

Fecha: - 4 JUN. 2021

Hora: 8-12:55
Número:

Alertas RAPEX mascarillas
Referencia: SOFM/BBG/apf
Fecha: 04/06/2021

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 adquirieran a través de comercio electrónico.

Las alertas del sistema RAPEX son incluidas por un Estado Miembro, en esta 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, las INFO/00102/21, INFO/00103/21, INFO/00104/21, INFO/00108/21, INFO/00109/21 e INFO/00110/21, y las A12/00572/21, A12/00573/21, A12/00574/21, A12/00575/21, A12/00580/21, A12/00591/21, A12/00642/21, A12/00643/21, A12/00644/21, A12/00657/21, A12/00658/21, A12/00659/21, y la A12/00660/21

Las calificadas como INFO los son porque existe un incumplimiento documental, sin haberse realizado ensayos acerca de la seguridad del producto. Los fallos documentales encontrados en estos casos son haberse puesto en el mercado sin el «marcado CE» o haberse emitido el mismo por organismo no competente.

Las calificadas como A12 han sido sometidas a ensayos y en las ahora notificadas presentan todas una capacidad de filtrado insuficiente acorde a lo dispuesto en la Norma Europea EN 149:2009 sobre dispositivos de protección respiratoria.

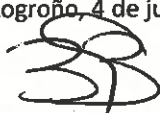
En todos los casos se ha dispuesto la **retirada del mercado** de las mismas.

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, 4 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



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Disposable 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?
No

Professional product?
No

Product description
KN 95 non medical protective mask.

Packaging description
Every mask is wrapped individually in a white-blue transparent plastic bag.

Product Recall

Type/number of model
• KN 95

Batch number
Unknown

Bar code
• 0745125313672

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
INFO/00102/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product advertises a protective potential against particles 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

Compulsory measures

Importer

Import rejected at border
25/03/2021

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Romania



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
**FFP2 Face Mask
KN95**

Brand (on the product or the packaging)
• **Hope and Light
TM**

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

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

Professional product?
No

Product description
Filtering Half Mask (non medical)

Packaging description
The product is sold in printed cardboard packaging containing 20 pieces. The cardboard packaging is white in colour.

Product Recall

Type/number of model
• **YL-95**

Batch number
• **2020710-2**

Bar code
• **None**

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?
No

Case number
INFO/00103/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product's packaging only bears a CE marking and it is not certified as protective equipment 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 the Personal Protective Equipment Regulation.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Voluntary measures

Importer

Destruction of the product
21/03/2021

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Ireland



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)
Unknown

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

Is the product (also) sold online?
No

Professional product?
No

Product description
FFP2 protective mask

Packaging description

Product Recall

Type/number of model
• **FFP2**

Batch number
• **D373853-573627**

Barcode
• **6971998588158**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00104/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)

The product advertises a protective potential against particles 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 the PPE Regulation and with the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Compulsory measures

Distributor

Withdrawal of the product from the market 10/03/2021

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Italy



Product (what the product is)
Particle filter mask

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

Brand (on the product or the packaging)
• **Jiangyin Rongyi Textile Technology Co., Ltd.**

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

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

Professional product?
No

Product description
Disposable protective mask. The mask is of black color.

Packaging description
Sold in a white and blue cardboard packaging containing 50 pieces.

Product Recall

Type/number of model
Unknown

Batch number
Unknown

Bar code
• **8000020200086**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00108/21

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, 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 the Personal Protective Equipment (PPE) Regulation.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Distributor

Ban on the marketing of the product and any accompanying measures
14/04/2021

Year

Country of origin

Alert submitted by

DRAFT

Submission number	LU/02622/21
Case number	INFO/00109/21
Version	1

This notification transcript might contain personal data (as defined in Article 3 of Regulation (EU) 2018/1725) or a trade secret (as defined in Article 2 of Directive (EU) 2016/943).

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For your communication with third parties, a PDF of the notification containing only public data is available in the application.

