NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L.performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Jiangsu Medomics Medical Technology Co., Ltd.

ADDRESS: F3, Building C, No.3-1 Xinjinhu road, Jiangbei new area, Nanjing, China

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices: SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA)

Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notifed of the manufacture's device and has allocated registration. The registration number is **RPS/1170/2023**

Issue date: 18/May/2023
Cert. No.: R20220608-18

CE

File No: CE-TCF-084

EC Declaration of Conformity

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:

Name:Jiangsu Medomics Medical Technology Co.,Ltd.

Address:F3,Building C,No.3-1 Xinjinhu road,Jiangbei new area, Nanjing,China

EC Representative

Name Riomavix S.L.

Add: Calle de Almansa 55, 1D, Madrid 28039 Spain

Product

Name:SARS-CoV-2/Flu A/Flu B+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA)

Specifications： 1 pc/Box; 2 pcs/Box; 5 pcs/Box,20 pcs/Box; 50 pcs/Box; 100 pcs/Box

REF：123015-01-01，123015-02-01，123015-05-01，123015-20-01，123015-50-01，123015-100-01

Intended Use：SARS-CoV-2/Flu A/Flu B+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2, Influenza A ,Influenza B virus,Adenovirus(ADV), Respiratory syncytial virus(RSV) and Group A streptococci (STREP A) antigen in swab samples from individuals suspected of COVID-19, Influenza A , Influenza B, Adenovirus(ADV), Respiratory syncytial virus(RSV) and Group A streptococci (STREP A).It can be used for detecting SARS-CoV-2, Influenza A ,Influenza B virus,Adenovirus(ADV), Respiratory syncytial virus(RSV) and Group A streptococci (STREP A).which is often used as an auxiliary method in the clinical diagnosis,but not as the only basis.

Classification: IVDD Others

Conformity Assessment Route: IVDD 98/79/EC Annex III

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2012	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 18113-3:2011	ISO 13485:2016	EN 13612:2016

Signature: Zongzhi Chai

Place and Date of issued: Nanjing, China May 17th, 2022

N/REF: PS/RPS/1170/2023

O F I C I O

Comunicación: RPS/1170/2023
Nº AEMPS: 23-01775
Fecha: 18/05/2023
Asunto: **Anotación de la comunicación en el Registro de Responsables de la puesta en el mercado de Productos Sanitarios**

RIOMAVIX SL
Calle de Almansa 55,1D
28039 - Madrid
MADRID
Madrid, Comunidad de

Con fecha **18/05/2023** 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 **RIOMAVIX SL**, con la siguiente información:

1. Número de identificación asignado en el registro

RPS/1170/2023

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

Empresa **RIOMAVIX SL**
Calle de Almansa 55,1D
28039 - Madrid (MADRID)
Madrid, Comunidad de

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

N/REF: PS/RPS/1170/2023

ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
1 - SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	01/05/2022 El kit de detección rápida combinado de antígenos SARS - COV - 2 / virus de la gripe A / virus de la gripe B + adv / RSV / strep a (lfia) se utiliza para la detección rápida y cualitativa de antígenos sospechosos de neumonía coronaria, virus de la gripe a, virus de la gripe b, Adenovirus (adv), virus sincitiales respiratorios (rsv) y estreptococos del Grupo a (strep a -), Virus sincicial respiratorio (rsv) y estreptococos del Grupo a (strep a).

Fabricante	**Pais**
Jiangsu Medomics Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China

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

Sertio Oy
Biokatu 10
33520 Tampere
Finland

5.8.2025

Notified Body Confirmation Letter

Reference: 800035 (customer ID)

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2024/1860 amending Regulations (EU) 2017/746 as regards the transitional provisions for certain in vitro diagnostic medical devices.

This letter confirms that, Sertio Oy, a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 3018 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

Jiangsu Medomics Medical Technology Co.,Ltd.
Building 01, Phase 6, No.71, Xinghui Road, Jiangbei New Area,
Nanjing, 210000, Jiangsu,
P.R. China

SRN Number (if available): CN-MF-000030226

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the Directive 98/79/EC.

Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the Directive 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54 of IVDR or Article 92 of the IVDR respectively, by the 09 July 2024 for the relevant devices. The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
  - 31 December 2027, for class D devices;
  - 31 December 2028, for class C devices;
  - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of the Notified Body,

Mikko Soikkeli
Deputy Head of the Notified Body 3018
Notified Body 3018
Biokatu 10, 33520 Tampere, Finland
info@sertio.fi
www.sertio.fi

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	**IVDR Device classification (as proposed by the manufacturer and verified at the preapplication stage)**	**If the IVDR device is a substitute device, identification of the corresponding IVDD device**	**IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification**
SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)	*Class C*	*N/A*	*Certificate#: 1434-IVDD-193/2022 NB#: 1434(POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.)*
SARS-CoV-2 Antigen Test Kit (LFIA)	*Class C*	*N/A*	*Certificate#: 1434-IVDD-194/2022 NB#:1434(POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.)*

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	**IVDR Device classification (as proposed by the manufacturer and verified at the preapplication stage)**	**If the IVDR device is a substitute device, identification of the corresponding IVDD device**	**IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification**
SARS-CoV-2/FluA/FluB+ADV/RSV/SA Antigen Combo Rapid Test Kit (LFIA)	*Class B*	*N/A*	*N/A Device did not require a Notified Body certificate under Directive*

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
5.8.2025	800035-CL-1	Initial issue