CERTYFIKATY FLUORECARE

CeCert.

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

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

in vitro diagnostic medical device for self-testing

fluorecare SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit
catalogue numbers: MF-71-1, MF-71-2, MF-71-5

in term of the design conforms to the requirements of Annex III section 6 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 12.05.2022 – 26.05.2025
Edition issue date: 18.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
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www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/092/W/E.2

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
Product Name:	fluorecare SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit
Common Name:	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
Brand:	fluorecare®
Catalogue No.:	MF-71-1, MF-71-2, MF-71-5
Classification:	Self-testing Device of IVDD 98/79/EC

Conformity Assessment Route: Annex III of 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

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.

DIRECTIVES

General applicable directives:

In Vitro Diagnostic Medical Device Directive: COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning in vitro diagnostic medical devices (IVDD 98/79/EC).

Notified Body:	CeCert
Identification number:	CE 2934
(EC) Certificate(s):	CeCert/092/W/E.1
Expire date of the Certificate:	2025.05.26

DATE OF ISSUE: **2022.05.12**

SIGNATURE:

N/REF: PS/RPS/3418/2022

O F I C I O

Comunicación: RPS/3418/2022
Nº AEMPS: 22-03417
Fecha: 24/05/2022
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
Horacio lengo, 18
29006 - Málaga
MÁLAGA
Andalucía

Con fecha **24/05/2022** 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/3418/2022

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

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

En calidad de **Representante**

3. 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

N/REF: PS/RPS/3418/2022

ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Nombre comercial Tipo de producto	**Fecha de comercialización** Finalidad
1 - SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay) PARA DIAGNÓSTICO "IN VITRO" Autodiagnóstico	23/05/2022 The fluorecare® SARS-CoV-2 & Influenza A/B & RSV Antigen Combined Test Kit is applicable to the simultaneous qualitative detection and differentiation of novel Coronavirus (SARS-CoV-2 Antigen), Influenza A virus, Influenza B virus Antigen and/or RSV Antigen in population Nasal swabs samples in vitro. It can be used as an aid to diagnose coronavirus infection disease (COVID-19), caused by SARS-CoV-2, in symptomatic patients within 7 days of onset. It can also be used to aid in the diagnosis of diseases caused by Influenza A/B or RSV. For in vitro diagnostic use only. For self-testing use.
Fabricante	**Pais**
Shenzhen Microprofit Biotech Co.,Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
2 - SARS-CoV-2 Antigen Test Kit(Colloidal Gold Chromatographic Immunoassay) ¿ Saliva¿ PARA DIAGNÓSTICO "IN VITRO" Autodiagnóstico	23/05/2022 The fluorecare® SARS-CoV-2 Antigen Test Kit is applicable to the qualitative detection novel Coronavirus (SARS-CoV-2) Antigen in population saliva samples in vitro. It is intended as an aid in the diagnosis of coronavirus infection disease (COVID-19) for symptomatic patients within 7 days after onset of symptoms, which is caused by SARSCoV-2. For in vitro diagnostic use only. For self-testing use. This kit is suitable for people over 2 years old.People under the age of 2-12 cannot operate by themselves. This kit should be used by adults or parents (18-60 years old) for sample collection and testing. People aged 13-17 can use this kit to collect samples and test samples under the supervision of adults or parents (18-60 years old). Supervisors should ensure that users have a detailed understanding of the requirements of the instructions and watch whether the user's operation is correct. For people over 75 years old, it is recommended that family members or guardians (18-60 years old) use this kit to collect samples and test samples.
Fabricante	**Pais**
Shenzhen Microprofit Biotech Co.,Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China

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