www.larioja.org

Gobierno de La Rioja

Salud

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Humanización, Prestaciones y Farmacia



**Alertas RAPEX mascarillas**
**Referencia:** SOFM/BBG/crm
**Fecha:** 10/01/2022

## ALERTAS EUROPEAS SOBRE MASCARILLAS QUE PRESENTAN RIESGOS PARA LA SALUD DE LOS USUARIOS

RAPEX es un sistema unificado de alerta e intercambio de información de productos peligrosos para la salud de los consumidores de la Unión Europea. Algunos de los productos notificados puede que no se encuentren disponibles en nuestro país, salvo que se adquieran a través de comercio electrónico.

| ALERTA | AFECTA | CALIFICACIÓN | OBSERVACIONES |
|---|---|---|---|
| A12/01580/21 | FFP2 PriuMask-PRINTEXMedical | grave | La retención de partículas/filtros del material es insuficiente. |
| A12/01596/21 | FFP2 Dust Mask | grave | La retención de partículas / filtro del material es insuficiente. |
| A12/01597/21 | KN 95 mask-ZSYONGLAI | grave | La retención de partículas / filtro del material es insuficiente |
| A12/01598/21 | KN 95 Mask Dr+9020 KN95 | grave | La retención de partículas / filtro del material es insuficiente |
| A12/01633/21 | KN95 Protective mask-UEACON | grave | La retención de partículas / filtro del material es insuficiente |
| A12/01636/21 | Face mask -GAOZHEN | grave | El producto lleva el marcado CE, pero su capacidad de filtrado no ha sido probado por un organismo europeo competente |
| A12/01699/21 | FFP2 Mask- Masvan | grave | La retención de partículas / filtro del material es insuficiente |
| A12/01751/21 | FFP2 Mask-MagisPharma | grave | La retención de partículas / filtro del material es insuficiente |
| A12/01757/21 | KN95 desconocido | grave | El producto no dispone de la documentación técnica suficiente para su autorización. |
| A12/01758/21 | FFP2 Mask-Pharmaplast | grave | La retención de partículas / filtro del material es insuficiente |

| | | | |
|---|---|---|---|
| A12/01762/21 | 3231 FFP3 NR D KN95 | grave | La retención de partículas / filtro del material es insuficiente |
| A12/01794/21 | Kids Mask Kadi-001-Mundosalud | grave | El producto lleva el marcado CE, pero su capacidad de filtrado no ha sido probado por un organismo europeo competente |
| A12/01808/21 | KN95 GH-LT001-Letian | grave | La filtración es mayor que la requerida existiendo riesgo de cotaminación. |
| INFO/00168/21 | Face mask desconocido | info | El producto no dispone de la documentación técnica suficiente para su autorización. |

Dichos productos no cumple con la regulación de los Equipos de Protección Personal (EPI) y con la norma europea pertinente EN 149, así como los requisitos de salud y seguridad, por lo que se ha dispuesto la retirada del mercado de las mismas.

Le solicitamos que consulten frecuentemente las alertas emitidas por las autoridades europeas sobre mascarillas en el siguiente enlace, porque existen muchas en vigor en la actualidad y se incorporan continuamente.
https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&lng=es

Para cualquier duda puede dirigirse al Servicio de Ordenación Farmacéutica y Medicamentos:

- Tlfno: 941 299 923
- mail: alertas.productossanitarios@larioja.org
- Carta: Servicio de Ordenación Farmacéutica y Medicamentos - Productos Sanitarios C/ Obispo Lepe s/n 26071 Logroño

European Commission | Safety Gate RAPEX

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|---|---|
| Case number | **A12/01580/21** |
| Product (what the product is) | **Particle filter mask** |

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|---|---|
| Name (on the product or the packaging) | **priuMask** |
| Brand (on the product or the packaging) | • **PRINTEXMedical** |
| OECD Portal category (if known) | **85000000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **No** |
| Professional product? | **No** |
| Product Recall | **https://ffp.productions/wp-content/uploads/2021/08/Kundenhinweis.pdf German (de)** |
| Type/number of model | **P21H1** |
| Batch number | **21.12.2020** |
| Bar code | **Unknown** |
| Product description | **5-pack of respiratory face masks branded as FFP2, in a transparent foil packaging.** |
| Packaging description | **The product is sold in packs of 5 items, in a transparent foil packaging.** |

