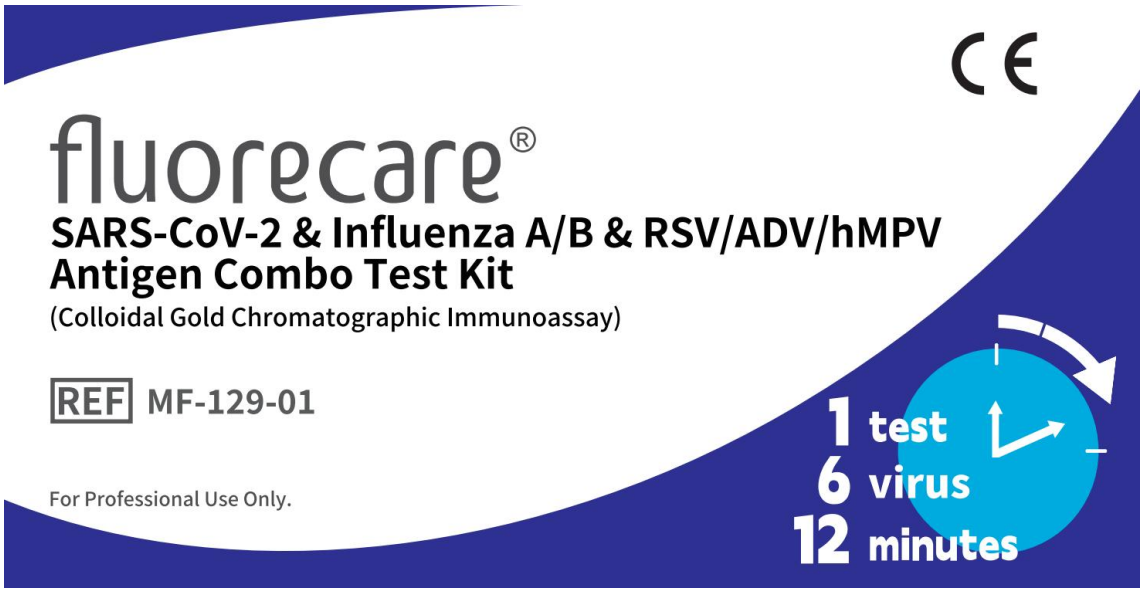
MICROPROFIT | fluorecare®
Creating a NEW impact on point-of-care testing

fluorecare SARS-CoV-2 & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit

Summary Data

(For Professional Use Only)



Shenzhen Microprofit Biotech Co., Ltd.

Contents

Company Profile

The predecessor of Shenzhen Microprofit Biotech Co., Ltd. is the Medical Division established by the Group in 1996, which is specialized in the research, development, product on and sales of biotechnology and intelligent medical equipment. It is a national high-tech enterprise, specialized in speciality, and a new enterprise integrating the research, development, product on and sales of biological reagents, cell therapies, bio-core raw materials, and intelligent medical equipment. The company always adheres to independent innovation, and constantly devotes itself to the research and development of new technology and new products, undertakes several national projects, and has been awarded 51 patents (invention patents, utility models, etc.).

The company has about 10,000 ㎡ GMP product on workshops (2 independent Class 100,000 clean product on workshops and 3 independent Class 10,000 clean workshops), 600 ㎡ instrument product on workshop, 500 ㎡ biochemistry and immunity laboratories, 900 ㎡ biosafety Level 2 laboratories (BSL-2), cellular drug laboratories (GMP Class-B) and GMP Class 100,000 standard PCR laboratory. The company has a high-level pragmatic and elite team, and puts 100% effort and demands into every detail.

We are committed to serving human health with advanced technology, high quality service and economic price, always adhering to the spirit of craftsmen, excellence.

