

Alertas RAPEX mascarillas
Referencia: SOFM/BBG/apf
Fecha: 16/06/2021

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.

Las alertas del sistema RAPEX son incluidas por un Estado Miembro, en este caso proceden de Italia, Alemania, Rumanía, Holanda, Islandia y Estonia. Se adjuntan las últimas referentes a mascarillas de filtración para protección frente al contagio por COVID19:

- La A12/00684/21, notificada desde Alemania por capacidad de filtrado insuficiente acorde a lo dispuesto en los ensayos establecidos en la Norma Europea EN 149:2009 sobre dispositivos de protección respiratoria.
- La A12/00685/21, notificada desde Rumanía porque no se adapta adecuadamente a la cara y en consecuencia, pueden pasar una cantidad excesiva de partículas o microorganismos.
- La A12/00690/21, notificada desde Malta porque el nivel de filtración no es acorde al declarado por el producto

En todos los casos se ha dispuesto la **retirada del mercado** de las mismas.

Le solicitamos que consulten frecuentemente las alertas emitidas por las autoridades europeas en:

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: Tfno: 941 299 923 - mail: alertas.productossanitarios@larioja.org

Logroño, 16 de junio de 2021



Beatriz Barrio García
JEFA DE SECCIÓN DE ATENCIÓN FARMACÉUTICA



**Gobierno
de La Rioja**
Salud y Portavocía del Gobierno
Humanización, Prestaciones
y Farmacia

Gobierno de La Rioja
Oficina Auxiliar de Registro
Salud

Fecha:

16 JUN. 2021

Hora:

S-125462

Número:



<p>Product (what the product is) Particle filter mask</p> <p>Name (on the product or the packaging) KN95 Protective Mask FOR ADULT</p> <p>Brand (on the product or the packaging) GAOZHEN</p> <p>OECD Portal category (if known) 85000000 - Safety / Protection - DIY</p> <p>Is the product (also) sold online? Unknown - Not known</p> <p>Professional product? No</p> <p>Product description White half-face masks</p> <p>Packaging description Cardboard box with 50 masks, each individually packed in transparent plastic packaging with labelling.</p>	<p>Product Recall</p> <p>Type/number of model • GZ-KN95</p> <p>Batch number • 20200501</p> <p>Bar code • 6935624000100</p> <p>Is the product counterfeit? Unknown</p> <p>Is this notification linked to a Business Gateway case?</p>	<p>Case number A12/00684/21</p> <p>Type of risk Health risk / other</p> <p>Risk description (technical defect and consequences) The particle filter retention of the material is insufficient (measured values as low as 44%). Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.</p> <p>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.</p> <p>(Overall) risk level Serious</p> <p>Product category Protective equipment</p> <p>Measures</p> <p>Voluntary measures</p> <p>Retailer</p> <p>Recall of the product from end users 20/04/2021</p>
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Year	Country of origin	Alert submitted by
2021	People's Republic of China	Germany



Case number
A12/00685/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The mask does not properly adapt to the face. Consequently, an excessive amount of particles or microorganisms might pass; thus, even if combined with other recommended measures, it may not properly protect.

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)
Disposable Mask (Non-medical)

Type/number of model
Unknown

Batch number
Unknown

Brand (on the product or the packaging)
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

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

Is this notification linked to a Business Gateway case?

Is the product (also) sold online?
No

Professional product?
No

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

Distributor

Withdrawal of the product from the market
11/05/2021

Product description
The face mask is of uniform light blue material, with white edges and without valve. The mask has white straps to be attached around the ears.

Packaging description
The product is sold in a white with blue highlights cardboard box containing 50 pieces.

Year

Country of origin

Alert submitted by



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Personal Face Mask N95

Brand (on the product or the packaging)
• Panodyne

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

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

Professional product?
No

Product description
Face masks packed in individual labelled transparent plastic, in boxes of 50 Face masks with ear lugs marked (PM2.5 95 FFP2 Panodyne CE)

Packaging description
Face masks packed in individual labelled transparent plastic, in boxes of 50 with dimensions of 200x100x100mm/box

Product Recall

Type/number of model
• FBN95M-U

Batch number
• V001 19.03.2020

Bar code
• 5060710519051

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00690/21

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. Additionally, the particle/filter retention of the material is insufficient (measured values: as low as 39%), the total filtration capacity of the mask is insufficient (measured mean 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

Other

**Recall of the product from end users
04/05/2021**

Year

Country of origin

Alert submitted by