



agencia española de  
medicamentos y  
productos sanitarios



DEPARTAMENTO DE  
PRODUCTOS SANITARIOS

N/REF: PS/CLV/EBL/1110/2024-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 Getein Biotech, Inc., con sede en No.9 Bofu Road, Luhe District, 211505, Nanjing, 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 Getein Biotech, Inc., based in No.9 Bofu Road, Luhe District, 211505, Nanjing, PEOPLE'S 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*, modificado por el Reglamento (UE) 2024/1860 del Parlamento Europeo y del Consejo de 13 de junio de 2024, 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, modified by Regulation (EU) 2024/1860 of the European Parliament and of the Council of June 13, 2024, 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)

Fecha de la firma: 16/09/2024

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soportecertps@aemps.es

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



  
**ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI TÂY BAN NHA**  
**EMBASSY OF THE S.R. VIETNAM IN SPAIN**  
**CHỨNG NHẬN/ HỢP PHÁP HÓA LÃNH SỰ**  
**CONSULAR AUTHENTICATION**

1. Quốc gia: **VIỆT NAM**  
*Country:*

*Giấy tờ, tài liệu này*  
*This public document*

2. Do Ông (Bà): **Sergio Yoldi Chaure** ký  
*Has been signed by*

3. Với chức danh: **Trưởng phòng**  
*Acting in capacity of*


4. Và con dấu của **Bộ Ngoại giao và Hợp tác Tây Ban Nha**  
*Bearing the seal/stamp of*  
*Được chứng nhận/ hợp pháp hóa lãnh sự*  
*Certified*


5. Tại Ma-dờ-rit Ngày **25/09** /2024  
*At the (dd/mm/yyyy)*

6. Cơ quan cấp: **Đại sứ quán Việt Nam tại Tây Ban Nha**  
*by*

7. Số: **141** /CNLS/HPHLS  
*No.*

*Ký tên và đóng dấu*  
*Signature and seal/ stamp*  
*Tham tán/ Counselor*

  
**Lê Thị Mai Khanh**





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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 **Vietnam**, lo firmo en Madrid.

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

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

Fdo. Carmen Ruiz-Villar Fernández-Bravo

MINISTERIO DE ASUNTOS EXTERIORES Y DE COOPERACIÓN  
LEGALIZACIONES

Visto Bueno para legalizar la firma que antecede por ser al parecer, auténtica sin prejuicio de la veracidad del contenido del documento ni ulterior destino que pueda dársele.

Madrid,

25 SEP 2024

P. EL SUBSECRETARIO

Sergio Yoldi Chaure  
Jefe de Negociado

Dña. Raquel María Manuel Garijo, Jefa 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,

19 SEP. 2024





SUBDIRECCIÓN GENERAL DE  
RELACIONES INTERNACIONALES  
Y PUBLICACIONES

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DEPARTAMENTO DE  
PRODUCTOS SANITARIOS

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**ANEXO I DEL CERTIFICADO N° 1110/2024-CEX**  
**ANNEX I TO THE CERTIFICATE N° 1110/2024-CEX**

PRODUCTOS SANITARIOS PARA DIAGNÓSTICO *IN VITRO* REFERENCIADOS EN EL CERTIFICADO  
*IN VITRO* DIAGNOSTIC MEDICAL DEVICES LISTED IN THE CERTIFICATE

<b>Producto / Product</b> Referencia y modelo / Reference and model	<b>Empresa(s) / Company(s)</b> Domicilio social / Registered office
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**1 - ACE Reagent Kit (FAPGG Substrate Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA  
POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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

**2 - ADA Reagent Kit (POD Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA  
POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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

**3 - AFU Reagent Kit CNPF Substrate Method**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA  
POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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

**4 - ALB Reagent Kit (BCG Colorimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA  
POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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

**5 - ALP Reagent Kit (NPP Substrate-AMP Buffer Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA  
POPULAR CHINA / PEOPLE'S 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

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**6 - ALT Reagent Kit (Alanine Substrate Method)**

**7 - AMM Reagent kit (GLDH Kinetic method)**

**8 - AMY Reagent Kit (EPS Substrate Method)**

**9 - ApoA1 Reagent Kit (Immunoturbidimetric Method)**

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<b>Producto / Product</b> Referencia y modelo / Reference and model	<b>Empresa(s) / Company(s)</b> Domicilio social / Registered office
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**10 - ApoB Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

**Representante autorizado / Authorised representative**  
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Horacio Lengo,18, ESPAÑA / SPAIN

**11 - ApoE Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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**12 - ASO Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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**13 - AST Reagent Kit (Asparaginic Acid Substrate Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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**14 - Beta2-MG Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**



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**15 - Ca Reagent Kit (Arsenazo III Colorimetric Method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

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**16 - CCP Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

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**17 - CG Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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**18 - CHE Reagent Kit (Butylthiocholine Kinetic method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

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	<b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
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<b>19 - CK Reagent Kit (Phosphocreatine Substrate method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
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<b>20 - CK-MB Reagent Kit (immunoinhibition method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
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<b>21 - CK-MB Reagent kit (Immunoturbidimetric Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
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**22 - CI Reagent Kit (Thiocyanate Colorimetric Method)**

<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
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**23 - Composite Calibrator serum**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

**Representante autorizado / Authorised representative**

CMC Medical Devices & Drugs S.L.

