

Alertas RAPEX mascarillas
Referencia: SOFM/BBG/apf
Fecha: 14/09/2021

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. Las alertas del sistema RAPEX son notificadas por un Estado Miembro. Algunos de los productos notificados puede que no se encuentren disponibles en nuestro país, salvo que se adquirieran a través de comercio electrónico.

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

| | |
|--------------|--------------|
| A12/01014/21 | A12/01159/21 |
| A12/01064/21 | A12/01173/21 |
| A12/01088/21 | A12/01183/21 |
| A12/01137/21 | |


Estas alertas han sido calificadas como A12 por haber sido sometidos los productos a ensayos y presentar en todos los casos una capacidad de filtrado insuficiente acorde a lo dispuesto en la Norma Europea EN 149:2009 sobre dispositivos de protección respiratoria, por ello se ha dispuesto la **retirada del mercado** de las mascarillas afectadas.

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, 14 de septiembre de 2021



Beatriz Barrio García
JEFA DE SERVICIO DE ORDENACIÓN
FARMACÉUTICA Y MEDICAMENTOS



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

Gobierno de La Rioja
Oficina Auxiliar de Registro
Salud

Fecha: 15 SET. 2021

Hora:

Número: 194630



Case number
A12/01014/21

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 35%), 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 Regulation and with the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Compulsory measures

Importer

Recall of the product from end users

Product (what the product is)
Particle filter mask

Product Recall

Type/number of model
• D373853

Name (on the product or the packaging)
Disposable Face Mask

Batch number
• 573627

Brand (on the product or the packaging)
Unknown

Bar code
Unknown

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

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Is the product (also) sold online?
No

Professional product?
No

Product description
Protective respiratory filtration half-face mask.

Packaging description
The product is sold in a white and blue plastic pouch containing 5 items per packaging. The package indicate the claims FFP2 and KN95 and the CE marking, and makes reference to the European standard EN 149.

Year

Country of origin

Alert submitted by

Confidential



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
atemious pro

Brand (on the product or the packaging)
Univent medical

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

Is the product (also) sold online?
Yes - Amazon

Professional product?
No

Product description
White respiratory face mask with ear loops. The product was sold online, in particular via Amazon.

Packaging description
The product is sold individually packaged or in larger packaging units. The claim FFP2 and the CE marking are printed both on the box and on the individual product.

Product Recall

Type/number of model
• 2001

Batch number
Unknown

Bar code
• 4260688380047

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/01064/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The total filtration capacity of the mask and the particle/filter retention of the material are insufficient

(measured mean values as low as 78%, and measured filter penetration values as low as 89%, respectively). 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

Voluntary measures

Other

Manufacturer

Recall of the product from end users

Stop of sales

Year

Country of origin

Alert submitted by

2021

Germany

Germany



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 Professional Protection

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 description
Protective respiratory filtration half-face mask. The product was also sold online, in particular on Ebay and AliExpress.

Packaging description
The masks are packaged in white plastic pouch with turquoise lettering and a sticker with hybrid labelling (KN95 and FFP2/CE). In contrast, there is no information on the masks about manufacturer, model or barcode.

Product Recall

Type/number of model
Unknown

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/01088/21

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 63%).

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 Voluntary measures

Retailer

Retailer

**Removal of this
product listing by
the online
marketplace
22/06/2021**

**Recall of the product
from end users
22/06/2021**

**Compulsory
measures**

Other

**Stop of sales
22/06/2021**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Protective Mask FFP2

Partikelfiltrierende Halbmask

Brand (on the product or the packaging)
• **Eversmart Nano**

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

Is the product (also) sold online?
Unknown - The dealer, Tisch und Herd, has, by its own account, mainly sold this offline, and online only to MÜB [Market surveillance authority] (government of Upper Bavaria); the dealer Tisch und Herd had 600 sales units from the batch in question, 460 of which remain in

Product Recall

Type/number of model
• **HZ-KN95 Super Safe**

Batch number
• **20201116**

Bar code
• **6925814400317**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/01137/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking but its declaration of conformity is not complete; additionally, the appropriate warnings and instructions for use are missing. The particle/filter retention of the material is insufficient (measured values: as low as 85%); hence, the product does not fulfil the health and safety requirements. Furthermore, the mask does not properly adapt to the face. Consequently, 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

store

Professional product?
No

Product description
Five white FFP2 NR protective face masks.
The product is also sold online.

