

Alertas RAPEX mascarillas
Referencia: SOFM/BBG/apf
Fecha: 21/07/2021

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 adquieran a través de comercio electrónico.

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

A12/00756/21	A12/00768/21	A12/00769/21
A12/00770/21	A12/00771/21	A12/00779/21
A12/00785/21	A12/00808/21	A12/00810/21
A12/00814/21		

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, 21 de julio de 2021



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

Beatriz Barrio García
JEFA DE SECCIÓN DE ATENCIÓN FARMACÉUTICA

Gobierno de La Rioja
Oficina Auxiliar de Registro
Salud

Fecha: 21 JUL. 2021

Hora: S-154527

Número:



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
TRNMT

Brand (on the product or the packaging)
• **TRN MedTeks**
Face Mask

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

Is the product (also) sold online?
Unknown - No
research has been carried out to ascertain whether there have been any online sales.

Professional product?
No

Product description
White half-face particle filter mask, branded FFP2.

Packaging description
Multi-pack cardboard holder containing 50 items, individually wrapped in cellophane envelopes.

Product Recall

Type/number of model
• **NRFM002**

Batch number
• **010750**

Bar code
• **8682780742039**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00756/21

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 85%). 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

Manufacturer

Ban on the marketing of the product and any accompanying measures



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 Protective mask (non-medical)

Brand (on the product or the packaging)
• YWSH

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

Is the product (also) sold online?
No

Professional product?
No

Product description
The mask is of grey-green camouflage coloured material and with a valve. The mask has white straps that fit around the ears.

Packaging description
10 masks in a white-red cardboard box. Every mask is wrapped individually in a transparent plastic bag.

Product Recall

Type/number of model
• SH-ZH12

Batch number
• 20200731

Bar code
• 6426450530722

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00768/21

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 65%). 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 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

Year

Country of origin

Alert submitted by



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 Stereo 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?
Unknown - not sure, tried to search but did not come across identical products

Professional product?
No

Product description
White protective respiratory filtration half-face mask, with elastic ear bands and nose strip, marked with "KN95".

Packaging description
The product is sold in packs of 5 items, packed in transparent plastic pouch with green trim measuring 200x130mm.

Product Recall

Type/number of model
• KN95

Batch number
Unknown

Bar code
Unknown

Is the product counterfeited?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00769/21

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 32%). The total filtration capacity of the mask is insufficient (measured mean values: as low as 65%). 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



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)
FRIEND JI

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

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

Professional product?
No

Product description
White disposable protective respiratory filtration half-face mask, foldable, marked with "KN95". The product is also sold online.

Packaging description
The product is sold in plastic pouches of 5 pieces, included in a cardboard box (20 x 10 x 10mm) containing 20 pieces (4 plastic pouches).

Product Recall

Type/number of model
• KN95 (folding disposable mask)

Batch number
• 20200417

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00770/21

Type of risk
Microbiological

Risk description (technical defect and consequences)

The total filtration capacity of the mask is insufficient (measured mean values: as low as 48%). 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



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
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 - Other

Professional product?
No

Product description
White foldable face mask with ear-loops and outside nose clip.

Packaging description
White/blue plastic bag with 5 masks inside.

Product Recall

Type/number of models
• **AP-83001**

Batch number
• **20.05.2020**

Bar code
• **4741491000563**

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/00771/21

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 78%). 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



<p>Product (what the product is) Particle filter mask</p> <p>Name (on the product or the packaging) KN95 mask</p> <p>Brand (on the product or the packaging) Unknown</p> <p>OECD Portal category (if known) 85000000 - Safety / Protection - DIY</p> <p>Is the product (also) sold online? No</p> <p>Professional product? No</p> <p>Product description White respiratory protective half-face mask.</p> <p>Packaging description The product is sold in a white cardboard box containing 10 pieces.</p>	<p>Product Recall https://rv.is/thjonust-a-innkollun-voru/ Portuguese (pt)</p> <p>Type/number of model Unknown</p> <p>Batch number Unknown</p> <p>Bar code Unknown</p> <p>Is the product counterfeit? Unknown</p> <p>Is this notification linked to a Business Gateway case?</p>	<p>Case number A12/00779/21</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 73%) and the total filtration capacity of the mask is insufficient (measured mean values: as low as 60%). Furthermore, the mask does not fit correctly to the face of the user. Consequently, 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>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.</p> <p>(Overall) risk level Serious</p> <p>Product category Protective equipment</p> <p>Measures</p> <p>Voluntary measures</p> <p>Distributor</p> <p>Recall of the product from end users 23/03/2021</p>
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Year.

Country of origin

Alert submitted by

2021

Unknown

Iceland



Product (what the product is)
KN95 Mask Disposable Protective Mask

Name (on the product or the packaging)

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

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

Packaging description
The masks are sold sealed in a paper/plastic packaging, six per pack. Product information (brand, model, company, instructions for use) are shown in black lettering on a white background with green markings on the back.

Product Recall

Type/number of model
 • **MD-PM001**

Batch number
 • **MFG: 20042101**
 • **LOT: 2020/4/21**

Barcode
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00785/21

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.

The particle/filter retention of the material is insufficient (measured values: as low as 69%).

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 the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Disposable KN95 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 - Other

Professional product?
No

Product description
White foldable KN95 mask with earloops and without valve.

Packaging description
Transparent plastic packaging with green print, 65 masks inside

Product Recall

Type/number of model
• **KN95**

Batch number
• **2020.04.20**

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00808/21

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 relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures Voluntary measures



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Filter Half Mask

Brand (on the product or the packaging)
• NQX

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

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

Professional product?
No

Product description
Protective respiratory filtration half-face mask. The product is also sold online, in particular via eBay.

Packaging description
The product is sold, one item per package, in a white plastic packaging with blue inscriptions, including the claim "FFP2".

Product Recall

Type/number of models
• NQX-2001

Batch number
Unknown

Bar code
• 6973182610296

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00810/21

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 80%).

Furthermore, 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



<p>Product (what the product is) Personal protective equipment</p> <p>Name (on the product or the packaging) Changmei</p> <p>Brand (on the product or the packaging) DFM-01</p> <p>OECD Portal category (if known) 85000000 - Safety / Protection - DIY</p> <p>Is the product (also) sold online? Unknown - No research has been carried out to ascertain whether there have been any online sales.</p> <p>Professional product? Yes</p> <p>Product description Particle filter half-face mask</p> <p>Packaging description Cellophane envelope containing five pieces.</p>	<p>Product Recall</p> <p>Type/number of model • FFP2 NR - CE 2834</p> <p>Batch number • DMF20051105</p> <p>Barcode • 806891395900</p> <p>Is the product counterfeit? Unknown</p> <p>Is this notification linked to a Business Gateway case?</p>	<p>Case number A12/00814/21</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 91%). 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 and with the relevant European standard EN 149.</p> <p>(Overall) risk level Serious</p> <p>Product category Protective equipment</p> <p>Measures</p> <p>Compulsory measures</p> <p>Distributor</p> <p>Withdrawal of the product from the market 16/03/2021</p>
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Year

Country of origin

Alert submitted by