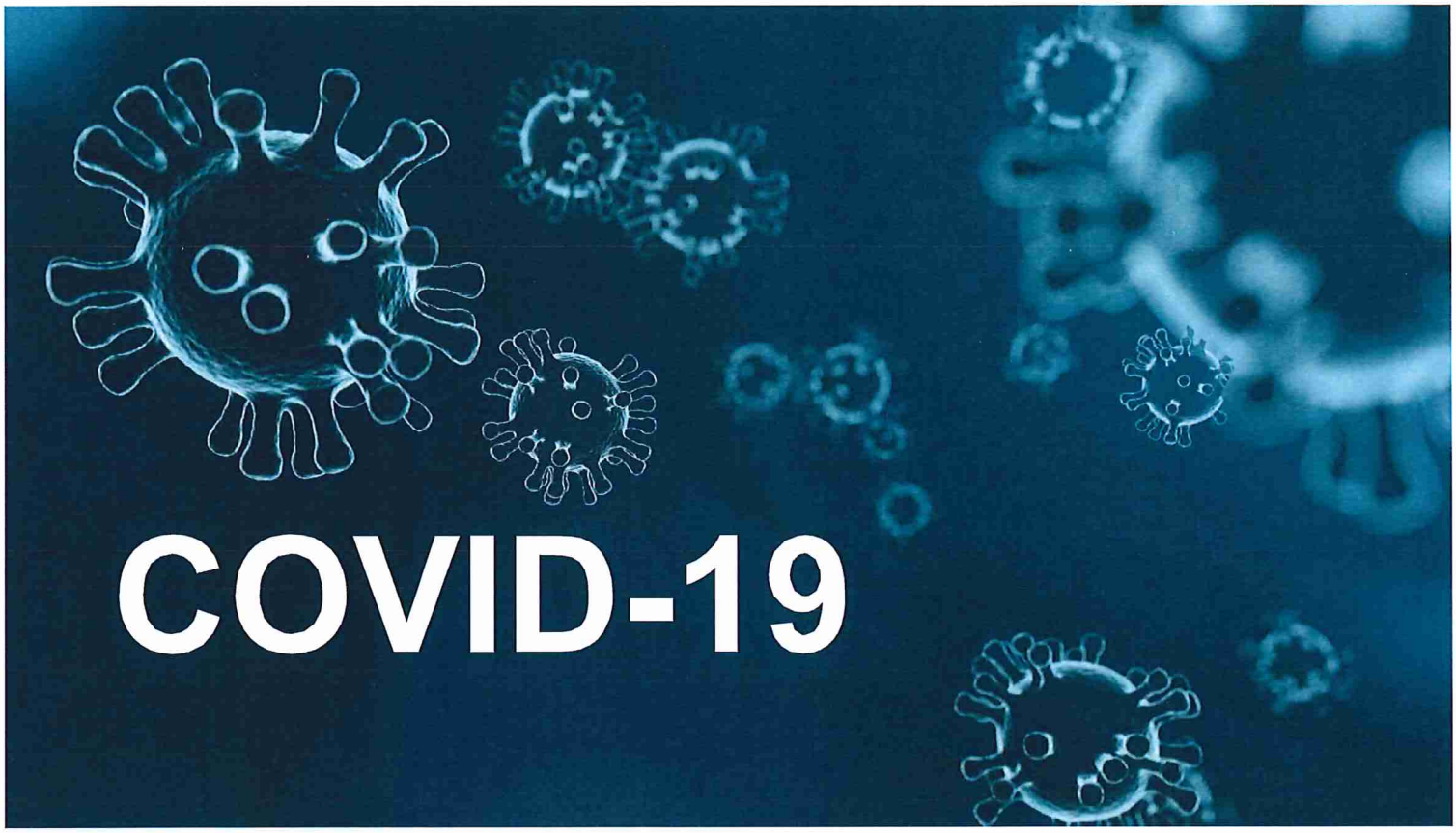
fluorecare®

GROUPE TRENOIS

CE 1434



SARS-CoV-2 Antigen Test Kit(MF-68)

