

Declaration of Conformity

Manufacturer: Address:	VivaChek Biotech (Hangzhou) Co., Ltd Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China
European Representative: Address: Tel: E-mail:	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, the Hague, Netherlands. +31644168999 peter@lotusnl.com

PRODUCT NAME	MODEL
VivaDiag™ POCT Analyzer	VIM1000/VIM2000
VivaDiag™ Whole C-Reactive Protein Test Kit	VID01
VivaDiag™ Procalcitonin Test Kit	VID02
VivaDiag™ Cystatin C Test Kit	VID03
VivaDiag™ Serum Amyloid A Protein Test Kit	VID04
VivaDiag™ Interleukin 6 Test Kit	VID05
VivaDiag™ Micro Albuminuria Test Kit	VID06
VivaDiag™ Beta-2 Microglobulin Test Kit	VID07
VivaDiag™ Neutropil Gelatinase-associated Lipocalin Test Kit	VID08
VivaDiag™ Cardiac Troponin I Test Kit	VID09
VivaDiag™ Creatine Kinase-MB Test Kit	VID10
VivaDiag™ D-Dimer Test Kit	VID11
VivaDiag™ Myoglobin Test Kit	VID12
VivaDiag™ Heart Fatty Acid Binding Protein Test Kit	VID13
VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Test Kit	VID14
VivaDiag™ Cardiac Combo (cTnl/CK-MB/MYO) Test Kit	VID15
VivaDiag™ Glycosylated Hemoglobin Test Kit	VID16
VivaDiag™ C-peptide Test Kit	VID17
VivaDiag™ Insulin Test Kit	VID18
VivaDiag™ Beta Human Chorionic Gonadotropin Test Kit	VID19
VivaDiag™ Thyroid Stimulating Hormone Test Kit	VID20
VivaDiag™ Triiodothyronine Test Kit	VID21
VivaDiag™ Thyroxine Test Kit	VID22



VivaDiag™ Luteinising Hormone Test Kit	VID23
VivaDiag™ Prostate Specific Antigen Test Kit	VID24
VivaDiag™ Alpha Fetoprotein Test Kit	VID25
VivaDiag™ Carcino-embryonic Antigen Test Kit	VID26
VivaDiag™ Fecal Occult Blood Test Kit	VID27
VivaDiag™ Ferritin Test Kit	VID28
VivaDiag™ 25-Hydroxyvitamin D3 Test Kit	VID29
VivaDiag™ Anti-Mullerian Hormone Test Kit	VID30
VivaDiag™ Follicle Stimulating Hormone Test Kit	VID31
VivaDiag™ Prolactin Test Kit	VID32
VivaDiag™ Inhibin B Test Kit	VID33
VivaDiag™ Homocysteine Test Kit	VID34
VivaDiag™ Morphine Test Kit	VID37
VivaDiag™ Methamphetamine Test Kit	VID38
VivaDiag™ Ketamine Test Kit	VID39
VivaDiag™ Tetrahydrocannabinol Test Kit	VID40
VivaDiag™ Cocaine Test Kit	VID41
VivaDiag™ MDMA Test Kit	VID42
VivaDiag™ SARS-CoV-2 Ag FIA Test	VID44
VivaDiag™ Cardiac Combo (cTnl/CK-MB) Test Kit	VID45
VivaDiag™ Drug of Abuse Combo (MOR/MET/KET) Test Kit	VID46
VivaDiag™ Whole C-Reactive Protein Control Solution	VIC01
VivaDiag™ Procalcitonin Control Solution	VIC02
VivaDiag™ Cystatin C Control Solution	VIC03
VivaDiag™ Serum Amyloid A Control Solution	VIC04
VivaDiag™ Interleukin 6 Control Solution	VIC05
VivaDiag™ Micro Albuminuria Control Solution	VIC06
VivaDiag™ Beta-2 Microglobulin Control Solution	VIC07
VivaDiag™ Neutropil Gelatinase-associated Lipocalin Control Solution	VIC08
VivaDiag™ Cardiac Troponin I Control Solution	VIC09
VivaDiag™ Creatine Kinase-MB Control Solution	VIC10
VivaDiag™ D-Dimer Control Solution	VIC11
VivaDiag™ Myoglobin Control Solution	VIC12
VivaDiag™ Heart Fatty Acid Binding Protein Control Solution	VIC13
VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Control Solution	VIC14
VivaDiag™ Cardiac Combo (cTnl/CK-MB/MYO) Control Solution	VIC15

VivaDiag™ Glycosylated Hemoglobin Control Solution	VIC16
VivaDiag™ C-peptide Control Solution	VIC17
VivaDiag™ Insulin Control Solution	VIC18
VivaDiag™ Beta Human Chorionic Gonadotropin Control Solution	VIC19
VivaDiag™ Thyroid Stimulating Hormone Control Solution	VIC20
VivaDiag™ Triiodothyronine Control Solution	VIC21
VivaDiag™ Thyroxine Control Solution	VIC22
VivaDiag™ Luteinising Hormone Control Solution	VIC23
VivaDiag™ Prostate Specific Antigen Control Solution	VIC24
VivaDiag™ Alpha Fetoprotein Control Solution	VIC25
VivaDiag™ Carcino-embryonic Antigen Control Solution	VIC26
VivaDiag™ Fecal Occult Blood Control Solution	VIC27
VivaDiag™ Ferritin Control Solution	VIC28
VivaDiag™ Vitamin D Control Solution	VIC29
VivaDiag™ Anti-müllerian Hormone Control Solution	VIC30
VivaDiag™ Follicle-stimulating Hormone Control Solution	VIC31
VivaDiag™ Prolactin Control Solution	VIC32
VivaDiag™ Inhibin B Control Solution	VIC33
VivaDiag™ Homocysteine Control Solution	VIC34
VivaDiag™ Influenza A+B Control Solution	VIC36
VivaDiag™ Morphine Control Solution	VIC37
VivaDiag™ Methamphetamine Control Solution	VIC38
VivaDiag™ Ketamine Control Solution	VIC39
VivaDiag™ Tetrahydrocannabinol Control Solution	VIC40
VivaDiag™ Ketamine Control Solution	VIC41
VivaDiag™ Cardiac Combo (cTnl/CK-MB) Control Solution	VIC45
VivaDiag™ Drug of Abuse Combo (MOR/MET/KET) Control Solution	VIC46

Classification (Article 9, 98/79/EC) : Others

Conformity Assessment procedure: 98/79/EC ANNEX III

We hereby declare that the above mentioned products meet the COUNCIL DIRECTIVE 98/79/EC and applicable Standards. All supporting documentations are retained in the manufacturer and EU representative.

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Hangzhou, China, 18th Jan, 2022

Place, Date of issue



Bekki Liu
Regulatory Affairs Department
VivaChek Biotech (Hangzhou) Co., Ltd

