

## 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:** 

**SRN:** CN-MF-000012160

**European Representative:** Lotus NL B.V.  
Koningin Julianaplein 10, 1e Verd, 2595AA, the Hague,  
Netherlands.  
Tel: +31644168999  
E-mial: [peter@lotusnl.com](mailto:peter@lotusnl.com)

**SRN:** NL-AR-000000121

**Trade name:** VivaDiag™ POCT Analyzer

**Product name:** POCT Analyzer

**Model:** VIM3000

**Basic UDI-DI:** 697022176VIM2000001DS

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

**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

**Title:**

RA Specialist

**Position:**

Hangzhou, China

**Date:**

August 22, 2021