Product Brochure

CE

fluorecare®

SARS-CoV-2 & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit

(Colloidal Gold Chromatographic Immunoassay)

REF MF-129

1 test
6 virus
12 minutes

6 in 1

COVID-19	FLU A	FLU B
RSV	ADV	hMPV

High Performance

Sensitivity:	92.93%
Specificity:	100.00%
Accuracy:	96.82%

Note: This is the clinical accuracy of COVID-19. Please refer to the IFU for more data.

Comprehensive

Effective for mutants Alpha, Beta, Gamma, Delta and Omicron of SARS-CoV-2 ; strains h3n2 and h1n1 of influenza A ; strains victoria and yamagata of influenza B; types A and B of RSV

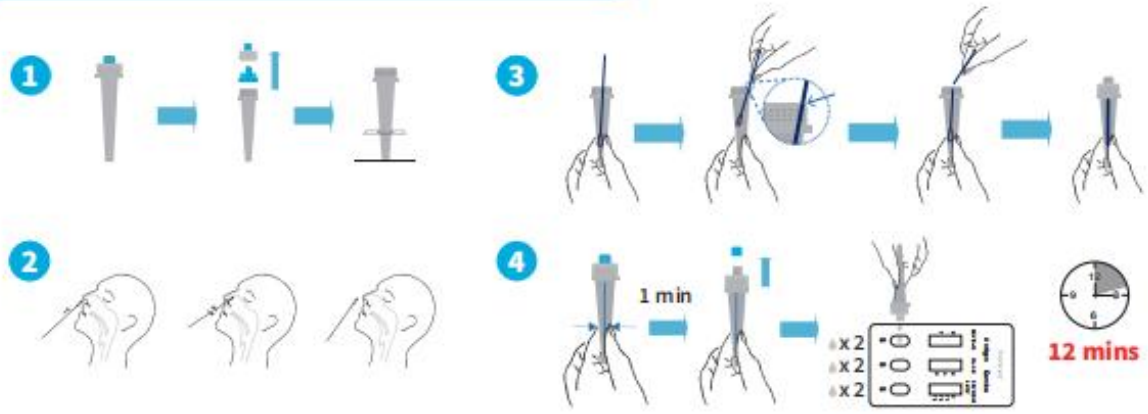
User-Friendly | **Cost-Effective** | **CE Certificate**

Shenzhen Microprofit Biotech Co., Ltd.
Add: Room 1101 of Unit 1, Building 2, Hongchuang Technology Center, Xikeng Community, Fucheng Sub-district, Longhua District, Shenzhen, Guangdong, P.R.China
Tel: 86-755-29303416, 86-755-61688835
E-mail: bio@microprofit.com/bio@microprofit-bio.com
Website: www.microprofit-bio.com

Characteristics

Method	Colloidal Gold Chromatographic Immunoassay
Reaction Time	12 mins
Shelf Life	24 months
Storage Temperature	2-30℃
Sample Types	Oropharyngeal swab, Nasal swab and Nasopharyngeal swab
Specification	1 Test/box, 25 Tests/box