Horacio Lengo,18, ESPAÑA / SPAIN

**24 - Composite quality control serum**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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CMC Medical Devices & Drugs S.L.

Horacio Lengo,18, ESPAÑA / SPAIN

**25 - CO2 Reagent Kit (PEPC Method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

**Representante autorizado / Authorised representative**

CMC Medical Devices & Drugs S.L.

Horacio Lengo,18, ESPAÑA / SPAIN

**26 - CRE-E Reagent Kit (Enzymatic Method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

**Representante autorizado / Authorised representative**

CMC Medical Devices & Drugs S.L.

Horacio Lengo,18, ESPAÑA / SPAIN

**27 - CRP Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

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	<b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>28 - CRP Reagent Kit (Latex-enhanced Immunoturbidimetric Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>29 - CSF Reagent Kit (Pyrogallol red Colorimetric Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>30 - CYS-C Reagent Kit (Latex-enhanced Immunoturbidimetric Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>31 - C3 Reagent Kit (Immunoturbidimetric Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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*IN VITRO* DIAGNOSTIC MEDICAL DEVICES LISTED IN THE CERTIFICATE

<b>Producto / Product</b> Referencia y modelo / Reference and model	<b>Empresa(s) / Company(s)</b> Domicilio social / Registered office
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<b>32 - C4 Reagent Kit (Immunoturbidimetric Method)</b>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b></p> <p>No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p> <p><b>Representante autorizado / Authorised representative</b> CMC Medical Devices &amp; Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN</p>
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<b>33 - DB Reagent Kit (Chemical Oxidation Method)</b>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b></p> <p>No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p> <p><b>Representante autorizado / Authorised representative</b> CMC Medical Devices &amp; Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN</p>
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<b>34 - D-Dimer Reagent Kit (Immunoturbidimetric Method)</b>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b></p> <p>No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p> <p><b>Representante autorizado / Authorised representative</b> CMC Medical Devices &amp; Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN</p>
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<b>35 - D3-H Reagent Kit (Kinetic Method)</b>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b></p> <p>No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p> <p><b>Representante autorizado / Authorised representative</b> CMC Medical Devices &amp; Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN</p>
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<b>36 - Fe Reagent Kit (Ferrozine Chromogenic Method)</b>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b></p> <p>No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p>
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**Producto / Product**  
Referencia y modelo / Reference and model

**Empresa(s) / Company(s)**  
Domicilio social / Registered office

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CMC Medical Devices & Drugs S.L.  
Horacio Lengo,18, ESPAÑA / SPAIN

**37 - Fer Reagent kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**38 - FMN Reagent Kit (NBT Reductive Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**39 - GA Reagent Kit (POD Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**40 - GGT Reagent Kit (GCANA substrate Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**41 - GLDH Reagent Kit (Kinetic Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

**42 - GLU-HK Reagent Kit (Hexokinase Enzymatic Method)**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

**43 - GLU-OX Reagent Kit-1 (GOD-POD Method)**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

**44 - GLU-OX Reagent Kit-2 (GOD-POD Method)**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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Horacio Lengo,18, ESPAÑA / SPAIN

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

**45 - GPDA Reagent Kit (Enzyme Kinetic Method)**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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**46 - GR Reagent Kit (Glutathione Substrate Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**47 - HbA1c Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**48 - HBDH Reagent Kit (Kinetic Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**49 - HCY Reagent Kit (Enzymatic Cycling Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**50 - HDL-C Reagent Kit (Direct Colorimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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<b>51 - hs-CRP Reagent Kit (Immunoturbidimetric Method)</b>	<b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN  <b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN  <b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN  <b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN  <b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>52 - IgA Reagent Kit (Immunoturbidimetric Method)</b>	
<b>53 - IgG Reagent Kit (Immunoturbidimetric Method)</b>	
<b>54 - IgM Reagent Kit (Immunoturbidimetric Method)</b>	

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ANEXO I DEL CERTIFICADO N° 1110/2024-CEX
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PRODUCTOS SANITARIOS PARA DIAGNÓSTICO IN VITRO REFERENCIADOS EN EL CERTIFICADO
IN VITRO DIAGNOSTIC MEDICAL DEVICES LISTED IN THE CERTIFICATE

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

55 - K Reagent Kit (Enzymatic Method)

Fabricante / Manufacturer
Getein Biotech, Inc.

