

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



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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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