



Alertas RAPEX mascarillas
Referencia: SOFM/BBG/crm
Fecha: 03/12/2021

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.

Se adjunta la alerta A12/01396/21 y A12/01421/21 referentes a mascarillas de filtración para protección frente al contagio por COVID19.

La alerta A12/01396/21 afecta a las mascarillas KN95 Minkang 9001-KN95 y está calificada como INFO, presenta un porcentaje de fuga total hacia adentro y la penetración a través de la máscara filtro es de hasta un 71,70 %.

La alerta A12/01421/21 afecta a las mascarillas FFP2 Biosis Healing Protective Mask y está calificada como GRAVE, la retención de partículas / filtro del material es insuficiente

Así mismo ambos 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

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 ELECTRÓNICAMENTE			an formato PDF/A 1.7 (Riesgo FALDIP) Custodiado en el repositorio seguro del Gobierno de La Rioja		Pág 1 / 1
Expediente	Tipo	Procedimiento	Nº Documento		
00860-2021/142490	Escrito	Solicitudes y remisiones generales	2021/1053328		
Cargo	Firma electrónica		Fecha hora		
1 Jefe Servicio de Ordenación Farmacéutica y Medicamentos	Beatriz Barrio García		09/12/2021 07:57:44		
2 SELLADO ELECTRÓNICAMENTE por Gobierno de La Rioja con CSV: E7NGZQC12XKDDPT			Dirección de verificación: http://www.larioja.org/verificacion		09/12/2021 07:57:56

Case number **A12/01396/21**

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



Name (on the product or the packaging) **Protective face masks GRAM KN95 (5 layers, 1 pc.)**

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

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 **Minkang 9001-KN95 Mask**

Batch number **Unknown**

Bar code **8050043166234**

Product description **Masks are white, disposable non-woven, cup-shaped, which are attached to the ears with rubber bands. Marking on the mask: Gram Minkang 9001-KN95 Mask, FFP2 Nr. D, EN 149:2001+A1 2009, CE.**

Packaging description **Soft plastic packaging. Marking on the packaging: Apsaugin veido kauk KN95, 1 vnt., 5 sluoksni, b/k 8050043166234, sertifikato Nr. OP200328S.PHM0S21, platintojas UAB „TITANIKA“ Servs g. 1, Vilnius.**

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 28%) and the total filtration capacity of the mask is insufficient (measured mean values: as low as 41%). 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
Importer

Withdrawal of the product from the market

Year

2021

Country of origin

People's Republic of China

Alert submitted by

Lithuania

Case number **A12/01421/21**

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



Name (on the product or the packaging) **Biosis Healing Protective Mask**

Brand (on the product or the packaging) **• Biosis Healing**

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

Is the product (also) sold online? **Unknown - Unknown**

Professional product? **No**

Product Recall

Type/number of model **BH-YEG-15.5x10.5**

Batch number **620071013**

Bar code **Unknown**

Product description **White protective respiratory filtration half-face mask with the brand name, the EN standard, FFP2 and the NR marking printed on.**

Packaging description **Box with logo, description of the product, quantity (50 units) and indication of the EN149:2001 + A1:2009 and the filter efficiency (>94%). Instructions for use in English.**

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 83%). Consequently, the product does not fulfil the health and safety requirements, and an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection; 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 the relevant European standard EN 149.

(Overall) risk level **Serious**

Product category **Protective equipment**

Measures **Compulsory measures**

Other

**Destruction of the product
05/08/2021**

Year

2021

Country of origin

People's Republic of China

Alert submitted by

Ireland