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56 - LAC Reagent Kit (LO - POD Enzymatic-Colorimetric Method)

Fabricante / Manufacturer
Getein Biotech, Inc.

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57 - LAP Reagent Kit (L-leucyl-nitroaniline substrate Method)

Fabricante / Manufacturer
Getein Biotech, Inc.

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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58 - LDH Reagent Kit (Lactate Substrate Method)

Fabricante / Manufacturer
Getein Biotech, Inc.

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59 - LDH1 Reagent Kit (L-P Method)

Fabricante / Manufacturer
Getein Biotech, Inc.

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

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**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

**60 - LDL-C Reagent Kit-1(Direct Method)**

**61 - LDL-C Reagent Kit-2(Direct Method)**

**62 - Lipid compound calibrator**

**63 - Lipid compound control**

**64 - Lp(a) Reagent Kit(Immunoturbidimetric Method)**

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**65 - Lp-PLA2 Reagent Kit14-NPC Substrate Method**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

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**66 - LPS Reagent Kit (Enzyme Colorimetric Method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

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**67 - MALB Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

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**68 - MAO Reagent Kit (Colorimetric method)**

**Fabricante / Manufacturer**

**Getein Biotech, Inc.**

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<p><b>69 - Mg Reagent Kit (Colorimetric Method)</b></p>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p> <p><b>Representante autorizado / Authorised representative</b> CMC Medical Devices &amp; Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN</p>
<p><b>70 - Myo Reagent kit (Immunoturbidimetric Method)</b></p>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p> <p><b>Representante autorizado / Authorised representative</b> CMC Medical Devices &amp; Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN</p>
<p><b>71 - NA Reagent Kit (Enzymatic Method)</b></p>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p> <p><b>Representante autorizado / Authorised representative</b> CMC Medical Devices &amp; Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN</p>
<p><b>72 - NAG Reagent Kit (MNP-GLcNAc Substrate Method)</b></p>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p> <p><b>Representante autorizado / Authorised representative</b> CMC Medical Devices &amp; Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN</p>
<p><b>73 - NEFA Reagent Kit Enzymatic Colorimetric Method</b></p>	<p><b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA</p>

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	<b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>74 - P Reagent Kit (Phosphomolybdate Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>75 - PA Reagent Kit (Immunoturbidimetric Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>76 - PGI Reagent Kit (Immunoturbidimetric Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>77 - PGII Reagent Kit (Immunoturbidimetric Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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PRODUCTOS SANITARIOS PARA DIAGNÓSTICO *IN VITRO* REFERENCIADOS EN EL CERTIFICADO  
*IN VITRO* DIAGNOSTIC MEDICAL DEVICES LISTED IN THE CERTIFICATE

<b>Producto / Product</b> Referencia y modelo / Reference and model	<b>Empresa(s) / Company(s)</b> Domicilio social / Registered office
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**78 - RBP Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**Representante autorizado / Authorised representative**  
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**79 - RF Reagent Kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**80 - SA Reagent Kit Enzymatic Method**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**81 - Special Protein Control**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**82 - TB Reagent Kit (Chemical Oxidation Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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	<b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>83 - TBA Reagent KitEnzymatic Cycling Method</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>84 - TCH Reagent Kit-1CHOD-PAP Enzymatic- Colorimetric Method</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>85 - TCH Reagent Kit-2CHOD-PAP Enzymatic- Colorimetric Method</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>86 - TG Reagent Kit-1GPO-PAP Enzymatic- Colorimetric Method</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b> No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN





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**87 - TG Reagent Kit-2GPO-PAP Enzymatic-Colorimetric Method**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**88 - TP Reagent Kit (Biuret Colorimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**89 - TRF Reagent kit (Immunoturbidimetric Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**90 - UA Reagent Kit-1 (Uricase Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

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**91 - UA Reagent Kit-2 (Uricase Method)**

**Fabricante / Manufacturer**  
**Getein Biotech, Inc.**

No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

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Fax: 91 822 52 89

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	<b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>92 - UIBC Reagent KitFerrozine Chromogenic Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>93 - Urea Reagent Kit-1(Urease-GLDH Kinetic method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>94 - Urea Reagent Kit-2(Urease-GLDH Kinetic method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN
<b>95 - 5'-NT Reagent Kit (POD Method)</b>	<b>Fabricante / Manufacturer</b> <b>Getein Biotech, Inc.</b>  No.9 Bofu Road, Luhe District, 211505, Nanjing, REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA  <b>Representante autorizado / Authorised representative</b> CMC Medical Devices & Drugs S.L. Horacio Lengo,18, ESPAÑA / SPAIN

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