1| General information

Submission number	LU/02622/21
Case number	INFO/00109/21
Creation date	07/05/2021
Validation/distribution date	11/05/2021
Notification type*	For Information
Notifying country	Luxembourg

2| Product identification

Professional product?*	No
Product category*	Protective equipment
OECD Portal category (if known)*	85000000 - Safety / Protection - DIY
Product (what the product is)*	Particle filter mask
Name (on the product or the	Disposable 3-Layer Mask

packaging)*

Brand (on the product or the packaging)*

Unknown

Type/number of model *

Unknown

Is the product counterfeit?*

Unknown

Batch number *

Unknown

Bar code *

6996850481066

Customs code*

Unknown

Product description*

Disposable face mask

Packaging description*

Sold in a white and blue cardboard packaging containing 50 pieces.

Total number of items covered by the notification *

Unknown

Photos (products, packaging and label)*



Foto1.jpg
Main picture



Foto2.jpg



Foto3.jpg



Foto4.jpg

3| Regulations and standards applicable

Legal provisions at EU level applicable? (directive, decision, regulation, etc.)*

Regulation (EU) 2016/425 - Regulation on personal protective equipment



Submission number **LU/02623/21**

Case number **INFO/00110/21**

Version **1**

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1| General information

Submission number **LU/02623/21**

Case number **INFO/00110/21**

Creation date **07/05/2021**

Validation/distribution date **11/05/2021**

Notification type* **For Information**

Notifying country **Luxembourg**

2| Product identification

Professional product?* **No**

Product category* **Protective equipment**

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

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

Name (on the product or the **Non-powered Air-purifying particulate mask**

packaging)*

Brand (on the product or the packaging)*

Airtao

Type/number of model *

AM02-KN95

Is the product counterfeit?*

Unknown

Batch number *

Unknown

Bar code *

6971253709757

Customs code*

Unknown

Product description*

Protective mask KN95-FFP2

Packaging description*

Sold in a white cardboard packaging containing 20 pieces.

Total number of items covered by the notification*

Unknown

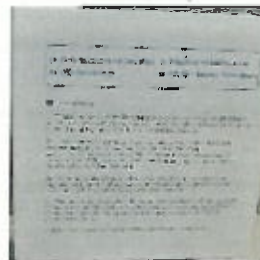
Photos (products, packaging and label)*



20210319_161557.jpg
Main picture



20210319_161605.jpg



20210319_161621.jpg



20210319_161627.jpg

3| Regulations and standards applicable

Legal provisions at EU level applicable? (directive, decision, regulation, etc.)*

Regulation (EU) 2016/425 - Regulation on personal protective equipment



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
FFP2 Mask

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

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
Protective mask, FFP2 model

Packaging description
Sold individually in a transparent plastic bag.

Product Recall

Type/number of model
• **FFP2 - ENKN95-001**

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00572/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The particle/filter retention of the material is insufficient (measured value: 84 %). 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

Measures

Compulsory measures

Distributor

Withdrawal of the product from the market
24/03/2021

Year

Country of origin

Alert submitted by

DRAFT



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 - Mask (non-medical use)

Brand (on the product or the packaging)
Unknown

OECD Portal category (if known)
80000000 - Tools / Equipment - hand

Is the product (also) sold online?
Unknown - The importer, Alex Cares GmbH, has a restricted customer base.

Professional product?
No

Product description
Respiratory protective mask, carrying the labels GB2626-2006, KN95, EN 149, FFP2 and CE.

Packaging description
The product is sold in various packaging types (cardboard boxes, plastic pouches) and sizes.

Product Recall
**<https://alex-cares.eu>
German (de)**

Type/number of model
• JK-001

Batch number
• 20200423

Bar code
Unknown

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/00573/21

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 13%).

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

Voluntary measures Voluntary measures

			Importer	Retailer
			Recall of the product from end users	Recall of the product from end users
			Compulsory measures	
			Other	
			Destruction of the product	
Year	Country of origin	Alert submitted by		
2021	People's Republic of China	Germany		



Case number
A12/00574/21

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 28%). 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

Warning consumers of the risks

Product (what the product is)
Particle filter mask

Name (on the product or the packaging)

Brand (on the product or the packaging)
ISSACANA

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

Is the product (also) sold online?
Unknown - The product was procured by Issacana GmbH for North Rhine-Westphalia.

