



Salud

C/ Obispo Lepe, 6 (C.A.R.P.A.)  
26071 – Logroño. La Rioja  
Teléfono: 941 299 923

Humanización,  
Prestaciones y Farmacia  
Gobierno de La Rioja  
Oficina Auxiliar de Registro  
Salud

Alertas RAPEX mascarillas  
Referencia: SOFM/BBG/crm  
Fecha: 19/01/2022

Fecha: 19 ENE, 2022

Hora:  
Número: S-10258

### 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
A12/00016/22	KN95 protective Mask	grave	La retención de partículas/filtros del material es insuficiente.
A12/01835/21	FFP2 protective Mask	grave	La retención de partículas / filtro del material es insuficiente.
A12/01838/21	KN 95 protective Mask	grave	La retención de partículas / filtro del material es insuficiente
A12/01858/21	KN 95 protective Mask	grave	La retención de partículas / filtro del material es insuficiente

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&ng=es](https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&ng=es)

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

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

DOCUMENTO FIRMADO ELECTRONICAMENTE			Pag 1 1	
Expediente	Tipo	Procedimiento	Nº Documento	
00860-2022/005813	Escrito	Solicitudes y remisiones generales	2022/0042227	
Cargo	Firma de / Ubicación		Fecha hora	
1 Jefe Servicio de Ordenación Farmacéutica y Medicamentos	Beatriz Barrio García		19/01/2022 11:13:12	
2 SELLADO ELECTRONICAMENTE por Gobierno de La Rioja con CSV: 4WAEBWQOEYC95C Dirección de verificación: <a href="http://www.larioja.org/verificacion">http://www.larioja.org/verificacion</a>			19/01/2022 11:13:20	

Case number **A12/00016/22**

Product (what the product is) **Particle filter mask**



Name (on the product or the packaging) **KN95 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? **No**

Product Recall

Type/number of model **Protective Mask KN95**

Batch number **Unknown**

Bar code **Unknown**

Product description **5 white five-layer respiratory masks labelled only with KN95 GB2626-2006, with visible nose bracket in a foil packaging with black imprint 'KN95 protective mask'. Product sold online, in particular via eBay sold via ebay under number 224389518393.**

Packaging description **Foil packaging with black print 'KN95 protective mask', no manufacturer's details**

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 57%), 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**

**Importer**

**Stop of sales**

**Compulsory measures**

**Other**

**Stop of sales**

Year

**2022**

Country of origin

**Unknown**

Alert submitted by

**Germany**



Case number

**A12/01835/21**

Product (what the product  
is)

**Particle filter mask**



Name (on the product or the  
packaging)

**Filtrierende atemschutzmaske FFP2 NR**

Brand (on the product or the  
packaging)

• **EN MED+**

OECD Portal category (if known)

**85000000 - Safety / Protection - DIY**

Is the product (also) sold online?

**Unknown - -**

Professional product?

**No**

Product Recall

Type/number of model

**712000000**

Batch number

**20210218**

Bar code

**8682431030195**

Product description

**White particle filter mask, marked with FFP2, and with the CE marking on the side.**

Packaging description

**The product is sold in a white and blue cardboard box with 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 particle/filter retention of the material is insufficient (measured values: as low as 45%). Furthermore, weld points may tear apart generating holes in the mask, and ear straps may break easily. 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 European standard EN 149.**

(Overall) risk level **Serious**

Product category **Protective equipment**

Measures **Compulsory measures**

**Importer**

**Ban on the marketing of the product and any accompanying measures**

**Year**

**2021**

**Country of origin**

**Turkey**

**Alert submitted by**

**Belgium**

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Case number **A12/01838/21**

Product (what the product is) **Particle filter mask**

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Name (on the product or the packaging) **KN 95 Particulate Respirator**

Brand (on the product or the packaging) **Unknown**

OECD Portal category (if known) **85000000 - Safety / Protection - DIY**

Is the product (also) sold online? **Unknown - L'adresse mail du fabricant chinois est mentionnée sur l'emballage des masques.**

Professional product? **No**

Product Recall

Type/number of model **Unknown**

Batch number **20200501**

Bar code **6973080410011**

Product description **White particle filter mask.**

Packaging description **White-and-red cardboard box containing 20 items.**

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 45%). 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 European standard EN 149.**

(Overall) risk level **Serious**

Product category **Protective equipment**

Measures **Compulsory measures**

**Importer**

**Withdrawal of the product from the market  
09/11/2021**

**Year**

**Country of origin**

**Alert submitted by**

**2021**

**People's Republic of China**

**Belgium**

Case number **A12/01858/21**

Product (what the product is) **Particle filter mask**



Name (on the product or the packaging) **Self-suction filter KN95 Respiratory Protective Face Mask**

Brand (on the product or the packaging) **• Sunjoy**

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 **K1**

Batch number **Unknown**

Bar code **6973225270012**

Product description **White particle filter mask. Product sold online, in particular via eBay under article number 264715766751.**

Packaging description **White and blue plastic packaging with 10 masks.**



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 51%), and the mask may not correctly fit to the face. Furthermore, the product may differ from one package to another. 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 European standard EN 149.**

(Overall) risk level **Serious**

Product category **Protective equipment**

Measures **Voluntary measures**

**Retailer**

**Stop of sales**

**Compulsory measures**

**Other**

**Stop of sales**

**Year**

**2021**

**Country of origin**

**People's Republic of China**

**Alert submitted by**

**Germany**