

N/REF: PS/RPS/567/2023

**O F I C I O**

**Comunicación:** RPS/567/2023  
**Nº AEMPS:** 23-00725  
**Fecha:** 02/03/2023  
**Asunto:** **Anotación de la comunicación en el Registro de Responsables de la puesta en el mercado de Productos Sanitarios**

Medunion S.L.  
CALLE TAPIOLES, 33, 2- 1,  
08004 - Barcelona  
BARCELONA  
Cataluña

Con fecha **02/03/2023** 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 **Medunion S.L.**, con la siguiente información:

**1. Número de identificación asignado en el registro**

**RPS/567/2023**

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

**Empresa** **Medunion S.L.**  
CALLE TAPIOLES, 33, 2- 1,  
08004 - Barcelona (BARCELONA)  
Cataluña

**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.*

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

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## ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Nombre comercial Tipo de producto	Fecha de introducción en el mercado Finalidad
<b>1 - SARS-CoV-2 &amp; Influenza A+B &amp; RSV Antigen Combo Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is used for the qualitative detection of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) antigens in human nasopharyngeal (NP) swabs or oropharyngeal swabs samples.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>2 - Respiratory Syncytial Virus Antigen Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is used for the qualitative detection of respiratory syncytial virus (RSV) viral antigens in human nasopharyngeal (NP) swabs or oropharyngeal swabs samples.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>3 - Adenovirus Antigen Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is used for the qualitative detection of adenovirus antigens in human nasopharyngeal (NP) swabs or oropharyngeal swabs samples.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>4 - Influenza A+B &amp; RSV &amp; ADV Antigen Combo Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is used for the qualitative detection of influenza A, influenza B, respiratory syncytial virus (RSV) and adenovirus antigens in human nasopharyngeal (NP) swabs or oropharyngeal swabs samples.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China

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<b>5 - 25-hydroxy vitamin D Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 25-hydroxy vitamin D Test Kit (Colloidal Gold) is a rapid chromatographic immunoassay for the semi-quantitative detection of 25-hydroxy vitamin D (25 (OH) D) in human whole blood. The test only provides preliminary diagnostic test result . Any use or interpretation of the test must be analyzed and confirmed with alternative testing method(s) and clinical findings based on professional judgment of health care providers.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>6 - Strep A Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a rapid and convenient immunochromatographic assay for the qualitative detection of Group A streptococcus (Strep A) antigen from patient oropharyngeal swabs specimens. It is intended for professional use as an aid in the diagnosis of Strep A infection. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>7 - Strep B Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a rapid and convenient immunochromatographic assay for the qualitative detection of Group B Streptococcus (GBS) antigens in specimens taken from vaginal or rectal swabs of pregnant women. It is intended for professional use as an aid in the diagnosis of Strep B infection. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China

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<b>8 - Multi-Drug Screening Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a rapid visual immunoassay for the qualitative, presumptive detection of drugs of abuse in human urine specimens at the cut-off concentrations listed below:Amphetamine (AMP):1000ng/ml,Barbiturates (BAR):300ng/ml,Benzodiazepines (BZO):300ng/ml,Buprenorphine (BUP):10ng/ml,Cocaine (COC):300ng/ml,Ketamine (KET):1000ng/ml,Marijuana (THC):50ng/ml, Methylendioxyamphetamine (MDMA):500ng/ml,Methadone (MTD):300ng/ml,Methamphetamine (MET):1000ng/ml,Opiates (OPI):300ng/ml,Phencyclidine (PCP):25ng/ml,Tramadol (TRA):200ng/ml,Tricyclic Antidepressants (TCA):1000ng/ml
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>9 - Ebola Antigen Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a rapid, serological, lateral flow chromatographic immunoassay for the qualitative detection of antigens from Ebola viruses in human whole blood, serum or plasma specimens as an aid in the diagnosis of Ebola virus infection.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>10 - Cardiac Troponin I (cTnI) Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a rapid, serological, lateral flow chromatographic immunoassay for the qualitative detection of cardiac Troponin I (cTnI) and its complex in human whole blood, serum or plasma specimens at a level of 1.0 ng/mL or greater. It is intended to be used by healthcare professionals as an aid in the diagnosis of acute myocardial infarction (AMI). The test only provides preliminary analysis results but not critical diagnosis criteria. Any use or interpretation of the test must be analyzed and confirmed with alternative testing method(s) and clinical findings based on professional judgment of health care providers.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China



