



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 11 november 2020
Betreft: exportverklaring(en) medische hulpmiddelen/AIMD/IVD/MDR/IVDR

Geachte heer Wei,

Hierbij ontvangt u de door u aangevraagde exportverklaring(en) voor:

29615, 29616

Afgegeven exportverklaringen IVD Klasse other producten of gecombineerde exportverklaringen van IVD Klasse other producten met hogere risicoklasse producten vervallen per 26 mei 2022.

Valt uw IVD product onder een hogere risicoklasse (lijst A, B of zelftesten)? Dan mag uw product tot en met uiterlijk 25 mei 2025 op de markt blijven als IVD product.

Met vriendelijke groet,
Farmatec

F.J.J. de Bas

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

Inlichtingen bij:

F.J.J. de Bas

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:

CIBG-20205266

Bijlagen

2

Uw aanvraag

2 november 2020

*Correspondentie uitsluitend
richten aan het retouradres met
vermelding van de datum en het
kenmerk van deze brief.*

Ministry of Health, Welfare and Sport
CIBG
P.O. Box 16114
2500 BC The Hague
THE NETHERLANDS



STATEMENT

The undersigned herewith declares that according to the Decree on In-Vitro Diagnostics, which is based on the European Directive 98/79/EC concerning in-vitro diagnostic medical devices,

Lotus NL B.V.
Koningin Julianaplein 10
2595 AA 's-Gravenhage
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

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

is authorised to manufacture and/or supply the medical device/devices mentioned below:

See product list

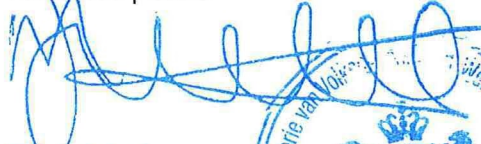
This device/these devices may be placed on the Dutch market and on the markets of the other Member States of the European Union, and be exported to non-EU Member States. This free sale certificate may only be used for export outside the European Union.

The present statement is drawn up at the request of the interested party in order to be submitted to the Health Authorities .

This statement is valid until May 26, 2022.

The Hague, November 11, 2020

On behalf of the Minister for Medical Care and Sport
Farmatec | CIBG


DR. M.J. van de Velde
Mr. M.J. van de Velde
Head of Department



Our reference: 20205266
Certificate number: 29615



FSC Attachment: Product list

Product Name	Proprietary Name	REF/Model
VivaDiag POCT Analyzer VIM 1000/VIM01/VIM02/VIM2000	VivaDiag POCT Analyzer	VIM01-00-011/ VIM02-00-011/ VIM1000-00-011/ VIM2000-00-011/ VIM100H-00-011
In Vitro Diagnostic Tests Kits based on fluorescent immunochromatography	VivaDiag SARS-CoV-2/Flu A/Flu B Ag FIA Test	VID47-08-011
	VivaDiag™ SARS-CoV-2 Ag FIA Test	VID44-08-011
	VivaDiag 25-Hydroxyvitamin D3 Test Kit	VID29-07-011
	VivaDiag Influenza A+B Ag FIA Test	VID36-08-011
	VivaDiag Whole C-Reactive Protein Test Kit	VID01-01-011
	VivaDiag Procalcitonin Test Kit	VID02-01-011
	VivaDiag Serum Amyloid A Protein Test Kit	VID04-01-011
	VivaDiag Interleukin 6 Test Kit	VID05-01-011
	VivaDiag Cystatin C Test Kit	VID03-02-011
	VivaDiag Micro Albuminuria Test Kit	VID06-02-011
	VivaDiag Beta-2 Microglobulin Test Kit	VID07-02-011
	VivaDiag Neutropil Gelatinase-associated Lipocalin Test Kit	VID08-02-011
	VivaDiag Cardiac Troponin I Test Kit	VID09-03-011
	VivaDiag Creatine Kinase-MB Test Kit	VID10-03-011
	VivaDiag D-Dimer Test Kit	VID11-03-011
	VivaDiag Myoglobin Test Kit	VID12-03-011

M.J. van de Velde
Ministry of Health, Welfare and Sport

In Vitro Diagnostic Tests Kits based on fluorescent immunochromatography	VivaDiag Heart Fatty Acid Binding Protein Test Kit	VID13-03-011
	VivaDiag N-terminal B-type Natriuretic Peptide Test Kit	VID14-03-011
	VivaDiag Cardiac Combo (CTN-I/CK-MB/MYO) Test Kit	VID15-03-011
	VivaDiag Homocysteine Test Kit	VID34-03-011
	VivaDiag Cardiac Combo (CTN-I/CK-MB) Test Kit	VID45-03-011
	VivaDiag Glycosylated Hemoglobin Test Kit	VID16-04-011
	VivaDiag C-peptide Test Kit	VID17-04-011
	VivaDiag Insulin Test Kit	VID18-04-011
	VivaDiag Beta Human Chorionic Gonadotropin Test Kit	VID19-05-011
	VivaDiag Thyroid Stimulating Hormone Test Kit	VID20-05-011
	VivaDiag Triiodothyronine Test Kit	VID21-05-011