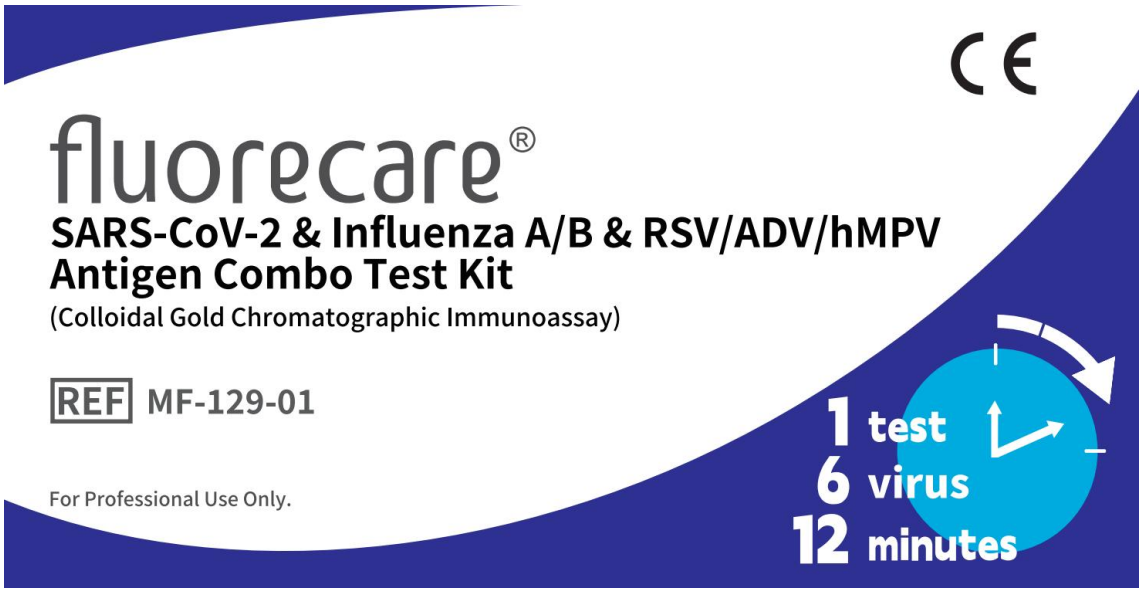
Brief Operation Procedure

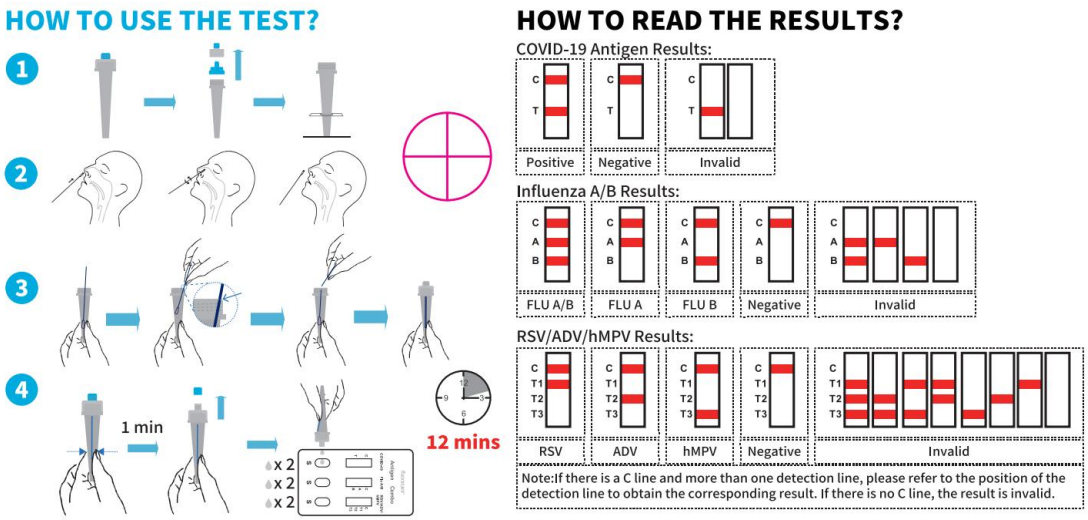


Components of 1 Test

Product Photos

1 Test/Kit:





25 Tests/Kit:


fluorecare®
25 Tests/Box
www.microprofit-bio.com
MICROPROFIT
SARS-CoV-2 & Influenza A/B & RSV/ADV/hMPV Antigen
Combo Test Kit
(Colloidal Gold Chromatographic Immunoassay)
REF MF-129
25 Tests
IVD
LOT 24002
2024.08.02
2026.08.01
For Professional Use Only!

