



N/REF: PS/CLV/MR/0094/2021-CLV

Carmen Ruiz-Villar Fernández-Bravo

LA JEFE DEL DEPARTAMENTO DE PRODUCTOS SANITARIOS

**AGENCIA ESPAÑOLA DE MEDICAMENTOS Y
PRODUCTOS SANITARIOS (AEMPS)**

**THE SPANISH AGENCY OF MEDICINES AND
MEDICAL DEVICES (AEMPS)**

CERTIFICA: Que en base a las declaraciones y/o
certificados aportados:

CERTIFIES: On the basis of the declarations and/or
certificates provided:

La empresa CMC MEDICAL DEVICES & DRUGS
S.L., con sede en Calle HORACIO LENGU, nº 18,
29006 - MÁLAGA ESPAÑA, es Representante
Autorizado en la Unión Europea del fabricante
SINGUWAY BIOTECH INC., con sede en B1302,
Life Science Park, Shen Cheng Tou Innovation Factory,
Julongshan A Road, Xiuxin Community, Kengzi Street,
Pingshan District, Shenzhen City, 518122, Guangdong
Province, REPÚBLICA POPULAR CHINA, de los
productos relacionados en el **Anexo I**.

The company CMC MEDICAL DEVICES & DRUGS
S.L., based in Calle HORACIO LENGU, nº 18, 29006
- MÁLAGA SPAIN, is the Authorised Representative
in the European Union of the manufacturer
SINGUWAY BIOTECH INC., based in B1302, Life
Science Park, Shen Cheng Tou Innovation Factory,
Julongshan A Road, Xiuxin Community, Kengzi Street,
Pingshan District, Shenzhen City, 518122, Guangdong
Province, PEOPLES REPUBLIC OF CHINA, of the
products listed in **Annex I**.

Los productos relacionados en el **Anexo I**, disponen de
marcado CE de acuerdo a lo previsto en el Real
Decreto 1662/2000 de 29 de septiembre, transposición
a la legislación nacional de la Directiva 98/79/CE del
Parlamento Europeo y del Consejo de 27 de octubre de
1998 sobre productos sanitarios para diagnóstico *in
vitro*, lo que permite su comercialización en España y
en el resto de países de la Unión Europea, no existiendo
trabas para su exportación.

The products listed in **Annex I**, have been affixed with
the CE mark under the Directive 98/79/EC of the
European Parliament and of the Council of 27 October
1998, on *in vitro* diagnostic medical devices and the
Royal Decree 1662/2000 of 29 September,
transposition to the Spanish legislation, and therefore
they can be marketed in Spain and in the rest of the
European Union countries, without export restrictions.

Ha realizado la notificación al Registro de responsables
de la comercialización de los citados productos de
acuerdo a lo previsto en el artículo 10 de la Directiva
98/79/CE.

Has submitted the notification to the Registration of
persons responsible for placing devices on the market,
according to the article 10 of the Council Directive
98/79/CE.

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 10/02/2021

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Tel.: 91 822 54 99
Fax: 91 822 52 89

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Este certificado se expide en base a la documentación presentada por la empresa en el momento de su emisión y no supone una autorización sanitaria de comercialización de los productos por parte de esta Agencia.

This certificate is issued on the basis of the documentation provided by the company at the time of its issuance and it should not be taken as an AEMPS marketing authorization of the products.

Y para que conste y surta los efectos oportunos ante quien corresponda, lo firmo en Madrid.

Signed and issued as evidence thereof to be effective to whom it may concern, in Madrid.

 **am** agencia española de
medicamentos y
productos sanitarios
Departamento de Productos Sanitarios

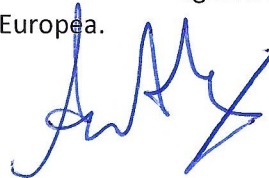
Fdo. Carmen Ruiz-Villar Fernández-Bravo

D. Antonio González Fernández, Jefe de Sección de la Subdirección General de Relaciones Internacionales y Publicaciones del Ministerio de Sanidad, reconoce como auténtica la firma de este documento mediante el certificado electrónico del sello AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) emitido por la FNMT-RCM (Fábrica Nacional de Moneda y Timbre - Real Casa de la Moneda), certificado conforme al Reglamento 910/2014, anexo III, de la Unión Europea.

Madrid,

15 FEB. 2021





SUBDIRECCIÓN GENERAL DE
RELACIONES INTERNACIONALES
Y PUBLICACIONES

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ANEXO I DEL CERTIFICADO N° 0094/2021-CLV
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PRODUCTOS SANITARIOS PARA DIAGNÓSTICO *IN VITRO* REFERENCIADOS EN EL CERTIFICADO
IN VITRO DIAGNOSTIC MEDICAL DEVICES LISTED IN THE CERTIFICATE

Producto / Product Referencia y modelo / Reference and model	Fabricante / Manufacturer Domicilio social / Registered office
1 - COVID-19 Ag Test (2019-nCoV) New Coronavirus Antigen Test(Colloidal Gold) (Mod: 25tests/kit)	SINGUWAY BIOTECH INC. B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN
2 - COVID-19 IgG/IgM Detection Kit (Colloidal Gold) (Mod: 20 tests / kit)	SINGUWAY BIOTECH INC. B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN
3 - Detection Kit For Coronavirus Disease 2019(COVID-19)(PCR Fluorescence Probe) (Mod: 48 tests/ kit)	SINGUWAY BIOTECH INC. B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN
4 - Disposable Virus Sampling Kit (Mod: 1test/pack)	SINGUWAY BIOTECH INC. B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L

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Producto / Product

Referencia y modelo / Reference and model

Fabricante / Manufacturer

Domicilio social / Registered office

CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN

5 - DNA Extractor

(Mod: Singu40)

SINGUWAY BIOTECH INC.

B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen

City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

Representante autorizado / Authorised representative

CMC Medical Devices & Drugs S.L

CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN

6 - DNA Extractor

(Mod: Singu42)

SINGUWAY BIOTECH INC.

B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen

City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

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CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN

7 - DNA Extractor

(Mod: Singu44)

SINGUWAY BIOTECH INC.

B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen

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8 - DNA Extractor

(Mod: Singu46)

SINGUWAY BIOTECH INC.

B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen

City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

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9 - DNA /RNA Extraction Reagent Kit (Mod: 48 tests/ kit)	SINGUWAY BIOTECH INC. B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN
10 - Nucleic Acid Extractor (Mod: Singu32)	SINGUWAY BIOTECH INC. B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN
11 - Nucleic Acid Extractor (Mod: Singu48)	SINGUWAY BIOTECH INC. B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN
12 - Nucleic Acid Extractor (Mod: Singu96)	SINGUWAY BIOTECH INC. B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN
13 - Real-time PCR Quantitative System (Mod: Singu9600)	SINGUWAY BIOTECH INC.

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Producto / Product

Referencia y modelo / Reference and model

Fabricante / Manufacturer

Domicilio social / Registered office

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City, 518122, Guangdong Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

Representante autorizado / Authorised representative

CMC Medical Devices & Drugs S.L

CALLE HORACIO LENGU 18, 29006 - ESPAÑA / SPAIN

14 - Real-time PCR Quantitative System

(Mod: Singu9600pro)

SINGUWAY BIOTECH INC.

B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen
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