

Declaration of Conformity

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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

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VivaDiag™ Alpha Fetoprotein Test Kit VID25 VivaDiag™ Carcino-embryonic Antigen Test Kit VID26 VivaDiag™ Fecal Occult Blood Test Kit VID27 VivaDiag™ Femitin Test Kit VID28 VivaDiag™ Femitin Test Kit VID29 VivaDiag™ Sch-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™ Inhibit B Test Kit VID33 VivaDiag™ Inhibit B Test Kit VID33 VivaDiag™ Momorysteine Test Kit VID34 VivaDiag™ Momorysteine Test Kit VID34 VivaDiag™ Momphine Test Kit VID37 VivaDiag™ Methamphetamine Test Kit VID38 VivaDiag™ Etrahydrocannabinol Test Kit VID40 VivaDiag™ Tetrahydrocannabinol Test Kit VID40 VivaDiag™ Tetrahydrocannabinol Test Kit VID40 VivaDiag™ Tetrahydrocannabinol Test Kit VID41 VivaDiag™ Cocaine Test Kit VID41 VivaDiag™ December Kit VID44 VivaDiag™ December Cov-2 Ag FIA Test V	VivaDiag™ Luteinising Hormone Test Kit	VID23
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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 VIC08 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 VIC13 Solution VIC14 VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Control VIC14 VivaDiag™ Cardiac Combo (cTnl/CK-MB/MYO) Control VIC15	VivaDiag [™] Procalcitonin Control Solution	VIC02
VivaDiag™ Interleukin 6 Control Solution VIC05 VivaDiag™ Micro Albuminuria Control Solution VIC06 VivaDiag™ Beta-2 Microglobulin Control Solution VIC07 VivaDiag™ Neutropil Gelatinase-associated Lipocalin VIC08 Control Solution VIC09 VivaDiag™ Cardiac Troponin I Control Solution VIC10 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 VIC13 Solution VIC14 VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Control VIC14 VivaDiag™ Cardiac Combo (cTnl/CK-MB/MYO) Control VIC15	VivaDiag [™] Cystatin C Control Solution	VIC03
VivaDiag™ Micro Albuminuria Control Solution VIC06 VivaDiag™ Beta-2 Microglobulin Control Solution VIC07 VivaDiag™ Neutropil Gelatinase-associated Lipocalin VIC08 Control Solution VIC09 VivaDiag™ Cardiac Troponin I Control Solution VIC10 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 VIC13 Solution VIC14 VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Control VIC14 VivaDiag™ Cardiac Combo (cTnI/CK-MB/MYO) Control VIC15	VivaDiag™ Serum Amyloid A Control Solution	VIC04
VivaDiag™ Beta-2 Microglobulin Control Solution VIC07 VivaDiag™ Neutropil Gelatinase-associated Lipocalin VIC08 Control Solution VIC09 VivaDiag™ Cardiac Troponin I Control Solution VIC10 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 VIC15	VivaDiag [™] Interleukin 6 Control Solution	VIC05
VivaDiag™ Neutropil Gelatinase-associated Lipocalin VIC08 Control Solution VIC09 VivaDiag™ Cardiac Troponin I Control Solution VIC10 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 (cTnI/CK-MB/MYO) Control VIC15	VivaDiag [™] Micro Albuminuria Control Solution	VIC06
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 (cTnI/CK-MB/MYO) Control VIC15	VivaDiag™ Beta-2 Microglobulin Control Solution	VIC07
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 (cTnI/CK-MB/MYO) Control VIC15	VivaDiag™ Neutropil Gelatinase-associated Lipocalin	VICOS
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 (cTnI/CK-MB/MYO) Control VIC15	Control Solution	VICO8
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 (cTnI/CK-MB/MYO) Control VIC15	VivaDiag [™] Cardiac Troponin I Control Solution	VIC09
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 (cTnI/CK-MB/MYO) Control VIC15	VivaDiag [™] Creatine Kinase-MB Control Solution	VIC10
VivaDiag™ Heart Fatty Acid Binding Protein Control VIC13 Solution VIC13 VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Control VIC14 Solution VIC15	VivaDiag™ D-Dimer Control Solution	VIC11
Solution VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Control Solution Vic13 VIC13 VIC14 VivaDiag™ Cardiac Combo (cTnl/CK-MB/MYO) Control	VivaDiag™ Myoglobin Control Solution	VIC12
VivaDiag TM N-terminal Pro-brain Natriuretic Peptide Control Solution VivaDiag TM Cardiac Combo (cTnl/CK-MB/MYO) Control	VivaDiag™ Heart Fatty Acid Binding Protein Control	\/IC12
Solution VIC14 VivaDiag™ Cardiac Combo (cTnl/CK-MB/MYO) Control	Solution	VIC 13
VivaDiag [™] Cardiac Combo (cTnI/CK-MB/MYO) Control	VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Control	V/IC14
VIC15		VIC14
Solution	25 25 34 € 1 × 2 × 2 × 2 × 2 × 2 × 2 × 2 × 2 × 2 ×	VIC15
	Solution	V1010

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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

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