Professional product?
No

Product description
White respiratory protective face masks with 'external' nose clips and ear loops.

Packaging description
The product is sold in a white cardboard box with red and, grey and black text.

Product Recall

Type/number of model
Unknown

Batch number
Unknown

Bar code
6947662229285

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Year

2021

Country of origin

People's Republic of China

Alert submitted by

Germany



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Filtering Half Mask SMK-02

Brand (on the product or the packaging)
• **Changzhou Shuangma Medical Devices Co Ltd.**

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

Is the product (also) sold online?
No

Professional product?
No

Product description
FFP2 mask

Packaging description
The product is sold in a white cardboard box containing 25 pieces.

Product Recall

Type/number of model
• **Filtering half mask FFP2 NR**

Batch number
Unknown

Barcode
• **Barcode 6945144 700000**

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/00575/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)

The total filtration capacity of the mask is insufficient (measured mean value above the maximum limit of 11%). 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

Import rejected at border 25/03/2021

Year

Country of origin

Alert submitted by

DRAFT



Product (what the product is)
Particle filter mask

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

Brand (on the product or the packaging)
• **CML**
• **ML**

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

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

Professional product?
No

Product description
White particle filter half-face mask, with printed CE marking.

Packaging description
The product is sold in a cardboard packaging with 20 pieces, each individually packaged.

Product Recall

Type/number of model
• **FFP2 JX95**

Batch number
• **20201120**

Bar code
• **8403267623234**

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/00580/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The particle/filter retention of the material is insufficient (measured value: 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**

Distributor

Distributor

**Withdrawal of the
product from the
market**

Stop of sales

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany

DRAFT



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
**SELF-PRIMING
FILTER
RESPIRATOR**

Brand (on the product or the packaging)
• IVROU

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

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

Professional product?
No

Product description
White half-face particle filter mask, sold as "FFP2"

Packaging description
The product is packed in single white-transparent plastic pouches, which are sold in cardboard boxes.

Product Recall

Type/number of model
• IRYS-01

Batch number
• HLB20200906W
• date of manufacture: 06.09.2020 (MFG: 20200906)
• expiry date: 20220905

Bar code
• 8719327230893

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/00591/21

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 19%); additionally, 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

Voluntary measures

Voluntary measures

Distributor

Distributor

Stop of sales

**Withdrawal of the
product from the
market**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany

DRAFT



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Protection Mask

Brand (on the product or the packaging)
• **Dr. Frei**

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

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

Professional product?
No

Product description
Black particle filter mask with small valve.

Packaging description
The product is sold packed in a black and red plastic wrapping, containing a single item.

Product Recall

Type/number of model
Unknown

Batch number
• **exp. 2022**

Bar code
• **3800732484840**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00642/21

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 5%). The total filtration capacity of the mask is insufficient (measured values: as low as 45%). 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.

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

Importer

Recall of the product from end users
01/04/2021

Year

Country of origin

Alert submitted by

2021

Unknown

Iceland



Case number
A12/00643/21

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 73%). Furthermore, the total filtration capacity of the mask is insufficient (measured mean values: as low as 60%). 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.

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

Voluntary measures

Importer

Recall of the product from end users
18/03/2021

Product (what the product is)
Particle filter mask

Product Recall

Type/number of model
Unknown

Name (on the product or the packaging)
Rykgrimir FFP2V 10 stk

Batch number
Unknown

Brand (on the product or the packaging)
Unknown

Bar code
• 2 900058 502007

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

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Is the product (also) sold online?
No

Professional product?
No

Product description
White respiratory protective half-face mask

Packaging description
The product is sold in a soft clear plastic pouch with the CE marking and barcode printed on it. Each pouch contains 10 masks.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Iceland



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Mund- und Nasenmaske

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 particle filter mask in a white/blue box. Each packaging unit contains 10 masks. The CE marking was affixed as an addition. The product is also sold online.