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|---|---|
| Is the product counterfeit? | **No** |
| Is this notification linked to a Business Gateway case? | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The particle/filter retention of the material is insufficient (measured values: as low as 84%). Furthermore, the mask may lack a nose clip, therefore it cannot be correctly adapted to the user's face. Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Voluntary measures**<br>**Manufacturer**<br>**Enclose required documents**<br>**26/08/2021**<br>**Compulsory measures**<br>**Other**<br>**Ban on the marketing of the product and any accompanying measures**<br>**26/08/2021**<br>**Voluntary measures**<br>**Manufacturer**<br>**Destruction of the product**<br>**26/08/2021**<br>**Compulsory measures**<br>**Other**<br>**DIN EN 149: Respiratory protective devices – Filtering half-masks to protect against part**<br>**26/08/2021**<br>**Voluntary measures**<br>**Manufacturer**<br>**Withdrawal of the product from the market**<br>**26/08/2021** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| | | |

| 2021 | Unknown | Germany |
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European Commission | Safety Gate RAPEX

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|---|---|
| Case number | **A12/01594/21** |
| Product (what the product is) | **Particle filter mask** |


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|---|---|
| Name (on the product or the packaging) | **KN95 Steroscopic Protective Mask** |
| Brand (on the product or the packaging) | **Unknown** |
| OECD Portal category (if known) | **85000000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **Yes - eBay** |
| Professional product? | **Yes** |
| Product Recall | |
| Type/number of model | **Self-priming filtering protective face mask** |
| Batch number | **Production date: 14 April 2020** |
| Bar code | **Unknown** |
| Product description | **Product embossed with KN95 only. Product sold online, in particular via eBay, under article number: 254764162327.** |
| Packaging description | **White-blue packaging containing ten units, with an additional sticker with further information.** |

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|---|---|
| Is the product counterfeit? | **Unknown** |
| Is this notification linked to a Business Gateway case? | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The particle/filter retention of the material is insufficient (measured values: as low as 11%). Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Voluntary measures**<br>**Retailer**<br>**Stop of sales**<br>**30/08/2021** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| 2021 | People's Republic of China | Germany |

European Commission

# Safety Gate RAPEX

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|---|---|
| Case number | **A12/01596/21** |
| Product (what the product is) | **Particle filter mask** |

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|---|---|
| Name (on the product or the packaging) | **Dust Mask Partikelfiltrierende Halbmaske FFP2** |
| Brand (on the product or the packaging) | **Unknown** |
| OECD Portal category (if known) | **85000000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **No** |
| Professional product? | **No** |
| Product Recall | |
| Type/number of model | **FFP2 Dust Mask** |
| Batch number | **25.02.2021** |
| Bar code | **Unknown** |
| Product description | **5 black respiratory protective masks, with the claims of FFP2 and a CE marking printed on the side.** |
| Packaging description | **The product is sold in foil packaging with no label.** |

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|---|---|
| Is the product counterfeit? | **Unknown** |
| Is this notification linked to a Business Gateway **case?** | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The particle/filter retention of the material is insufficient (measured values: as low as 81%). Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Compulsory measures**<br>**Other**<br>**Ban on the marketing of the product and any accompanying measures**<br>**Voluntary measures**<br>**Importer**<br>**Recall of the product from end users**<br>**Voluntary measures**<br>**Importer**<br>**Stop of sales** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| 2021 | People's Republic of China | Germany |

European Commission | Safety Gate RAPEX

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|---|---|
| Case number | **A12/01597/21** |
| Product (what the product is) | **Particle filter mask** |


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|---|---|
| Name (on the product or the packaging) | **Protective Mask KN95** |
| Brand (on the product or the packaging) | • **ZSYONGLAI** |
| OECD Portal category (if known) | **85000000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **No** |
| Professional product? | **No** |
| Product Recall | |
| Type/number of model | **ZX-168** |
| Batch number | **2020.04** |
| Bar code | **Unknown** |
| Product description | **20-pack of particle filter masks marked with both FFP2 and KN95 and with the CE marking printed on the side as well.** |
| Packaging description | **The product is sold in packs of 20 items in a white box with green/red label ZSYONGLAI.** |