Product Brochure

Self-Test

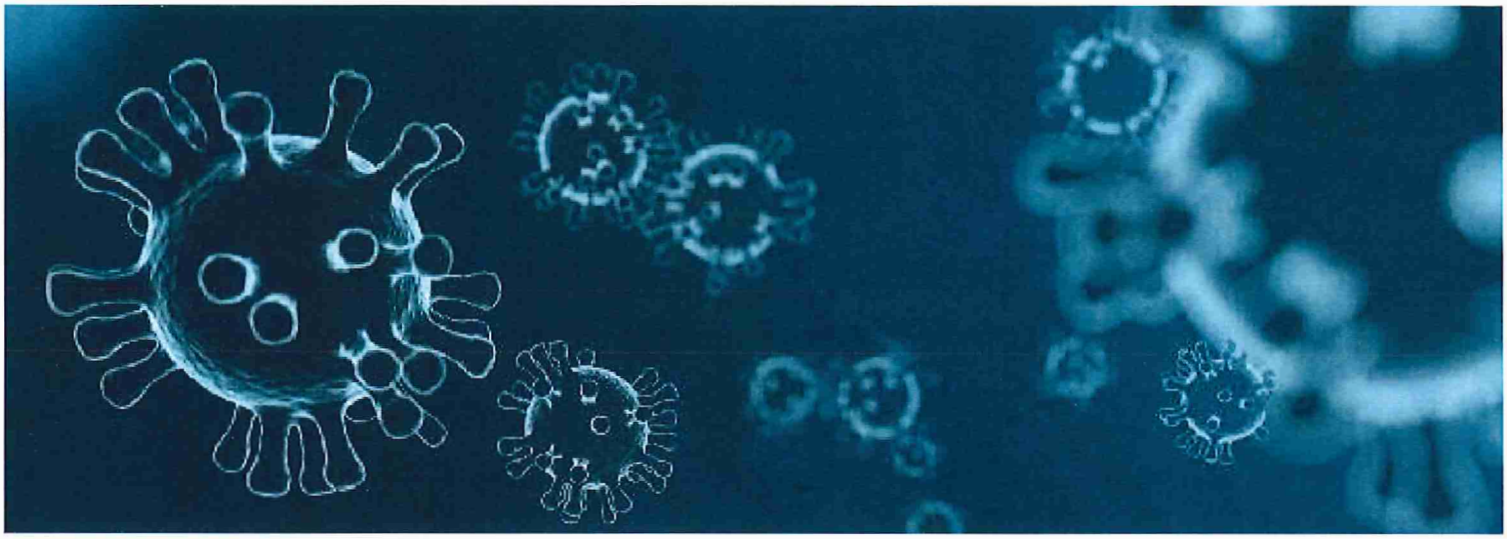
2021-12

MICROPROFIT BIOTECH

fluorecare®

GROUPE TRENOIS

CE 1434



Advantages

- **Accessible** - Can be used in a wide variety of non-laboratory settings
- **User-friendly** - Easy-to-operate, less trauma & discomfort
- **Economical** - No additional instruments require
- **High performance** - Fast identification of potentially infectious individuals

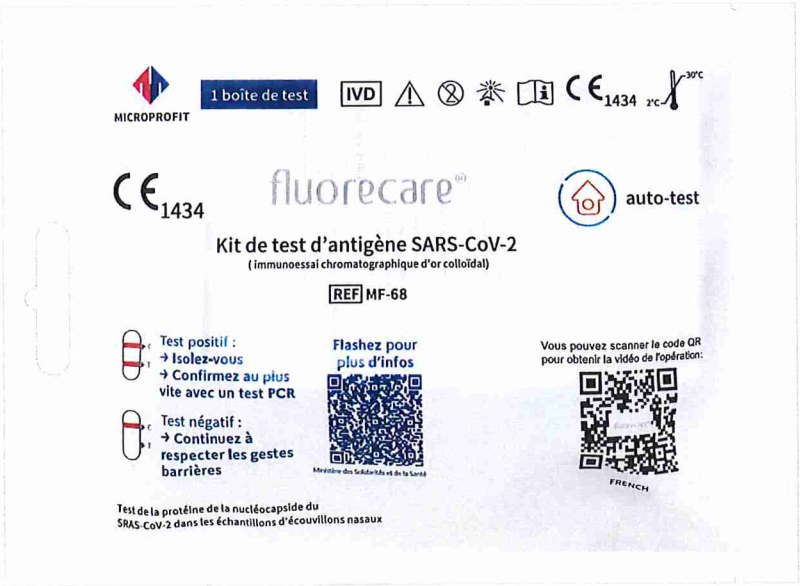
Characteristics

Method	Colloidal Gold
Test Time	10-15 min
Shelf Life	12 months
Sample Type	Nasal swab
Specification	Kits for 1T, 5T
Storage	Room temperature (2-30℃)