Packing Information

1T/ Kit								
Packaging type	length (cm)	Width (cm)	height (cm)	Kits(t) /Carton	Net weight (kg)/Kit	Gross weight (kg)/Carton	Net weight (kg)/Carton	Volume weight (kg)/Carton
carton	67	35	43	500	0.030kg	17.2kg	15.15kg	16.8kg

25T/ Kit								
Packaging type	length (cm)	Width (cm)	height (cm)	Kits(t) /Carton	Net weight (kg)/Kit	Gross weight (kg)/Carton	Net weight (kg)/Carton	Volume weight (kg)/Carton
carton	58	44	43	40	0.49kg	21.60kg	19.60kg	18.3kg

For reference only, shipping cost according to the actual weight of the airline department.

CE Certificate

CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 证书 자격증

EC REP

Ver. CERT-202303.V1

CERTIFICATE

ECREP20240517.1

CMC MEDICAL DEVICES

CMC MEDICAL DEVICES & DRUGS S.L.

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Shenzhen Microprofit Biotech Co.,Ltd.
Room 1001 of Unit 2, Room 1001 and Room 1101 of Unit 1, Building 2, Hongchuang Technology Center, Xikeng Community, Fucheng Sub-district, Longhua District, 518000 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

The certificate remains valid until the expiration date of the EC REP agreement, or until manufacturing conditions, quality system or relevant legislation are modified. The validity is subject to positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive/regulation mentioned in Annex I of this certificate and the applicable standards. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix the appropriate CE marking to the relevant models of the medical devices mentioned below.
These products included in the Annex I have been registered in the Spanish MOH (AEMPS) if applicable. In this case, the column categorized as RPS reffers to their registration number.

CE

CMC

Authorized Signature

Issue date: 17/05/2024

Expiration date: 08/03/2025

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification code

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EC REP

CERTIFICATE

ECREP20240517.1

Ver. CERT-202303.V1

CMC MEDICAL DEVICES

ANNEX I

Product Name	CLASS	REGULATION	RPS	Status RPS
VB12 Control	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
Thyroid Stimulating Hormone (TSH) Diagnostic Kit (Immunochromatographic Assay)	IVD OTHERS•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
Thyroid peroxidase antibody (Anti-TPO) Diagnostic Kit (Immunochromatographic Assay)	IVD OTHERS•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2/RhV/PIV & Influenza A/B & RSV/ADV/ hMPV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVDD - Directive 98/79	RPS/1206/2024	Registered with AEMPS
SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)	IVD OTHERS	IVDD - Directive 98/79	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 Neutralizing Antibody Test Kit (Fluorescence Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 Neutralizing Antibody Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 IgG and IgM Antibody Combined Test Kit (Fluorescence Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 IgG and IgM Antibody Combined Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 Antigen Test Kit (Fluorescence Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)(Saliva)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) (Saliva)	CLASS SELF TESTING•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS

Issue date: 17/05/2024 **Expiration date: 08/03/2025**

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EC REP

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ECREP20240517.1

Ver. CERT-202303.V1

CMC MEDICAL DEVICES

Product Name	CLASS	REGULATION	RPS	Status RPS
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	CLASS SELF TESTING	IVD - Directive 98/79•	-	Obsolete
SARS-CoV-2 Antibody Test Kit (Fluorescence Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 Antibody Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 & Influenza A/ B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 & Influenza A/ B & RSV/ADV/hMPV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVD - Directive 98/79	RPS/531/2024	Registered with AEMPS
SARS-CoV-2 & Influenza A/ B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
SARS-CoV-2 & Influenza A/ B RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	CLASS SELF TESTING•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
Rubella Virus IgG Antibody (RV-IgG) Diagnostic Kit (Immunochromatographic Assay)	IVD OTHERS	IVDD - Directive 98/79	-	Obsolete
Malaria Pf/Pv antigen Test Kit (Immunochromatographic Assay)	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
Malaria Pf/Pan Antigen Test Kit (Immunochromatographic Assay)	others	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
Malaria Pf / Pv Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
I-PTH Control	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
Herpes Simplex Virus-1 IgG (HSV-1 IgG) Diagnostic Kit (Immunochromatographic Assay)	IVD OTHERS	IVDD - Directive 98/79	RPS/1206/2024	Registered with AEMPS

