



Salud

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

Fecha: 17 DIC. 2021

Alertas RAPEX mascarillas  
Referencia: SOFM/BBG/crm  
Fecha: 17/12/2021

Hora:  
Número: 5-259940

### 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	APECTA	CALIFICACIÓN	OBSERVACIONES
A12/01489/21	RESPIRADOR FFP2 NR	grave	La retención de partículas/filtros del material es insuficiente.
A12/01530/21	KN95 Face Mask	grave	La retención de partículas / filtro del material es insuficiente.
A12/01531/21	TEX-TECH FFP2 Premium	grave	La retención de partículas / filtro del material es insuficiente
A12/01553/21	Disponible 3-Layer Mask	grave	La retención de partículas / filtro del material es insuficiente
INFO/00161/21	KN95 desconocido	info	El producto lleva el marcado CE, pero su capacidad de filtrado no ha sido probado por un organismo europeo competente.
INFO/00162/21	KN95 desconocido	info	El producto lleva el marcado CE, pero su capacidad de filtrado no ha sido probado por un organismo europeo competente.
INFO/00163/21	KN95 desconocido	info	El producto lleva el marcado CE, pero su capacidad de filtrado no ha sido probado por un organismo europeo competente.

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.

DOCUMENTO FIRMADO ELECTRONICAMENTE			en formato PDF/A-1.7 Firma PAdES Custodiado en repositorio seguro del Gobierno de La Rioja.	Pág. 1 / 2
Expediente	Tipo	Procedimiento	Nº Documento	
00860-2021/146473	Escrito	Solicitudes y remisiones generales	2021/1088277	
Cargo	Firma de Quien emite		Fecha hora	
1 Jefe Servicio de Ordenación Farmacéutica y Medicamentos	Beatriz Barrio García		17/12/2021 09:15:31	
2 SELLADO ELECTRONICAMENTE por Gobierno de La Rioja con CSV: 8MHXSUCTRRHHVO3			Dirección de verificación: <a href="http://www.larioja.org/verificacion">http://www.larioja.org/verificacion</a>	
			17/12/2021 09:15:48	



**Gobierno  
de La Rioja**

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](mailto:alertas.productossanitarios@larioja.org)
- Carta: Servicio de Ordenación Farmacéutica y Medicamentos - Productos Sanitarios C/ Obispo Lepe s/n 26071 Logroño

DOCUMENTO FIRMADO ELECTRÓNICAMENTE			en formato PDF/A-1.7 Firma PAdES Custodiado en repositorio seguro del Gobierno de La Rioja.		Pág 2 / 2
Expedient	Tip	Procedimiento	Nº Documento		
00860-2021/148473	Escrito	Solicitudes y remisiones generales	2021/1088277		
Cargo			Fecha hora		
1	Jefe Servicio de Ordenación Farmacéutica y Medicamentos	Beatriz Barrio García	17/12/2021 09:15:31		
2	SELLADO ELECTRÓNICAMENTE por Gobierno de La Rioja con CSV: 8MHXSUCTRRHV03 Dirección de verificación: <a href="http://www.larioja.org/verificacion">http://www.larioja.org/verificacion</a>		17/12/2021 09:15:48		

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Case number **INFO/00161/21**

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

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Name (on the product or the packaging) **Disposable anti particle respirator**

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

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 **Unknown**

Batch number **20200422**

Bar code **Unknown**

Product description **Black foldable mask with white ventilation hole. Product sold online.**

Packaging description **Black/white/transparent plastic bag, marked with KN95 and CE-mark**

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. 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 Personal Protective Equipment Regulation.**

(Overall) risk level **Unknown**

Product category **Protective equipment**

Measures

**Voluntary measures**

**Retailer**

**Withdrawal of the product from the market  
27/10/2021**

Year

2021

Country of origin

People's Republic of China

Alert submitted by

Estonia

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Case number **INFO/00162/21**

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

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Name (on the product or the packaging)

**Particle mask**

Brand (on the product or the packaging)

• **Wanbang**

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

**KN95**

Batch number

**Unknown**

Bar code

**6973097730034**

Product description

**White foldable mask with ear straps and without valve.**

Packaging description

**White/dark blue/transparent plastic pouch, with two masks inside. The packaging has a CE marking printed on it.**

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. 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 Personal Protective Equipment Regulation.**