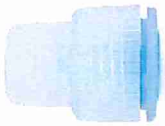
fluorecare®

GROUPE TRENOIS

CE 1434

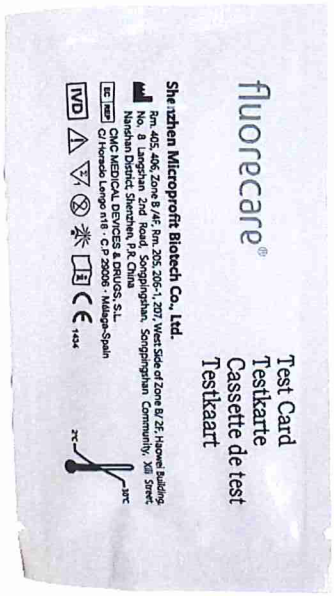


Test Kit



Sample Diluent

Multilingual instruction



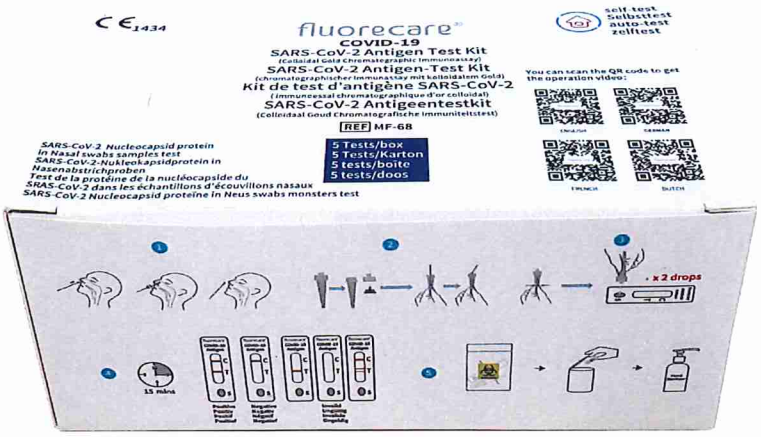
Test Card

Swab

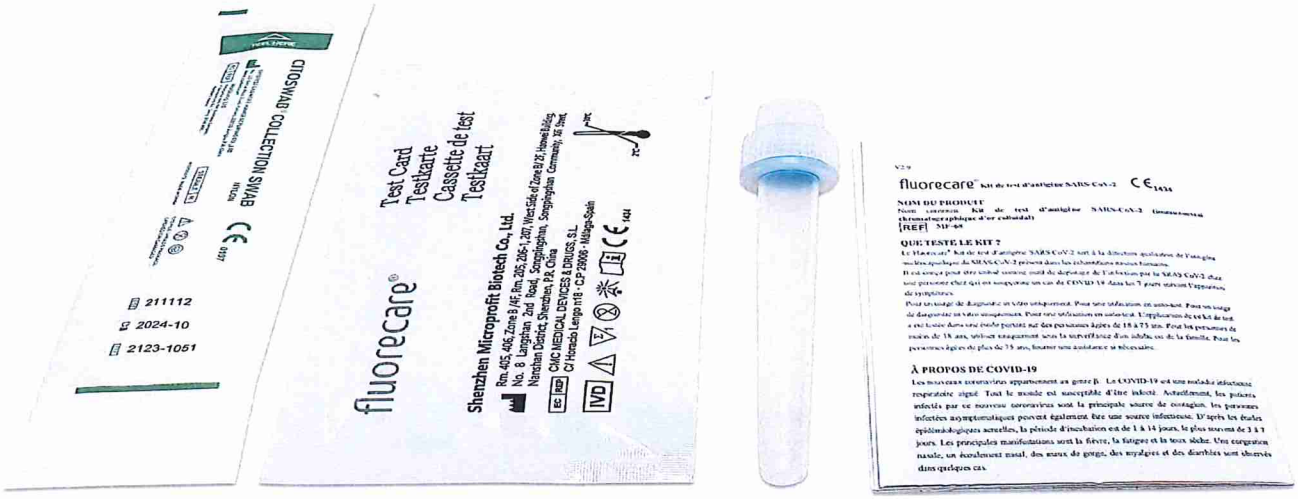
fluorecare®

GROUPE TRENOIS

CE 1434



Test Kit



Swab *5

Test Card*5

Sample Diluent *5

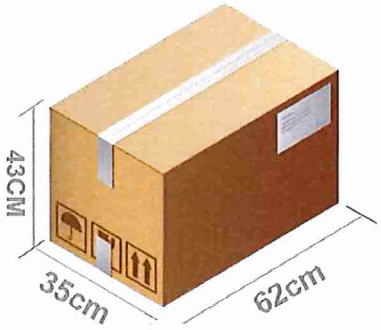
Multilingual instruction *1

fluorecare®

GROUPE TRENOIS

CE 1434

Catalog	MF-68 SARS-Cov-2 Antigen Test Kit (Self -Test)	MF-68 SARS-Cov-2 Antigen Test Kit (Self -Test)
package	soft package	box package
Tests	1T	5T
packages/Carton	650	200
Tests/Carton	650	5*200=1000
Size	62*35*43	63*35*43
Volume(cm^3)	93310	93310
Net weight Carton (KG)	13.5	15.5
Gross weight Carton (KG)	16.5	16.6



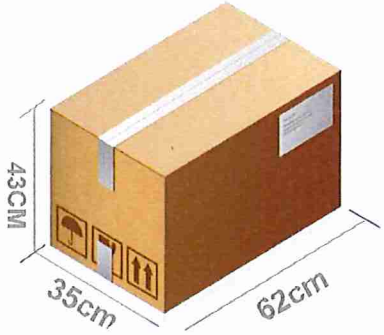
1T

*650 Tests/Carton

*650 Packages/Carton

*Size:62*35*43cm

*Gross weight:16.5kg



5T

*1000 Tests/Carton

*200 Boxes/Carton

*Size:62*35*43cm

*Gross weight:16.6kg

About us

Microprofit Biotech is a national high-tech enterprise from China, the headquarter – Microprofit Building located in the center of Shenzhen city. As an ISO13485 qualified manufacturer since 2009, microprofit biotech specialized in R&D, Manufacture, and Marketing of In-Vitro Diagnostics (IVD) analyzers and test kits, with the idea of POCT (point-of-care-testing), all her products were reliable, easy to use and easily accessible.

Our official brand fluorecare, is dedicated to entire products of point-of-care (POC) tests using immunofluorescence quantitative assay to monitor and prognosis of human diseases with comprehensive parameters, including tumor, hormone, cardiac, infectionand diabetes markers.

Up to the year 2020, the laboratory diagnostic kits of microprofit biotech has been serving almost every top hospitals in China, and laboratories/hospitals/clinics in 40+ countries globally, including Germany, Belgium, Italy, Philippines, Indonesia, Ecuador, Peru, Nigeria，South Africa...