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| Is the product counterfeit? | **Unknown** |
| Is this notification linked to a Business Gateway case? | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The particle/filter retention of the material is insufficient (measured values: as low as 61%). Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Voluntary measures**<br>**Retailer**<br>**Recall of the product from end users**<br>**Voluntary measures**<br>**Retailer**<br>**Stop of sales**<br>**Compulsory measures**<br>**Other**<br>**Stop of sales** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| 2021 | People's Republic of China | Germany |

European Commission | Safety Gate RAPEX

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|---|---|
| Case number | **A12/01598/21** |
| Product (what the product is) | **Particle filter mask** |

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|---|---|
| Name (on the product or the packaging) | **KN 95 Mask Dr+9020 KN95** |
| Brand (on the product or the packaging) | • **Dr+9020** |
| OECD Portal category (if known) | **85000000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **Yes - eBay** |
| Professional product? | **No** |
| Product Recall | |
| Type/number of model | **Unknown** |
| Batch number | **Unknown** |
| Bar code | **Unknown** |
| Product description | **White respiratory protective masks. Product sold online, in particular via eBay.** |
| Packaging description | **The product is sold in a transparent unlabelled foil packaging.** |

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| Is the product counterfeit? | **Unknown** |
| Is this notification linked to a Business Gateway case? | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The particle/filter retention of the material is insufficient (measured values: as low as 45%), and the mask does not properly adapt to the face. Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Voluntary measures**<br>**Retailer**<br>**Stop of sales** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| 2021 | People's Republic of China | Germany |

European Commission | Safety Gate RAPEX

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|---|---|
| Case number | **A12/01633/21** |
| Product (what the product is) | **Particle filter mask** |

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|---|---|
| Name (on the product or the packaging) | **KN95 Protective mask** |
| Brand (on the product or the packaging) | • **UEACON** |
| OECD Portal category (if known) | **85000000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **No** |
| Professional product? | **No** |
| Product Recall | |
| Type/number of model | **9501** |
| Batch number | **2020/04/17** |
| Bar code | **Unknown** |
| Product description | **Particle filter masks marked with both FFP2 and KN95, as well as with the CE marking printed on the side.** |
| Packaging description | **Cardboard box with 50 pieces.** |

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| Is the product counterfeit? | **No** |
| Is this notification linked to a Business Gateway **case?** | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The particle/filter retention of the material is insufficient (measured values: as low as 57%). Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Voluntary measures**<br>**Distributor**<br>**Recall of the product from end users**<br>**08/11/2021** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| 2021 | People's Republic of China | Belgium |

European Commission | Safety Gate RAPEX

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|---|---|
| Case number | **A12/01636/21** |
| Product (what the product is) | **Particle filter mask** |


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|---|---|
| Name (on the product or the packaging) | **Disposable Face Mask** |
| Brand (on the product or the packaging) | • **GAOZHEN** |
| OECD Portal category (if known) | **85000000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **Unknown - No research has been carried out to ascertain whether there have been any online sales.** |
| Professional product? | **No** |
| Product Recall | |
| Type/number of model | **Type Adult GZ1**<br>**2020DFM LIP** |
| Batch number | **20A-LIP-GZ**<br>**Production date: 05.2020**<br>**Expiry date: 11.2021** |
| Bar code | **Unknown** |
| Product description | **Protective respiratory filtration half-face mask with the CE marking printed on.** |
| Packaging description | **Masks wrapped in cellophane envelopes and placed in cardboard** |

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| | **packaging bearing information on the batch, the year and month of production and the expiry date; CE marking mentions the standard EN 149.** |
| Is the product counterfeit? | **Unknown** |
| Is this notification linked to a Business Gateway case? | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The product bears a CE marking but its filtering capacity has not been tested by a relevant competent European conformity assessment body. The visual inspection of the product reveals that its material composition, structure and shape are inappropriate. Consequently, it is not proven that the product fulfils the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Compulsory measures**<br>**Importer**<br>**Ban on the marketing of the product and any accompanying measures 04/08/2020** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| 2021 | People's Republic of China | Italy |