Packaging description
The product is sold in a white/blue box; each packaging unit contains 10 masks. The CE marking was affixed as an addition.

Product Recall

Type/number of model
D13003

Batch number
Unknown

Bar code
4333692653626

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00644/21

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 54%). Additionally, the product's packaging bears a CE marking but not the product itself, which is not certified as protective equipment by a relevant body.

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

Withdrawal of the product from the market

Year

Country of origin

Alert submitted by

DRAFT



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Kokkuklapitav mask KN95

Brand (on the product or the packaging)
• GOOYU

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

Is the product (also) sold online?
Unknown - Kesko Senukai has a web-shop another company UAB Kesko Senukai Digital is operated with it.

Professional product?
No

Product description
White foldable mask with outer nose clip and with ear harnesses. The product is labeled CE FFP2, EN 149, GOOYU KN95. The product was also sold online.

Packaging description

Product Recall
<https://www.k-rauta.ee/kp/uudised/>

9 Estonian (et)

Type/number of model
Unknown

Batch number
• 2025/05

Bar code
• 4772013226321

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/00657/21

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. Additionally, the particle/filter retention of the material is insufficient (measured values: up to 85%), and the mask does not properly adapt to the face leading to an insufficient total filtration capacity (measured mean values: up to 72%). 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)

Light transparent plastic pouch, with the contact details of the manufacturer and the importer printed on one side.

Regulation and with the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures

Voluntary measures

Retailer

Retailer

Withdrawal of the product from the market
03/05/2021

Recall of the product from end users
03/05/2021

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Estonia



Product (what the product is)
Particle filter mask

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

Brand (on the product or the packaging)
• FUPING

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

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

Professional product?
No

Product description
Respiratory protective face mask in white and blue packaging with 'KN95' printed in red, pack of 10

Packaging description
Respiratory protective face mask in white and blue packaging with 'KN95' printed in red, pack of 10

Product Recall

Type/number of model
• KN95

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00658/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product advertises a protective potential against particles but its filtering capacity has not been tested by a relevant competent European conformity assessment body. Additionally, it was found that the particle/filter retention of the material is insufficient (measured values: up to 67%), 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 (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

**Withdrawal of the
product from the
market**

**Stock will be
returned to LAVIKA**

Voluntary measures

Retailer

**Recall of the product
from end users**

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)
Disposable Face Mask

Brand (on the product or the packaging)
• HG

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

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

Professional product?
No

Product description
White respiratory protective masks with external metal nose clip, five layers, and "KN95" embossed on the side. The product is also sold online.

Packaging description
white/blue plastic packaging, five respiratory protective masks per pack

Product Recall

Type/number of model
• KN95-A

Batch number
• 20200423
(production batch)
• MFD: 032020
• LOT: 573627
• EXP: 032023

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00659/21

Type of risk
Health risk / other

Risk description
(technical defect and consequences)
The product advertises a protective potential against particles but its filtering capacity has not been tested by a relevant competent European conformity assessment body. Additionally, it was found that the particle/filter retention of the material is insufficient (measured values: up to 30%); 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

Importer

Importer

**Withdrawal of the
product from the
market**

**Removal of this
product listing by
the online
marketplace
03/05/2021**

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)
Partikelfiltrierende Halbmaske

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?
Yes

Product description
The mask has a nose clip sewn into the nose area, accompanied by a foam strip for sealing. The product is also sold online.

Packaging description
The product is sold in a white cardboard packaging containing 20 items per box. There is an additional packaging as a double pack in a plastic bag with printed instructions for use.

Product Recall

Type/number of model
• **CY2020-KZ002**
FFP2 NR Non-medical

Batch number
• **202008**

Bar code
• **6973181510016**

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/00660/21

Type of risk
Health risk / other

Risk description
(technical defect and consequences)
The mask does not properly adapt to the face leading to an insufficient total filtration capacity

(measured mean values: up to 66%). 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

Measures

Voluntary measures **Voluntary measures**

Importer

Importer

Recall of the product from end users **Stop of sales**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany

DRAFT