Issue date: 17/05/2024

Expiration date: 08/03/2025

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

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EC REP

CERTIFICATE

ECREP20240517.1

Ver. CERT-202303.V1

CMC MEDICAL DEVICES

Product Name	CLASS	REGULATION	RPS	Status RPS
Helicobacter pylori Antigen (Hp-Ag) Diagnostic Kit (Immunochromatographic Assay)	IVD OTHERS•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
Glycosylated Hemoglobin(Hb A1c)Diagnostic Kit(Immunochromatographic Assay)	IVD OTHERS•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
FOB Quantitative Control	IVD OTHERS	IVDD - Directive 98/79	RPS/1206/2024	Registered with AEMPS
fluorecare COVID-19 & Influenza A/B Antigen Combo Test Kit(Colloidal Gold)	IVD OTHERS•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
Ferritin (FERR) Diagnostic Kit (Immunochromatographic Assay)	IVD OTHERS•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
Fecal Occult Blood (FOB) Quantitative Detection Kit (Immunochromatographic Assay)	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
Fecal Calprotectin Quantitative Detection Kit (Immunochromatographic Assay)	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
Fecal Calprotectin Quantitative Control	IVD OTHERS	IVDD - Directive 98/79	RPS/1206/2024	Registered with AEMPS
cTnT Control	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
C-Reactive Protein (CRP) Diagnostic Kit (Immunochromatographic Assay)	IVD OTHERS•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS
ASO Contorol	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
Anti-TPO Control	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
Anti-cyclic citrullinate peptide antibody (Anti-CCP) Diagnostic Kit (Immunochromatographic Assay)(semi-quantitative)	IVD OTHERS	IVD - Directive 98/79	RPS/611/2024	Registered with AEMPS
25-Hydroxyvitamin-D (25-OH-D) Diagnostic Kit (Immunochromatographic Assay)	IVD OTHERS•	IVD - Directive 98/79•	RPS/611/2024	Registered with AEMPS

#41

Issue date: 17/05/2024

Expiration date: 08/03/2025

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification code

GOBIERNO DE ESPAÑA · MINISTERIO DE SANIDAD · agencia española de medicamentos y productos sanitarios

DEPARTAMENTO DE
PRODUCTOS SANITARIOS

N/REF: PS/RPS/1206/2024

O F I C I O

Comunicación: RPS/1206/2024
Nº AEMPS: 24-01816
Fecha: 13/05/2024
Asunto: **Anotación de la comunicación en el Registro de Responsables de la puesta en el mercado de Productos Sanitarios**

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo, 18.
29006 - Málaga
MÁLAGA
Andalucía

Con fecha **13/05/2024** ha sido **registrada** en la aplicación de Registro de Responsables de la puesta de mercado de Productos Sanitarios (RPS) de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) la comunicación presentada por **CMC Medical Devices & Drugs S.L.**, con la siguiente información:

1. Número de identificación asignado en el registro

RPS/1206/2024

2. Responsable de la puesta en el mercado de los productos sanitarios

Empresa **CMC Medical Devices & Drugs S.L.**
C/ Horacio Lengo, 18.
29006 - Málaga (MÁLAGA)
Andalucía

En calidad de **Representante**

3. Legislación que declara cumplir:

DIV - Directiva 98/79/EC.

4. Página(s) adicional(es) de productos sanitarios incluidos en esta comunicación.

REGISTRO DE RESPONSABLES DE LA PUESTA EN EL MERCADO DE PRODUCTOS SANITARIOS
DEPARTAMENTO DE PRODUCTOS SANITARIOS

Nota.- Esta notificación no tiene el carácter de una autorización sanitaria de comercialización, ni entraña un juicio sobre la conformidad del producto con la legislación vigente.Únicamente avala el cumplimiento del Registro de Responsables según el artículo 9 del RD 1662/2000 por el que se regulan los Productos Sanitarios para Diagnóstico in vitro.