CERTIFICATE

EC Certificate No. 1434-IVDD -491/2021

EC Design -examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

**Shenzhen Microprofit Biotech Co., Ltd. ,
Rm. 405, 406, Zone B /4F, Rm. 205, 206 -1, 207, West Side of Zon e B/ 2F, Haowei Building, No. 8 Langshan 2nd Road, Songpingshan, Songpingshan Community, Xili Street, Nanshan District, Shenzhen, P.R.China**

in vitro diagnostic medical devices
for self-testing

SARS -CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) REF: MF-68

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate : from 22.11.2021 to 27.05.2024

The date of issue of the C ertificate: 22.11.2021

The date of the first issue of the Certificate : 22.11.2021

CE 1434

Issued under the Contract No. MD-76/2021
Application No: 111/2021
Certificate bears the qualified signature.
Warsaw, 22/11/2021
Module A1

Vice -President

fluorecare®

GROUPE TRENOIS

CE 1434

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum Administration

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste.

Microprofit | Los | Aktionen | Zurücksetzen

Nach 'Microprofit' suchen

			Hersteller		Europäischer Bevollmächtigter			Sensitivität		Spezifität		
Test-ID	Name des Tests	Evaluier... PEI	Name	Land	Name	Land	Probennah...	%	95%iges Vertrauensi...	%	95%iges Vertrauensi...	Gebrauc.
AT1308/21	SARS-CoV-2 Antigen Test Kit (...	Nein	Shenzhen Microprofit Biotech ...	CN	CMC MEDICAL DEVICES & DR...	ES	nasal	92,93	89,82 - 95,33	100,00	98,78 - 100	Li...

listed in BfArm Germany

Nombre de tests

3/524

Dans le cadre de la stratégie nationale du schéma vaccinal complet à une dose chez les personnes immunocompétentes sans antécédent connu d'infection au SARS-CoV2, **les TROD sérologiques utilisés doivent détecter a minima les cibles suivantes : IgG antiprotéine S ou IgG antiprotéine N+S.**