(Overall) risk level **Unknown**

Product category **Protective equipment**

Measures **Voluntary measures**

**Distributor**

**Withdrawal of the product from the market  
27/10/2021**

**Year**

**2021**

**Country of origin**

**People's Republic of China**

**Alert submitted by**

**Estonia**

Case number **INFO/00163/21**

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



Name (on the product or the packaging) **KN95 folding respiratory resistance folding mask**

Brand (on the product or the packaging) **YZX - Protective mask**

OECD Portal category (if known) **8800000 - Safety / Protection - DIY**

Is the product (also) sold online? **No**

Professional product? **No**

Product Recall

Type/number of model **YZX-1066**

Batch number **Unknown**

Bar code **6973207110015**

Product description **White foldable mask with ear straps and without valve, market only with YZX.**

Packaging description **White/green plastic pouch, with one mask inside. The packaging has a CE marking and a reference to the EN 149 standard printed on it.**

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. Consequently, it is not proven that the product fulfills 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 Personal Protective Equipment Regulation.**

(Overall) risk level **Unknown**

Product category **Protective equipment**

Measures **Voluntary measures**

**Distributor**

**Withdrawal of the product from the market  
27/10/2021**

Year

**2021**

Country of origin

**People's Republic of China**

Alert submitted by

**Estonia**



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Case number **A12/01489/21**

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

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Name (on the product or the packaging) **RESPIRADOR FFP2 NR**

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

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

Is the product (also) sold online? **Unknown - We have no information about this.**

Professional product? **No**

Product Recall

Type/number of model **BTRFFP2**

Batch number **BTRFFP220210202**

Bar code **5602481003928**

Product description **White half mask with five layers of protection**

Packaging description **Blue and white box containing 50 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 62%). 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**

**Manufacturer**

**Recall of the product from end users  
06/09/2021**

**Year**

**2021**

**Country of origin**

**Portugal**

**Alert submitted by**

**Belgium**

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Case number **A12/01530/21**

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

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Name (on the product or the packaging) **KN95 Face Mask**

Brand (on the product or the packaging) **• Yiwu Ori-Power Medtech**

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

Is the product (also) sold online? **Unknown - Not known**

Professional product? **No**

Product Recall

Type/number of model **Unknown**

Batch number **200411**

Bar code **Unknown**

Product description **Protective respiratory filtration white half-face mask with no markings.**

Packaging description **The product is sold in a mainly white cardboard packaging containing 10 items; the package is marked with KN95 and bears an illustration of a black mask and the CE marking without NB numbers.**

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 27%). 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**

**Recall of the product from end users**

**Compulsory measures**

**Other**

**Importer has voluntarily carried out a recall.**

Year

**2021**

Country of origin

**People's Republic of China**

Alert submitted by

**Germany**

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Case number **A12/01531/21**

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

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Name (on the product or the packaging) **FFP2 respiratory mask high filtration efficiency**

Brand (on the product or the packaging) **• TEX-TECH**

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 **FFP2 Premium**

Batch number **01102020/T**

Bar code **8594176575094**

Product description **White masks with 'TEX-TECH FFP2 Premium' labelling. The number 1040 appears next to the CE mark on the masks.**

Packaging description **The product is sold in a coloured cardboard box.**

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; thus, even if combined with other recommended measures, it may not properly protect. Furthermore, the physical resistance of the filtering material is too high (measured values of exhalation resistance: up to 3,8 mbar). Consequently, it may prevent a sufficient quantity of air to be exhaled, causing difficulties to breathe.**

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**

**Other**

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

**Voluntary measures**

**Retailer**

**Recall of the product from end users**

**Year**

**2021**

**Country of origin**

**Czechia**

**Alert submitted by**

**Germany**

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Case number **A12/01553/21**

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

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Name (on the product or the packaging) **Disposable 3-Layer 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 - no information available**

Professional product? **No**

Product Recall

Type/number of model **EPM003**

Batch number **Unknown**

Bar code **EAN 5901299957714**

Product description **Particle filter mask.**

Packaging description **Plastic packaging containing 5 pcs. of product.**

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%). 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	Voluntary measures Importer Withdrawal of the product from the market 19/10/2021	
Year	Country of origin	Alert submitted by
2021	People's Republic of China	Poland