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: 91 822 54 99
Fax: 91 822 52 89

GOBIERNO DE ESPAÑA · MINISTERIO DE SANIDAD · agencia española de medicamentos y productos sanitarios

DEPARTAMENTO DE
PRODUCTOS SANITARIOS

N/REF: PS/RPS/1206/2024

ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
1 - Fecal Calprotectin Quantitative Control PARA DIAGNÓSTICO "IN VITRO" Autocertificación	07/05/2024 Fecal Calprotectin Quantitative Control is intended for in vitro diagnostic use in the quality control of Fecal Calprotectin Quantitative Detection Kit. For in vitro diagnostic use only. For professional use only.

Fabricante	**Pais**
Shenzhen Microprofit Biotech Co., Ltd.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

2 - FOB Quantitative Control PARA DIAGNÓSTICO "IN VITRO" Autocertificación	07/05/2024 FOB Quantitative Control is intended for in vitro diagnostic use in the quality control of Fecal Occult Blood (FOB) Quantitative Detection Kit. For in vitro diagnostic use only. For professional use only.

Fabricante	**Pais**
Shenzhen Microprofit Biotech Co., Ltd.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

3 - Herpes Simplex Virus-1IgG (HSV-1IgG) Diagnostic Kit (Immunochromatographic Assay) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	07/05/2024 The fluorecare® HSV-1IgG is applicable to the quantitative detection of the concentration of HSV-1IgG in human serum or plasma. It is mainly used for auxiliary diagnosis of HSV-1IgG infection.For Professional Use Only.

Fabricante	**Pais**
Shenzhen Microprofit Biotech Co., Ltd.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: 91 822 54 99
Fax: 91 822 52 89

GOBIERNO DE ESPAÑA · MINISTERIO DE SANIDAD · agencia española de medicamentos y productos sanitarios

DEPARTAMENTO DE PRODUCTOS SANITARIOS

N/REF: PS/RPS/1206/2024

ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
4 - SARS-CoV-2/RhV/PIV & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	07/05/2024 The fluorecare® SARS-CoV-2 / RhV/ PIV & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit is applicable to the simultaneous qualitative detection and differentiation in vitro of novel Coronavirus (SARS-CoV-2) antigen, Influenza A virus antigen, Influenza B virus antigen, RSV antigen, Adenovirus(ADV) antigen, Human Metapneumovirus(hPMV) antigen , RhV antigen , PIV antigen in Oropharyngeal swab, Nasal swab and Nasopharyngeal swab samples. It can be used as an aid in the diagnosis of coronavirus infectious disease (COVID-19) caused by SARS-CoV-2 in symptomatic patients within 7 days of onset and in the diagnosis of diseases caused by RhV, PIV, Influenza A/B, RSV,ADV,hMPV. For professional use only. For in vitro diagnostic use only.

Fabricante	**Pais**
Shenzhen Microprofit Biotech Co., Ltd.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: 91 822 54 99
Fax: 91 822 52 89

MICROPROFIT | fluorecare®
Creating a NEW impact on point-of-care testing

ISO13485 Certificate

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

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

TÜV SÜD Product Service

Certificate

No. Q5 109172 0001 Rev. 01

Holder of Certificate: **Shenzhen Microprofit Biotech Co., Ltd**
Room 1001 of Unit 2
Room 1001 and Room 1101 of Unit 1
Building 2, Hongchuang Technology Center
Xikeng Community, Fucheng Sub-district
Longhua District
518000 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents and In Vitro Diagnostic instruments for Immunochemistry**

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. 01

Report No.: GZ2343602, GZ2343602-CN

Valid from: 2024-03-24
Valid until: 2027-03-23

Date, 2024-02-01

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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. 01