Cliquez pour accéder à la liste commune européenne TAG

Signalement

JE SIGNALE

Contextes juridiques

Cliquez pour déplier et télécharger les fichiers des contextes juridiques

Statut: ☐CE ☐CNR ☐UE ☐HAS | Type de test: ---- | Sous-type de test: ---- | Cibles: -- | Type prélèvement: ---- | Rechercher: microprofit

Tableau de bord des tests

Cliquez pour déplier et visualiser les graphes du tableau de bord

3 tests affichés

Options

NOM	FABRICANT	DISTRIBUTEUR	CE	UE	CNR	SOUS-TYPE DE TEST	CIBLES	TYPE DE PRÉLÈVEMENT
SARS-CoV-2 Antigen Test Kit (Colloïdal Gold Chromatographic Immunoassay)(Fluorecare - REF MF-68)	Shenzhen Microprofit Biotech		✓	✓		Antigénique non automatisé (dont TROD)	N	Nasopharyngé
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd.		✓			Autotest	N	
SARS-CoV-2 Antigen Test Kit (Fluoresence Immunoassay) (Fluorecare - REF MF-67)	Shenzhen Microprofit Biotech Co., Ltd.		✓			Antigénique non automatisé (dont TROD)	N	Nasopharyngé

Listed in ANSM France

fluorecare®

GROUPE TRENOIS

CE 1434

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [16]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [17]	Included in EU common list since:
Shenzhen Microprofit Biotech Co., Ltd	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	1967	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Sensitivity: 92.93% Clinical Specificity: 100 % Nasal/NP/OP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	7 July 2021
Shenzhen Microprofit Biotech Co., Ltd.	SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	1178	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct < 25; Manufacturer specificity: 100%	Sensitivity: 86.3%, Specificity: 100% Nasal Swab	DE[2]	Spike protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	23 July 2021
Shenzhen Microprofit Biotech Co., Ltd	SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)	1228	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct < 25; Manufacturer specificity: 100%	Sensitivity: 93.46%, Specificity: 100%	DE[2]	Nucleo-protein, S protein (S1)	Nasopharyngeal swab	8 December 2021

EU Commun List

La notificación se ha realizado correctamente.

Datos de registro	
Código de Expediente:	RPS/2483/2021
Fecha Registro:	29/11/2021 09:18:29
Nº registro General:	RPS/2483/2021
Oficina:	ETEL
Nº registro Oficina:	RPS/2483/2021

Registro de Responsables de Productos Sanitarios - RPS/2483/2021

Datos de la notificación

Datos de registro

Nº Registro	RPS/2483/2021	Fecha Registro	29/11/2021

Datos del Responsable

Tipo de Responsable (*)	Rep. Autorizado	Tipo de entidad	Empresa
CIF(*)	B93316149	Nombre (*)	CMC MEDICAL DEVICES & DRUGS S.L.
Dirección(*)	C/ HORACIO LENGO Nº 18		
Localidad (*)	MALAGA		
Provincia(*)	Málaga	CP(*)	29006
Teléfono(*)	951214054	Fax	
e-mail(*)	info@cmcmedicaldevices.	Web	

Datos del Fabricante

Nombre o Razón Social (*)	Shenzhen Microprofit Biotech Co., Ltd.		
Dirección(*)	Rm.405,406,Zone B/4F,Rm.205,206-1,207,West Side of Zone B/2F,Haowei Building		
Localidad (*)	No. 8 Langshan 2nd Road, Songpingshan, Songpingshan Community, Xili Street,Nanshan District,Shenzhen		
País(*)	República Popular China	CP	
Teléfono(*)	008675561688888	Fax	
e-mail(*)	ts@microprofit.com	Web	

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila

Listado de Productos Sanitarios

Nombre Comercial	Tipo de Producto	Estado del producto	Acción
SARS-COV-2 ANTIGEN TEST KIT (COLLOIDAL GOLD CHROMATOGRAPHIC IMMUNOASSAY)	Diagnostico In Vitro	Primera Comunicación	

