diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Signature:



Bekki Liu
Bekki Liu
RA Specialist

Title:

Position:

Hangzhou, China

Date:

June 10, 2022