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies): **Shenzhen Microprofit Biotech Co., Ltd**
Room 1001 of Unit 2, Room 1001 and Room 1101 of Unit 1, Building 2, Hongchuang Technology Center, Xikeng Community, Fucheng Sub-district, Longhua District, 518000 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Declaration of Conformity

MICROPROFIT

DECLARATION OF CONFORMITY

MANUFACTURER	**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, Shenzhen, P.R. China
EUROPEAN REPRESENTATIVE	CMC MEDICAL DEVICES & DRUGS, S.L. C/ Horacio Lengo n18 · C.P 29006 · Málaga-Spain
BRAND	fluorecare®
PRODUCT	See the attachment
CLASSIFICATION	Other Device of IVDD 98/79/EC
CONFORMITY ASSESSMENT	Annex III of IVDD 98/79/EC

We the manufacturer herewith declare on our solo responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.
The products comply with the essential requirements in accordance with Annex I of the IVDD 98/79/EC.

STANDARDS APPLIED	EN 13612:2002/AC: 2002	EN ISO 13485:2016
	EN ISO 14971:2012	EN ISO 23640:2015
	EN ISO 18113-1:2011	EN ISO 18113-2:2011
	EN ISO 15223-1:2016	EN 13641:2002
	EN 62366-1:2015	

PLACE	Shenzhen, China
DATE OF ISSUE	2022-5-25
SIGNATURE	General Manager

CE

ATTACHMENT

No.	Catalog No.	Product name
1	MF-120	25-Hydroxyvitamin-D (25-OH-D) Diagnostic Kit (Immunochromatographic Assay)
2	MF-127	Anti-cyclic citrullinate peptide antibody (Anti-CCP) Diagnostic Kit (Immunochromatographic Assay)(semi-quantitative)
3	MF-278	Anti-TPO Control
4	MF-275	ASO Control
5	MF-118	C-Reactive Protein (CRP) Diagnostic Kit (Immunochromatographic Assay)
6	MF-274	cTnT Control
7	MF-125	Fecal Calprotectin Quantitative Detection Kit (Immunochromatographic Assay)
8	MF-126	Fecal Occult Blood (FOB) Quantitative Detection Kit (Immunochromatographic Assay)
9	MF-119	Ferritin (FERR) Diagnostic Kit (Immunochromatographic Assay)
10	MF-66	fluorecare COVID-19 & Influenza A/B Antigen Combo Test Kit(Colloidal Gold)
11	MF-122	Glycosylated Hemoglobin(HbA1c)Diagnostic Kit(Immunochromatographic Assay)
12	MF-80	Helicobacter pylori Antigen (Hp-Ag) Diagnostic Kit (Immunochromatographic Assay)
13	MF-276	I-PTH Control
14	MF-123	Malaria Pf / Pv Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
15	MF-116	Malaria Pf/Pan Antigen Test Kit (Immunochromatographic Assay)
16	MF-124	Malaria Pf/Pv antigen Test Kit (Immunochromatographic Assay)
17	MF-71-1	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
18	MF-71-2	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
19	MF-71-5	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
20	MF-71	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
21	MF-69	SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
22	MF-59	SARS-CoV-2 Antibody Test Kit (Colloidal Gold Chromatographic Immunoassay)
23	MF-62	SARS-CoV-2 Antibody Test Kit (Fluorescence Immunoassay)
24	MF-68	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
25	MF-91-1	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic

		Immunoassay) (Saliva)
26	MF-91-2	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) (Saliva)
27	MF-91-5	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) (Saliva)
28	MF-91	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)(Saliva)
29	MF-67	SARS-CoV-2 Antigen Test Kit (Fluorescence Immunoassay)
30	MF-61	SARS-CoV-2 IgG and IgM Antibody Combined Test Kit (Colloidal Gold Chromatographic Immunoassay)
31	MF-64	SARS-CoV-2 IgG and IgM Antibody Combined Test Kit (Fluorescence Immunoassay)
32	MF-90	SARS-CoV-2 Neutralizing Antibody Test Kit (Colloidal Gold Chromatographic Immunoassay)
33	MF-70	SARS-CoV-2 Neutralizing Antibody Test Kit (Fluorescence Immunoassay)
34	MF-60	SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)
35	MF-63	SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)
36	MF-121	Thyroid peroxidase antibody (Anti-TPO) Diagnostic Kit (Immunochromatographic Assay)
37	MF-117	Thyroid Stimulating Hormone (TSH) Diagnostic Kit (Immunochromatographic Assay)
38	MF-277	VB12 Control
39	MF-129	SARS-CoV-2 & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
40	MF-83	Herpes Simplex Virus-1IgG (HSV-1IgG) Diagnostic Kit (Immunochromatographic Assay)
41	MF-130	SARS-CoV-2/RhV/PIV & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
42	MF-283	Fecal Calprotectin Quantitative Control
43	MF-282	FOB Quantitative Control

Shenzhen Microprofit Biotech Co., Ltd.

Declaration of Conformity (DOC) Corrigendum

Product name:	See the attachment
Model:	See appendix for details
Class:	Other Device of IVDD 98/79/EC
Date of the DOC:	2022-05-25

This corrigendum intends to correct the following information in DoC(s) of the above listed product(s).

Change Old Manufacturing Address:	*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, Shenzhen, P.R. China.*
To new Manufacturing Address:	*Room 1001 of Unit 2, Room 1001 and Room 1101 of Unit 1, Building 2, Hongchuang Technology Center, Xikeng Community, Fucheng Sub-district, Longhua District, 518000 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA*

According to Regulation (EU) 2017/746 (IVDR), for legacy devices according to Art. 110 (3), no changes to DOCs signed prior to May 26, 2022 can be performed. In case of the above described non-significant change(s) (as defined in MDCG 2022-6), the existing DOC(s) is (are) still valid and this Corrigendum will be attached to the originally signed DOC(s). The DOC(s) will be updated upon transition to IVDR.

...Shenzhen, China.....2024.03.07
Place/Date

.....
legally binding signature

...Liu Ying.....General Manager....
Name and function

ATTACHMENT

No.	Catalog No.	Product name
1	MF-120	25-Hydroxyvitamin-D (25-OH-D) Diagnostic Kit (Immunochromatographic Assay)
2	MF-127	Anti-cyclic citrullinate peptide antibody (Anti-CCP) Diagnostic Kit (Immunochromatographic Assay)(semi-quantitative)
3	MF-278	Anti-TPO Control
4	MF-275	ASO Control
5	MF-118	C-Reactive Protein (CRP) Diagnostic Kit (Immunochromatographic Assay)
6	MF-274	cTnT Control
7	MF-125	Fecal Calprotectin Quantitative Detection Kit (Immunochromatographic Assay)
8	MF-126	Fecal Occult Blood (FOB) Quantitative Detection Kit (Immunochromatographic Assay)
9	MF-119	Ferritin (FERR) Diagnostic Kit (Immunochromatographic Assay)
10	MF-66	fluorecare COVID-19 & Influenza A/B Antigen Combo Test Kit(Colloidal Gold)
11	MF-122	Glycosylated Hemoglobin(HbA1c)Diagnostic Kit(Immunochromatographic Assay)
12	MF-80	Helicobacter pylori Antigen (Hp-Ag) Diagnostic Kit (Immunochromatographic Assay)
13	MF-276	I-PTH Control
14	MF-123	Malaria Pf / Pv Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
15	MF-116	Malaria Pf/Pan Antigen Test Kit (Immunochromatographic Assay)
16	MF-124	Malaria Pf/Pv antigen Test Kit (Immunochromatographic Assay)
17	MF-71-1	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
18	MF-71-2	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
19	MF-71-5	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
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