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

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

Digitally signed by Apostol Eduard
Date: 2021.02.04 14:20:48 EET
Reason: MoldSign Signature
Location: Moldova

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 in vitro diagnostic device:

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

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

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