European Commission | Safety Gate RAPEX

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|---|---|
| Case number | **A12/01699/21** |
| Product (what the product is) | **Particle filter mask** |


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|---|---|
| Name (on the product or the packaging) | **FFP2 non-medical protective mask** |
| Brand (on the product or the packaging) | • **Masvan** |
| OECD Portal category (if known) | **85000000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **Yes - Other** |
| Professional product? | **No** |
| Product Recall | |
| Type/number of model | **KND-003** |
| Batch number | **20201001** |
| Bar code | **6973167894222** |
| Product description | **FFP2 non-medical protective mask as depicted; white and blue packaging with 5 masks: Masvan CE2163** |
| Packaging description | **Milky white plastic packaging with 5 masks and partially blue inscription, English text** |

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|---|---|
| Is the product counterfeit? | **Unknown** |
| Is this notification linked to a Business Gateway case? | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The particle/filter retention of the material is insufficient (measured values: as low as 75%). Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Compulsory measures**<br>**Other**<br>**Recall of the product from end users**<br>**Voluntary measures**<br>**Retailer**<br>**Ban on the marketing of the product and any accompanying measures** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| 2021 | People's Republic of China | Germany |

European Commission | Safety Gate RAPEX

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|---|---|
| Case number | **A12/01751/21** |
| Product (what the product is) | **Particle filter mask** |

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|---|---|
| Name (on the product or the packaging) | **FFP2 [illegible]askers Masques pour la Bouche** |
| Brand (on the product or the packaging) | **[illegible] Magis Pharma** |
| OECD Portal category (if known) | **[illegible]00000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **No** |
| Professional product? | **No** |
| Product Recall | **https://magis-pharma.be/nl/terugroep-ffp2-maskers-magis-pharma Dutch (nl)** |
| Type/number of model | **LK-008** |
| Batch number | **202012** |
| Bar code | **4267571** |
| Product description | **Particle filter mask** |
| Packaging description | **Cardboard box with 20 pieces. Each mask has its own individual packaging.** |

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|---|---|
| Is the product counterfeit? | **No** |
| Is this notification linked to a Business Gateway case? | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The particle/filter retention of the material (measured values: as low as 92%) and the total filtration capacity of the mask (measured mean values: as low as 86%) are insufficient. Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Voluntary measures**<br>**Importer**<br>**Recall of the product from end users**<br>**20/11/2021** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| 2021 | People's Republic of China | Belgium |

European Commission | Safety Gate RAPEX

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|---|---|
| Case number | **A12/01757/21** |
| Product (what the product is) | **Particle filter mask** |


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|---|---|
| Name (on the product or the packaging) | **KN95 MASK** |
| Brand (on the product or the packaging) | **Unknown** |
| OECD Portal category (if known) | **85000000 - Safety / Protection - DIY** |
| Is the product (also) sold online? | **Unknown - -** |
| Professional product? | **No** |
| Product Recall | **https://www.fdspromotions.com/nl/nieuws/2021/11/terugroepactie-kn95-mondmasker** **Dutch (nl)** |
| Type/number of model | **KN95 / PM2.5** |
| Batch number | **Unknown** |
| Bar code | **Unknown** |
| Product description | **Particle filter mask.** |
| Packaging description | **Cardboard box containing 10 masks.** |

| | |
|---|---|
| Is the product counterfeit? | **No** |
| Is this notification linked to a Business Gateway case? | |
| Type of risk | **Health risk / other** |
| Risk description (technical defect and consequences) | **The safety of the product cannot be demonstrated due to the absence of important proof from the technical documentation. Furthermore, the pack contained different types of masks. Due to this deficiencies, the product does not fulfil the requirements and thus, even if combined with other recommended measures, it may not properly protect.** |
| Legal provisions (at EU level) and European standards against which the product was tested and did not comply | **The product does not comply with the Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.** |
| (Overall) risk level | **Serious** |
| Product category | **Protective equipment** |
| Measures | **Voluntary measures**<br>**Importer**<br>**Recall of the product from end users**<br>**24/11/2021** |

| Year | Country of origin | Alert submitted by |
|---|---|---|
| 2021 | People's Republic of China | Belgium |