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## ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

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<b>11 - Myoglobin (Myo) Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is intended for qualitative detection of myoglobin in human serum, plasma or whole blood, applying to auxiliary diagnosis of acute myocardial infarction (AMI). This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>12 - cTnI/CK-MB/Myo Combo Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a rapid chromatographic immunoassay for the qualitative detection of human cardiac troponin I (cTnI), Creatine Kinase MB (CK-MB) and Myoglobin in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>13 - Creatine Kinase Isoenzymes (CK-MB) Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is an immunochromatography based one step in vitro test. It is designed for qualitative determination of CK-MB in human whole blood specimens as an aid in the diagnosis of myocardial infarction.
<b>Fabricante</b>	<b>Pais</b>
Anhui Deepblue Medical Technology Co., Ltd.	REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>14 - Prostate Specific Antigen (PSA) Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a rapid and convenient immunochromatographic assay for the qualitative detection of human Prostate Specific Antigen in secretions. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the tests.



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		<b>Fabricante</b>
		<b>Pais</b>
		REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>15 - Follicle-Stimulating Hormone (FSH) Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product aims to realize the qualitative detection of Follicle-Stimulating Hormone (FSH) in the urine of female, which can provide the important information for women who are preparing for pregnancy and/or concerned with ovarian health, function and fertility and it plays an auxiliary role in the diagnosis and treatment of pituitary and gonad dysfunction.	
		<b>Fabricante</b>
		<b>Pais</b>
		REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>16 - Ferritin Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a rapid chromatographic immunoassay for the qualitative detection of human Ferritin in human whole blood, serum and plasma. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.	
		<b>Fabricante</b>
		<b>Pais</b>
		REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>17 - Neutrophil gelatinase-associated lipocalin (NGAL) Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is used for the qualitative detection of neutrophil gelatinase-associated lipocalin (NGAL) in human urine, and it is mainly used clinically for the auxiliary diagnosis of renal dysfunction.	
		<b>Fabricante</b>
		<b>Pais</b>
		REPÚBLICA POPULAR CHINA / Peoples Republic of China



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<b>18 - C-Reactive Protein (CRP) Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a rapid and convenient immunochromatographic assay for the qualitative detection of CRP at or above the cutoff level of 3 µg/ml in human serum or plasma samples. It is intended as an aid in evaluating the risk of myocardial infarction (heart attack) and in the early detection of coronary cardiac diseases. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.
<b>Fabricante</b>  Anhui Deepblue Medical Technology Co., Ltd.	<b>Pais</b>  REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>19 - Salmonella Antigen Test Kit (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a lateral flow immunoassay for the simultaneous detection and differentiation of Salmonella typhi and Salmonella P. Typhoid in feces.
<b>Fabricante</b>  Anhui Deepblue Medical Technology Co., Ltd.	<b>Pais</b>  REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>20 - HCG Pregnancy Test (Urine/Serum/Plasma) (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a visual, rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum or plasma specimens to aid in the early detection of pregnancy.
<b>Fabricante</b>  Anhui Deepblue Medical Technology Co., Ltd.	<b>Pais</b>  REPÚBLICA POPULAR CHINA / Peoples Republic of China
<b>21 - HCG Pregnancy Test (Urine) (Colloidal Gold)</b> PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/03/2023 This product is a visual, rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine specimens to aid in the early detection of pregnancy.
<b>Fabricante</b>  Anhui Deepblue Medical Technology Co., Ltd.	<b>Pais</b>  REPÚBLICA POPULAR CHINA / Peoples Republic of China

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