In Vitro Diagnostic Tests Kits based on fluorescent immunochemistry	VivaDiag Thyroxine Test Kit	VID22-05-011
	VivaDiag Luteinising Hormone Test Kit	VID23-05-011
	VivaDiag Anti-müllerian Hormone Test Kit	VID30-05-011
	VivaDiag Follicle-stimulating Hormone Test Kit	VID31-05-011
	VivaDiag Prolactin Test Kit	VID32-05-011
	VivaDiag Inhibin B Test Kit	VID33-05-011
	VivaDiag Prostate Specific Antigen Test Kit	VID24-06-011
	VivaDiag Alpha Fetoprotein Test Kit	VID25-06-011
	VivaDiag Carcino-embryonic Antigen Test Kit	VID26-06-011
	VivaDiag Fecal Occult Blood Test Kit	VID27-06-011
	VivaDiag Ferritin Test Kit	VID28-07-011

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	VivaDiag Influenza A Rapid Test	VID43-08-011
	VivaDiag Morphine Test Kit	VID37-09-011
	VivaDiag Methylamphetamine Test Kit	VID38-09-011
	VivaDiag Ketamine Test Kit	VID39-09-011
	VivaDiag Tetrahydrocannabinol Test Kit	VID40-09-011
	VivaDiag Cocaine Test Kit	VID41-09-011
	VivaDiag MDMA Test Kit	VID42-09-011
	VivaDiag Drug of Abuse Combo (MOR/MET/KET) Test Kit	VID46-09-011
	VivaDiag Control Solution	VIC01/VIC02/VIC03/VIC04/ VIC05/VIC06/VIC07/ VIC08/VIC09/VIC10/VIC11/ VIC12/VIC13/VIC14/
	VivaDiag Control Solution	VIC15/VIC16/VIC17/VIC18/VIC19/ VIC20/VIC21/VIC22/VIC23/VIC24 /VIC25/VIC26/VIC27/VIC28/ VIC29/VIC30/VIC31/ VIC32/VIC33/VIC34
In Vitro Diagnostic Test Kits (Colloidal Gold)	VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test	VCD16-01-011
	VivaDiag™ SARS-CoV-2 Ag Rapid Test	VCD05-01-011
	VivaDiag SARS-CoV-2/Flu A/Flu B Ag Rapid Test	VLD01-03-13

**In Vitro Diagnostic Test Kits
(Colloidal Gold)**

VivaDiag™ SARS-CoV-2 IgM/IgG Rapid Test (COVID-19 IgM/IgG rapid test)	VID35-08-011/ VID35-08-012/ VID35-08-013 VID35-08-014/ VID35-08-015
VivaDiag™ Adenovirus Ag Rapid Test	VLD01-01-02
VivaDiag™ Respiratory Syncytial Virus Ag Rapid Test	VLD01-01-03
VivaDiag™ Mycoplasma Pneumoniae Ag Rapid Test	VLD01-01-04
VivaDiag™ Dengue IgG/IgM Ab Rapid Test	VLD01-02-05
VivaDiag™ Dengue NS1 Ag Rapid Test	VLD01-01-06
VivaDiag™ Malaria Pf/Pv Rapid Test	VLD01-02-07
VivaDiag™ Malaria Pf/Pan Rapid Test	VLD01-02-08
VivaDiag™ Malaria Pf Rapid Test	VLD01-01-09
VivaDiag™ Malaria Pan Rapid Test	VLD01-01-10
VivaDiag™ Typhoid Ab Rapid Test	VLD01-01-11
VivaDiag™ Procalcitonin Rapid Test	VLD01-01-12
VivaDiag™ D-Dimer Rapid Test	VLD02-01-01
VivaDiag™ Ferritin Rapid Test	VLD06-01-01

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The manufacturer:

VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone
Hangzhou, Zhejiang 311100
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Dr. M.J. van de Velde
Mr. M.J. van de Velde
Head of Department


Our reference: 20205266
Certificate number: 29616



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	VivaDiag Interleukin 6 Test Kit	VID05-01-011
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Dr. M. J. van de Vede
Minister of Health, Welfare and Sport
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VivaDiag™ Malaria Pf/Pv Rapid Test	VLD01-02-07
VivaDiag™ Malaria Pf/Pan Rapid Test	VLD01-02-08
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VivaDiag™ Typhoid Ab Rapid Test	VLD01-01-11
VivaDiag™ Procalcitonin Rapid Test	VLD01-01-12
VivaDiag™ D-Dimer Rapid Test	VLD02-01-01
VivaDiag™ Ferritin Rapid Test	VLD06-01-01