



Salud

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

Fecha -3 FEB. 2022

Hora S- 23463

Número

Alertas RAPEX mascarillas
Referencia: SOFM/BBG/cm
Fecha: 02/02/2022

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.

Se adjuntan las últimas alertas RAPEX referentes a mascarillas de filtración para protección frente al contagio por COVID19:

ALERTA	APECTA	CALIFICACIÓN	OBSERVACIONES
A12/00016/22	KN95 protective Mask	grave	La retención de partículas/filtros del material es insuficiente.
A12/00054/22	Filtering half mask- DY-9	grave	La retención de partículas / filtro del material es insuficiente.

Dichos productos no cumplen 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			Pag. 1 / 1	
Expediente:	Tipo:	Procedimiento:	Nº Documento:	
00860-2022/012180	Escrito	Solicitudes y remisiones generales	2022/0086970	
Cargo:		Firmante/Reservaciones:	Fecha:	
1 Jefe Servicio de Ordenación Farmacéutica y Medicamentos		Beatriz Barrio Garcia	03/02/2022 08:57:38	
2 SELLADO ELECTRÓNICAMENTE por Gobierno de La Rioja con CSV: 45IIBBSZKR5WXDJ			Dirección de verificación: http://www.larioja.org/verificacion	03/02/2022 08:57:46



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 **A12/00054/22**

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



Name (on the product or the packaging) **Filtering half mask**

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

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 **DY-9**

Batch number **Unknown**

Bar code **Unknown**

Product description **White particle filter mask. The product is sold online.**

Packaging description **Cardboard box with 20 pieces.**

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 total filtration capacity of the mask is insufficient (measured mean values: as low as 83%). 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

**Recall of the product from end users
30/11/2021**

Year

2022

Country of origin

People's Republic of China

Alert submitted by

Belgium