

# Declaration of Conformity

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

We declare under our sole responsibility that the medical device:

In Vitro Diagnostic Tests Kits used in the detection of Cardiac Markers,  
Infection, Inflammation, Renal Function, Diabetes, Hormone, Drug of  
Abuse, Anemia and Vitamins base on fluorescent immunochromatography

meets all the provisions of the directive 98/79/EEC and its transpositions in national laws which apply to it.

**Conformity assessment procedure:**  
98/79/EEC ANNEX III

### Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany,  
notified under No. 0197 to the EC Commission.

### Authorized Representative:

Landlink GmbH  
Dorfstrasse, 2/4, Emmendingen, Germany  
Tel: + 0049 7641 9626855  
Fax: + 0049 7641 9626855

Signed this 22 day of March, 2018  
in Hangzhou, China

*Handwritten signature*



Rocky Zhu  
Regulatory Affairs Manager  
VivaChek Biotech (Hangzhou) Co., Ltd.

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We declare under our sole responsibility that the in vitro diagnostic device:

VivaDiag™ D-Dimer Test Kit  
VivaDiag™ The Whole C Reactive Protein Test Kit  
VivaDiag™ Cystatin C Test Kit  
VivaDiag™ Beta2 Microglobulin Test Kit  
VivaDiag™ Neutrophil Gelatinase-associated Lipocalin Test Kit  
VivaDiag™ Micro-albuminuria Test Kit  
VivaDiag™ Cardiac Troponin I Test Kit  
VivaDiag™ Heart Fatty Acid Binding Protein Test Kit  
VivaDiag™ Serum Amyloid A Protein Test Kit

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