Packaging description
The product is sold per blocks of five white,
packed in a plastic bag printed red-white.

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 Voluntary measures

Retailer Retailer

Stop of sales Recall of the product
from end users

Compulsory
measures

Other

Stop of sales

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany



| | | |
|--|---|--|
| <p>Product (what the product is) Particle filter mask</p> | <p>Product Recall Type/number of model • FL0616</p> | <p>Case number A12/01159/21</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 60%) and the total filtration capacity of the mask is insufficient (measured mean values: as low as 69%). Furthermore, the mask does not properly adapt to the face. Consequently, the product does not fulfil the health and safety requirements, and an excessive amount of particles or microorganisms might pass through the mask; thus, even if combined with other recommended measures, it may not properly protect.</p> |
| <p>Name (on the product or the packaging) Particulate Respirator FFP2 PRO - SERIES</p> | <p>Batch number Unknown</p> <p>Bar code Unknown</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 and with</p> |
| <p>Brand (on the product or the packaging) • Giebielok®</p> | <p>Is the product counterfeit? No</p> | |
| <p>OECD Portal category (if known) 85000000 - Safety / Protection - DIY</p> | <p>Is this notification linked to a Business Gateway case?</p> | |
| <p>Is the product (also) sold online? No</p> | | |
| <p>Professional product? No</p> | | |
| <p>Product description White particle filter with the brand, model and claim FFP2/EN 149 printed on it, as well as with the CE 1282 marking.</p> | | |
| <p>Packaging description The product is sold in a white/blue cardboard box with the following information: Giebielok® PRO - SERIES; FFP2 Particulate Respirator; Adult Size. The product is packed in boxes of 30 pieces; 6 pieces in cellophane package.</p> | | |

**the relevant
European standard
EN 149.**

**(Overall) risk level
Serious**

**Product category
Protective equipment**

Measures

**Compulsory
measures**

**Compulsory
measures**

Importer

Importer

**Withdrawal of the
product from the
market
25/05/2021**

**Recall of the product
from end users
25/05/2021**

**Compulsory
measures**

Importer

**Warning consumers
of the risks
25/05/2021**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Slovakia



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
**Particulate
Respirator FFP2
Lexuslance**

Brand (on the product or the packaging)
• **Huizhou
LexusLance
Technology
LexusLance**

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

Is the product (also) sold online?
Yes - Other

Professional product?
No

Product description
White particle filter mask with the brand/name, model and claim FFP2/EN 149 printed on it, as well as with the CE 202003 marking. The product is also sold online.

Packaging description
The product is packed in 5 pieces in a white-blue plastic bag.

Product Recall.
<https://blog.mall.sk/mall-sk/dolezite-upozornenie-pre-nasich-zakaznikov-nebezpecny-respirator-filtracna-polmaska-ffp2-nr-lexuslance-ik-003-988.html>
Slovak (sk)

Type/number of model
• **LK-003**

Batch number
• **2402708**

Bar code
• **8595243843078**

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/01173/21

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 61%) and the total filtration capacity of the mask is insufficient (measured mean values: as low as 74.5%). Furthermore, the mask does not properly adapt to the face. Consequently, the product does not fulfil the health and safety requirements, and an excessive amount of particles or microorganisms might pass through the mask; 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**

**Compulsory
measures**

Retailer

Retailer

**Warning consumers
of the risks
27/05/2021**

**Withdrawal of the
product from the
market
27/05/2021**

**Compulsory
measures**

Retailer

**Recall of the product
from end users
27/05/2021**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Slovakia



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 Professional Protection

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 description
Yellow protective respiratory filtration half-face mask with white elastics, marked with KN95 and a reference to EN 149; the CE 2163 marking is also printed on the mask. The product was sold online, in particular via eBay (224376460742) and AliExpress.

Packaging description
The masks are packaged in plastic pouches with turquoise lettering, and containing 10 items each. The packaging bears the claim of "95% filtration efficiency" and is marked

Product Recall

Type/number of model
Unknown

Batch number
• 224376460742

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/01183/21

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 71%).

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.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Compulsory measures

Other

Voluntary measures

Distributor

Removal of this

with KN95 and CE and does not state the manufacturer's name, model references, an appropriate barcode or other information.

Removal of this product listing by the online marketplace
26/07/2021

product listing by the online marketplace
27/07/2021

Voluntary measures

Voluntary measures

Retailer

Retailer

Withdrawal of the product from the market
26/07/2021

Recall of the product from end users
26/07/2021

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany