

Alertas RAPEX mascarillas
Referencia: SOFM/MJA/apf
Fecha: 05/02/2021

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.

Se adjuntan las últimas alertas RAPEX referentes a mascarillas de filtración para protección frente al contagio por COVID19. La citas alertas son INFO-00004/21, INFO-00006/21, INFO-00007/21, INFO-00008/21, INFO-00009/21, INFO-00010/21, INFO-00012/21, INFO-00013/21, INFO-00014/21, INFO-00015/21, INFO-00016/21.

Estas alertas han sido incluidas en RAPEX por un Estado Miembro en cada caso. Las alertas calificadas como INFO, todas en esta ocasión, presentan un incumplimiento documental que en las arriba citadas consiste en no haber sido acreditadas por un organismo europeo competente como corresponde, pero todavía no se han realizado ensayos analíticos acerca de la seguridad del producto.


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&lng=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

Logroño, 5 de febrero de 2021



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

Dra. M^a José Aza Pascual-Salcedo
JEFA DE SERVICIO DE ORDENACIÓN
FARMACÉUTICA Y MEDICAMENTOS

Gobierno de La Rioja
Oficina Auxiliar de Registro
Salud

Fecha: / 5 FEB. 2021

Hora:

Número.

S. 24575



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Disposable face mask

Brand (on the product or the packaging)
DMC

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

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

Professional product?
No

Product description
Black or pink three-layer masks, with the indication "PPE category 1/type IIR".

Packaging description
White cardboard box with blue text, containing 50 black or pink masks inside. The package is marked with CE and "PPE category I". The product is also sold online.

Product Recall

Type/number of models
DM-100

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00004/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking but is not certified as

protective equipment by a relevant body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Compulsory measures

Retailer

Retailer

**Withdrawal of the
product from the
market
25/12/2020**

**Removal of this
product listing by
the online
marketplace
25/12/2020**

Year

Country of origin

Alert submitted by

2021

Unknown

Estonia

DRAFT



Case number
INFO/00006/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product advertises a protective potential against (viral) particles but its filtering capacity has not been certified by a relevant (European) body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.

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.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Voluntary measures

Retailer

Withdrawal of the product from the market
23/09/2020

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)
KN95

Type/number of model
• **BH1083X-010**

Brand (on the product or the packaging)
Unknown

Batch number
Unknown

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

Bar code
• **5902628219800**

Is the product counterfeit?
Unknown

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

Is this notification linked to a Business Gateway case?

Professional product?
No

Product description
White respiratory protective half-face mask.

Packaging description
Plastic bag containing 10 pieces. On the label it is indicated that the product is a "hygienic mask KN95", and in the instructions it is advertised as a personal protective equipment.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Latvia



Case number
INFO/00007/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking but is not certified as protective equipment by the relevant body. Consequently, the product might not fulfill the health and safety requirements and properly protect when combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Importer

Import rejected at border
17/06/2020

Product (what the product is)
Particle filter mask

Product Recall

Type/number of model
• SYM-001

Name (on the product or the packaging)

Batch number
Unknown

Brand (on the product or the packaging)
Unknown

Bar code
Unknown

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

Is the product counterfeit?
Unknown

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

Is this notification linked to a Business Gateway case?

Professional product?
No

Product description
White respiratory protective half-face mask.

Packaging description
Plastic bag, with the indication "KN95".

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Luxembourg



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Disposable medical mask FFP2 NR

Brand (on the product or the packaging)
Unknown

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

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

Professional product?
No

Product description
Disposable medical face mask.

Packaging description
The product is sold in a plastic bag, with a small label indicating compliance with category FFP2 NR.

Product Recall

Type/number of model
• DN-68

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00008/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking but is not certified as protective equipment by the relevant body. Consequently, the product might not fulfill the health and safety requirements and properly protect when combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Importer

**Import rejected at border
19/05/2020**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Luxembourg



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 Particulate Respirator

Brand (on the product or the packaging)
Unknown

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

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

Professional product?
No

Product description
White respiratory protective half-face mask.

Packaging description
The product is sold in a plastic bag containing 10 masks supposed to be packed into box of 40 pcs. The box indicates compliance to categories KN95 / FFP2.

Product Recall

Type/number of model
• KN95 FFP2

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00009/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking but is not certified as protective equipment by the relevant body. Consequently, the product might not fulfill the health and safety requirements and properly protect when combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Importer

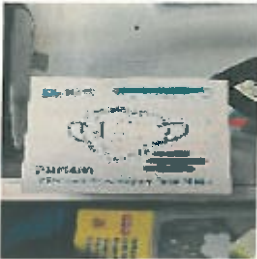
**Import rejected at border
29/04/2020**

Year

Country of origin

Alert submitted by

DRAFT



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Infection Prevention Face Mask

Brand (on the product or the packaging)
Daddy's Choice

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

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

Professional product?
No

Product description
White foldable filter mask without any marking. The product is also sold online.

Packaging description
White and green cardboard box with 20 masks inside.

Product Recall

Type/number of model
• Purism

Batch number
• produced 30.03.2020

Bar code
• 6938497150097

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00010/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking but is not certified as protective equipment by a relevant body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Voluntary measures

Importer

Withdrawal of the product from the market 08/12/2020

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Estonia



Case number
INFO/00012/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product advertises a protective potential against (viral) particles but its filtering capacity has not been certified by a relevant (European) body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Voluntary measures

Retailer

Withdrawal of the product from the market 08/09/2020

Product (what the product is)
Particle filter mask

Product Recall

Type/number of model
• YMS-AN95

Name (on the product or the packaging)
YOMASI KN95

Batch number
• 0371-27939196

Brand (on the product or the packaging)
Unknown

Bar code
Unknown

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

Is the product counterfeit?
Unknown

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

Is this notification linked to a Business Gateway case?

Professional product?
No

Product description
Protective mask type KN95. The product was also sold online.

Packaging description
Plastic bag white-blue

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Latvia



Case number
INFO/00013/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product is accompanied by a declaration of conformity to Regulation (EU) 2016/425 and to the European standard EN 149:2009, but it has not been certified as such by the relevant European body. Consequently, the product might not fulfil the health and safety requirements and properly protect when combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Importer

**Import rejected at border
19/05/2020**

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)

Type/number of model
• PEC-MS1

Brand (on the product or the packaging)
Unknown

Batch number
Unknown

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

Bar code
Unknown

Is the product counterfeit?
Unknown

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

Is this notification linked to a Business Gateway case?

Professional product?
No

Product description
Disposable civilian face mask

Packaging description
Box containing 50 masks in a plastic bag

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Luxembourg



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
**Protective Mask.
KN95**

Brand (on the product or the packaging)
Unknown

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

Is the product (also) sold online?
No

Professional product?
No

Product description
White respiratory protective half-face mask of category KN95

Packaging description
Box with 10 pieces of masks

Product Recall

Type/number of model
• KN95

Batch number
Unknown

Bar code
• 6973247460002

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00014/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)

The product is accompanied by a declaration of conformity to Regulation (EU) 2016/425 and to the European standard EN 149:2009, but it has not been certified as such by the relevant European body. Consequently, the product might not fulfil the health and safety requirements and properly protect when combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Compulsory measures

Retailer

Retailer

Withdrawal of the product from the market
06/01/2021

Ban on the marketing of the product and any accompanying measures
06/01/2021

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Luxembourg

DRAFT



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Protective Mask KN95

Brand (on the product or the packaging)
Xina

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

Is the product (also) sold online?
No

Professional product?
No

Product description
White respiratory protective half-face mask.

Packaging description
White cardboard box with red and black indications, containing 20 pieces of masks singularly wrapped in plastic pouches. The mentions KN95 and FFP2 are on the box.

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
INFO/00015/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking but is not certified as protective equipment by the relevant European body.

Consequently, the product might not fulfill the health and safety requirements and properly protect when combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Compulsory measures

Retailer

Retailer

**Withdrawal of the
product from the
market
09/11/2020**

**Ban on the
marketing of the
product and any
accompanying
measures
09/11/2020**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Luxembourg

DRAFT



Case number
INFO/00016/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product advertises a protective potential against (viral) particles but its filtering capacity has not been certified by a relevant (European) body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.

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
Unknown

Product category
Protective equipment

Measures

Voluntary measures

Distributor

Withdrawal of the product from the market 16/11/2020

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)
UEACON

Type/number of model
Unknown

Brand (on the product or the packaging)
Unknown

Batch number
Unknown

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

Bar code
• 3295249103358

Is the product counterfeit?
Unknown

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

Is this notification linked to a Business Gateway case?

Professional product?
No

Product description
White respiratory protective half-face mask.

Packaging description
Plastic bag containing 2 pieces. On the label and on the mask it is indicated "respirator FFP2"

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Latvia