Registration in Spain

fluorecare®

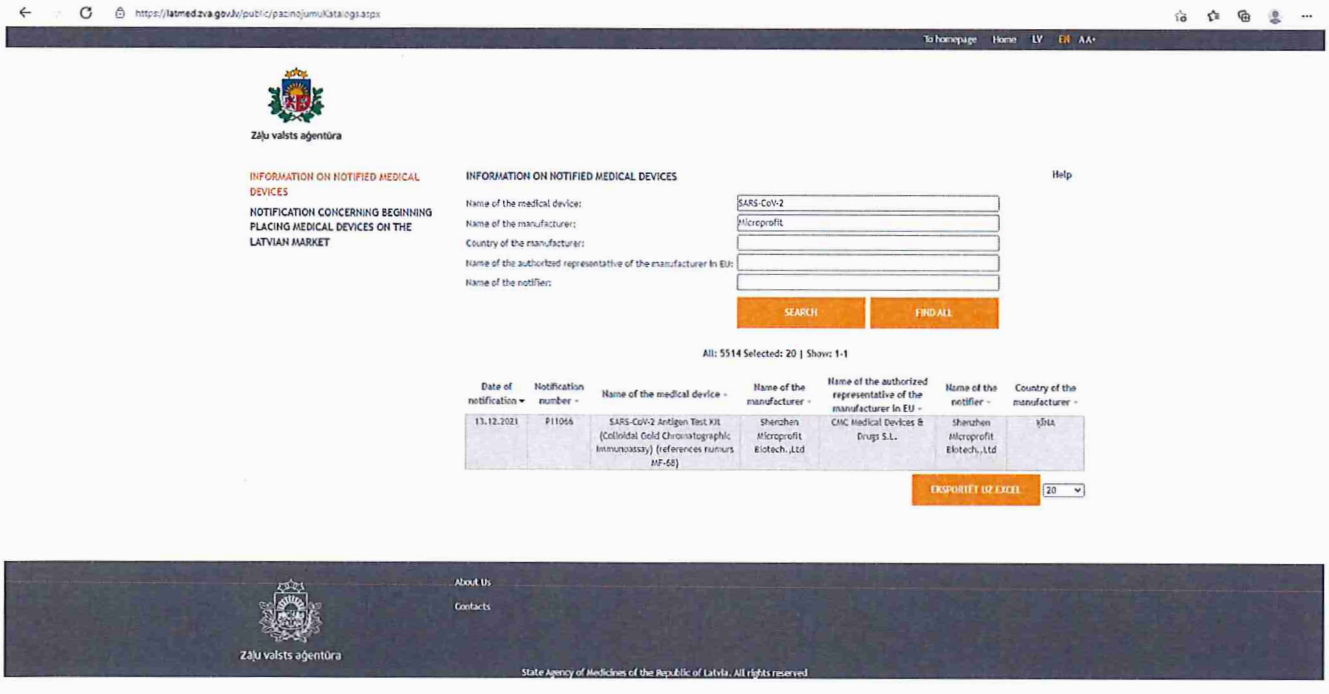
CE 1434

11 MAI 2021 - Arrêté royal portant exécution de l'article 3, § 2, de la loi du 22 décembre 2020 portant diverses mesures relatives aux tests antigéniques rapides et concernant l'enregistrement et le traitement de données relatives aux vaccinations dans le cadre de la lutte contre la pandémie de COVID-19
11 MEI 2021 - Koninklijk besluit tot uitvoering van artikel 3, § 2, van de wet van 22 december 2020 houdende diverse maatregelen met betrekking tot snelle antigeentesten en de registratie en verwerking van gegevens betreffende vaccinaties in het kader van de strijd tegen de COVID-19-pandemie

Fabrikant/Fabricant/Manufacturer	gemachtigde/représentant autorisé/authorised representative	Naam van de test/Nom du test/Name of the test	Referentie/Référence/Reference (marques commerciales/handelsmerken/trademarks)	Datum certificaat Date du certificat Certificate date
Xiamen Boson Biotech Co., Ltd. (CN)	Lotus NL B.V. (NL)	Rapid SARS-CoV-2 Antigen Test Card	1N40C5-2; 1N40C5-4; 1N40C5-6	2021/04/01
Healgen Scientific Limited Liability Company (US)	Shanghai International Holding Corp. GmbH (DE)	CLINITEST Rapid COVID-19 Antigen Self-Test	11556333; 11556327; 11556331; 11556072; 11556236	2021/04/30
Acon Biotech (Hangzhou) Co Ltd. (CN)	MedNet GmbH (DE)	Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	L031-11B5S; L031-11BL5; L031-11BT5;L031-11BA5; L031-11BU5; L031-11BV5; L031-11BQ5; L031-11BM5; L031-11BN5; L031-11BW5; L031-11BP5; L031-11BY5; L031-11BZ5; L031-11BR5	2021/05/14
Sugentech Inc (KR)	Mt Promedt Consulting Gmbh (DE)	SGTi-flex COVID-19 Ag	CAGT001E0	2021/05/07
Hangzhou Alltest Biotech Co, Ltd (CN)	MedNet GmbH (DE)	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H (ALLTEST; Benight; JusChek)	2021/05/28
SD Biosensor (KR)	MT Promedt Consulting GmbH (DE)	SARS-CoV-2 Antigen Self Test Nasal	9901-NCOV-06G	2021/06/04
Biosynex SWISS SA (CH)	/	BIOSYNEX Autotest antigénique COVID-19 Ag	859256; 859261	2021/07/13
Beijing Lepu Medical Technology Co., Ltd (CN)	Lepu Medical (Europe) Cooperatief U.A. (NL)	SARS-CoV-2 Antigen Rapid Tests for Self-testing	CG3601; CG3605; CG3610; CG3625; CG3650	2021/06/21
Hangzhou Alltest Biotech Co, Ltd (CN)	MedNet GmbH (DE)	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H (ALLTEST; Benight; JusChek)	2021/07/05
New Gene (Hangzhou) Bioengineering Co., Ltd (CN)	Sungo Europe B.V. (NL)	COVID-19 Antigen Detection Kit - Nasal Swab	COVID-19-NG21 (1 test - 5 tests - 25 tests /box)	2021/08/11
Abbott Rapid Diagnostics Jena GmbH (DE)	/	Panbio COVID-19 Antigen Self-Test	41FK51; 41FK71; 41FK81; 41FK91	2021/06/25
Hangzhou Sejoy Electronics & Instruments Co.,Ltd. (CN)	Shanghai International Holding Corp.GmbH (Europe) (DE)	SARS-CoV-2 Antigen Rapid Test Cassette	COVG-602ST (1 test - 3 tests - 5 tests /box)	2021/10/22
Acro Biotech, Inc. (USA)	MedNet GmbH (DE)	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	ACO-1001 (1 test - 5 tests/box)	2021/11/18
Shenzhen Microprofit Biotech Co., Ltd. (CN)	CMC MEDICAL DEVICES & DRUGS, S.L. (ES)	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	MF-68 (MF68-1; MF68-5) (Fluorecare)	2021/11/22
Citest Diagnostics Inc. (CA)	CMC MEDICAL DEVICES & DRUGS, S.L. (ES)	COVID-19 Antigen Rapid Test (Swab)	ICOV-5025 (1 test - 5 tests /box)	2021/11/25
Goldsite Diagnostics Inc.(CN)	CMC MEDICAL DEVICES & DRUGS, S.L. (ES)	SARS-CoV-2 Antigen Kit (Colloidal Gold)	CG123001; CG123005; CG123025	2021/11/10

Les versions de ces documents sont les plus récentes reçues par l'AFMPS (des mises à jours ont pu être réalisées)
Deze versies van de documenten zijn de meest recente die het FAGG ontvangen heeft (het zou kunnen dat er updates zijn geweest)
The versions of these documents are the most recent received by the FAMHP (updates may have been made)

Listed in FAMHP Belgium



Listed in Latvia

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Taskforce BAG Covid-19 AG Testung

Sars-CoV-2-Antigen-Schnelltests zur Eigenanwendung (Sars-CoV-2 Selbsttest)[1]
Tests rapides pour l'antigène du SARS-CoV-2 pour auto-application (autotest SARS-CoV-2)
Test rapidi dell'antigene SARS-CoV-2 per uso proprio (test autodiagnostici SARS-CoV-2)

17.12.2021

Die Schnelltests zur Eigenanwendung sind ausschliesslich für den **nasalen Abstrich** validiert und nur dementsprechend anzuwenden. Informationen bezüglich des Einsatzes der Schnelltests finden Sie auf der BAG-Webseite Covid-19-Testung.

Webseite Covid-19 Testung

Les tests rapides pour auto-application sont validés pour les **prélèvements nasaux** uniquement et ne doivent donc être utilisés qu'en conséquence. Ces informations sur l'emploi prévu des tests rapides sont disponibles sur le site web de l'OFSP Tests COVID-19.

Site internet Tests COVID-19

I test rapidi per uso proprio sono convalidati solo per i **tamponi nasali** e dovrebbero essere usati solo di conseguenza.. Le informazioni su come utilizzare i test rapidi sono disponibili sul sito internet dell'UFSP «Test COVID-19».

