

N/REF: PS/CLV/MGCO/1145/2022-CEX

**Certificado de exportación de
Productos Sanitarios de Diagnostico In Vitro**

**Export Certificate
In Vitro Diagnostics Medical Devices**

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 C/ Horacio Lengo, 18., 29006 - Málaga (MÁLAGA), ESPAÑA, es Representante Autorizado en la Unión Europea del fabricante HANGZHOU FUNWORLD BIOTECH CO., LTD, con sede en 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA, de los productos relacionados en el **Anexo I**.

The company CMC Medical Devices & Drugs S.L., based in C/ Horacio Lengo, 18., 29006 - Málaga (MÁLAGA), SPAIN, is the Authorised Representative in the European Union of the manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD, based in 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, 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* y se acogen al artículo 110 del Reglamento (UE) 2017/746 de 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 in accordance with article 110 of Regulation (UE) 2017/746 of In Vitro Medical Devices, 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 article 10 of the Council Directive 98/79/EC.

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

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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.

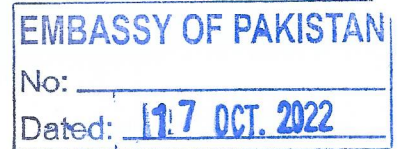
Y para que conste y surta los efectos oportunos ante las Autoridades Sanitarias de **Pakistán**, lo firmo en Madrid.

Signed and issued as evidence thereof to be effective with the Health Authorities of **Pakistan**, in Madrid.

The Embassy is not responsible for the contents of the documents, Seal and Signature of the Spanish Ministry of Foreign Affairs and Cooperation are legalized



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



Fdo. Carmen Ruiz-Villar Fernández-Bravo

MINISTERIO DE ASUNTOS EXTERIORES Y DE COOPERACION
LEGALIZACIONES
Visto Bueno para legalizar la firma que antecede por ser, al parecer, auténtica, sin prejuzgar la veracidad del contenido del documento ni ulterior destino que pueda dársele.

Madrid,

03 OCT 2022

P. EL SUBSECRETARIO


Mª Teresa Gómez García-Oliva
Jefe de Negociado



MUHAMMAD MOAZZAM MUNIR
CONSULAR ATTACHÉ
EMBASSY OF PAKISTAN
MADRID



SUBDIRECCIÓN GENERAL DE RELACIONES INTERNACIONALES Y PUBLICACIONES

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,

21 SEP. 2022



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ANEXO I DEL CERTIFICADO Nº 1145/2022-CEX
ANNEX I TO THE CERTIFICATE Nº 1145/2022-CEX
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	Empresa(s) / Company(s) Domicilio social / Registered office
1 - Adenovirus Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
2 - AMP One Step Amphetamine Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
3 - BAR One Step Barbiturates Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
4 - BUP One Step Buprenorphine Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
5 - BZO One Step Benzodiazepines Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

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	Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
6 - COC One Step Cocaine Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
7 - COT One Step Cotinine Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
8 - C-Reactive Protein Semi-Quantitative Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
9 - cTnI Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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10 - D-dimer Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
11 - Dengue IgG/ IgM+Ns1 Combo Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
12 - Dengue IgG/IgM Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
13 - Dengue Ns1 Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
14 - EDDP One Step Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

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15 - Ethyl Glucuronide (ETG) Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
16 - Ferritin Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
17 - fFN Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
18 - FOB Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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19 - FYL One Step Fentanyl Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
20 - H. Pylori Ab Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
21 - H. Pylori Ag Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
22 - HCG One Step Pregnancy Combo Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
23 - HCG One Step Pregnancy Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

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	Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
24 - Hs C-Reactive Protein Semi- Quantitative Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
25 - HSV-1 Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
26 - HSV-2 Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
27 - iGFBP-1 Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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28 - Influenza A+B Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
29 - Influenza A+B Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
30 - Influenza A+B/ SARS-CoV-2 Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
31 - KET One Step Ketamine Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
32 - K2 One Step Synthetic Cannabis Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD

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33 - Malaria pf Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
34 - Malaria pf/pan Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
35 - Malaria pf/pv Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
36 - MDMA One Step Ecstasy Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

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Producto / Product Referencia y modelo / Reference and model	Empresa(s) / Company(s) Domicilio social / Registered office
	Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
37 - MET One Step Methamphetamine Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
38 - Microalbumin Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
39 - MOP One Step Morphine Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
40 - MQL One Step Methaqualone Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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Producto / Product Referencia y modelo / Reference and model	Empresa(s) / Company(s) Domicilio social / Registered office
41 - MTD One Step Methadone Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
42 - Multi-Drug Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
43 - Multi-Drug Rapid Test key Cup	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
44 - Multi-Drug Rapid Test 1-Step Cup	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
45 - Norovirus GI+GII Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

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	Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
46 - OPI One Step Opiates Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
47 - OXY One Step Oxycodone Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
48 - PCP One Step Phencyclidine Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
49 - PPX One Step Propoxyphene Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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Producto / Product Referencia y modelo / Reference and model	Empresa(s) / Company(s) Domicilio social / Registered office
50 - Procalcitonin Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
51 - Rota/Adeno combo Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
52 - Rotavirus Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
53 - RSV Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
54 - SARS-CoV-2 Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD

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Table with 2 columns: Producto / Product (Referencia y modelo / Reference and model) and Empresa(s) / Company(s) (Domicilio social / Registered office)

3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA
Representante autorizado / Authorised representative
CMC Medical Devices & Drugs S.L.
Horacio Lengo,18, ESPAÑA / SPAIN

55 - SARS-CoV-2 IgG/IgM Rapid Test Device (WB/P/S)

Fabricante / Manufacturer
HANGZHOU FUNWORLD BIOTECH CO., LTD

3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

Representante autorizado / Authorised representative
CMC Medical Devices & Drugs S.L.
Horacio Lengo,18, ESPAÑA / SPAIN

56 - SARS-CoV-2 Neutralizing Antibody Rapid Test Device

Fabricante / Manufacturer
HANGZHOU FUNWORLD BIOTECH CO., LTD

3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

Representante autorizado / Authorised representative
CMC Medical Devices & Drugs S.L.
Horacio Lengo,18, ESPAÑA / SPAIN

57 - Strep A Rapid Test

Fabricante / Manufacturer
HANGZHOU FUNWORLD BIOTECH CO., LTD

3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

Representante autorizado / Authorised representative
CMC Medical Devices & Drugs S.L.
Horacio Lengo,18, ESPAÑA / SPAIN

58 - TB Rapid Test

Fabricante / Manufacturer
HANGZHOU FUNWORLD BIOTECH CO., LTD

3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA



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	Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
59 - TCA One Step Tricyclic Antidepressants Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
60 - THC One Step Marijuana Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
61 - TML One Step Tramado Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
62 - Typhoid Ab Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang,, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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Producto / Product Referencia y modelo / Reference and model	Empresa(s) / Company(s) Domicilio social / Registered office
63 - Typhoid Ag Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
64 - Typhoid/Para Typhoid Ag Rapid Test	Fabricante / Manufacturer HANGZHOU FUNWORLD BIOTECH CO., LTD 3# Floor, building 1#, 136 Zhiyi Rd, Yuhang sub-district, Yuhang district, Hangzhou, Zhejiang., REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA Representante autorizado / Authorised representative CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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