Sito web Test COVID-19

Hersteller Fabricant Azienda		**Antigen Schnelltest Tests rapides antigéniques Test antigenici rapidi**
Shenzhen Microprofit Biotech Co., Ltd	China	SARS-CoV-2 Antigen Test Kit (colloidal gold Chromatographic Immonoassay)

Wichtige Hinweise:
Information importante :
Avvertenza importante:

[1] Diese Liste beinhaltet SARS-CoV-2-Antigen-Schnelltest, welche die Anforderungen nach Art. 24 der Covid-19-Verordnung 3 erfüllen und zudem entweder eine CE-Zertifizierung als Produkt zur Eigenanwendung einer benannten Stelle besitzen oder eine Ausnahmebewilligung durch Swissmedic als Produkt zur Eigenanwendung besitzen.
Cette liste inclut les tests rapides pour la recherche de l'antigène du SARS-CoV-2 qui remplissent les exigences de l'art. 24 de l'ordonannce 3 COVID-19 et qui sont soit certifiés CE comme dispositif d'autotest par un organisme notifié ou qui ont une dérogation de Swissmedic pour l'auto-application.
Questo elenco comprende i test rapidi per l'antigene SARS-CoV-2 che soddisfano i requisiti dell'art. 24 dell'ordinanza 3 COVID-19 e che hanno una certificazione CE da parte di un organismo notificato come prodotto per uso proprio o un'esenzione di Swissmedic come prodotto per uso proprio.

listed in Switzerland

fluorecare®

GROUPE TRENOIS

CE 1434

Lista de autotestes com marcação CE destinados à deteção do Antigénio do vírus SARS-CoV-2 em amostra nasal notificados ao INFARMED, I.P.

1. A presente informação corresponde aos dispositivos notificados ao INFARMED, I.P. por fabricantes/mandatários e/ou distribuidores por grosso, no âmbito do cumprimento dos requisitos legais aplicáveis.

2. O INFARMED, I.P. disponibiliza a plataforma InfoDM, onde é possível pesquisar toda a informação de registo de dispositivos médicos, notificados ao INFARMED, I.P. por fabricantes/mandatários e/ou distribuidores por grosso, no âmbito do cumprimento dos requisitos legais aplicáveis.

3. A informação disponibilizada no InfoDM, bem como a sua atualização, incluindo as rotulagens e instruções de utilização/folhetos informativos dos dispositivos médicos, é da exclusiva responsabilidade da respetiva entidade notificadora.

4. Dada a possibilidade de atualização da informação relativa a notificações pré-existentes, os distribuidores deverão comunicar ao INFARMED, I.P. qualquer alteração às notificações a que se encontrem associados que reflitam uma incorreção das mesmas.

5. Para informação complementar relativa aos dispositivos incluídos na presente lista, incluindo distribuidores associados, consultar InfoDM.

6. Esta lista é atualizada periodicamente, sendo que o InfoDM apresenta a informação à medida que esta é registada pelas entidades notificadoras ao darem cumprimento aos requisitos de notificação.

Data: 20/12/2021

Nome Comercial	Referência	Fabricante	Distribuidor(es) associado(s)?
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd.	Não

listed in Portugal

fluorecare®

GROUPE TRENOIS

CE 1434

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 109172 0001 Rev. 00

Holder of Certificate: **Shenzhen Microprofit Biotech Co., Ltd**
Rm. 405, 406, Zone B /4F
Rm.205,206-1,207, West Side of Zone B/2F
Haowei Building, No. 8 Langshan 2nd Road
Songpingshan, Songpingshan Community
Xili Street, Nanshan District
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Immunochromatographic Assay Diagnostic Kit, Colloidal Gold Chromatographic Immunoassay Test Kit, and Dry-Type Immunofluorescence Quantitative Analyzer**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 109172 0001 Rev. 00

Report No.: GZ2043601

Valid from: 2021-03-24
Valid until: 2024-03-23

Date, 2021-03-24

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

fluorecare®

GROUPE TRENOIS

CE 1434

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 109172 0001 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Shenzhen Microprofit Biotech Co., Ltd
Rm. 405, 406, Zone B /4F, Rm.205,206-1,207, West Side of Zone B/2F, Haowei Building, No. 8 Langshan 2nd Road, Songpingshan, Songpingshan Community, Xili Street, Nanshan District, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

TÜV®