



Alertas RAPEX mascarillas
Referencia: SOFM/MJA/am
Fecha: 04/08/2021

Fecha: - 4 AGO. 2021

Hora: S-163357

Número:

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:

| | | | |
|--------------|--------------|--------------|---------------|
| A12/00878/21 | A12/00914/21 | A12/00929/21 | A12/00963/21 |
| A12/00916/21 | A12/00915/21 | A12/00931/21 | A12/00964/21 |
| A12/00835/21 | A12/00917/21 | A12/00932/21 | INFO-00122/21 |
| A12/00836/21 | A12/00918/21 | A12/00933/21 | INFO-00123/21 |
| A12/00837/21 | A12/00919/21 | A12/00943/21 | |
| A12/00912/21 | A12/00927/21 | A12/00944/21 | |
| A12/00913/21 | A12/00928/21 | A12/00962/21 | |

Los productos de las alertas calificadas como A12, se han sometido a ensayos y han presentado una capacidad de filtrado insuficiente acorde a lo dispuesto en la Norma Europea. En las alertas calificadas como INFO, presentan un incumplimiento documental sin haberse realizado ensayos analíticos acerca de la seguridad del producto.

En el caso de las A12/00835/21, A12/00836/21, A12/00837/21, A12/00943/21 y A12/00944/21, se han de advertir a los consumidores de los riesgos. En el resto se ha dispuesto la retirada de las mascarillas afectadas.

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



**Gobierno
de La Rioja**

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, 4 de agosto de 2021

Ana Marauri Baños

JEFA DE SECCIÓN DE MEDICAMENTOS



**Gobierno
de La Rioja**

Salud y Portavocía del Gobierno

Humanización, Prestaciones
y Farmacia

| | |
|-------------------|---------------------|
| Submission number | SI/03345/21 |
| Case number | A12/00878/21 |
| Version | 1 |

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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 | SI/03345/21 |
| Case number | A12/00878/21 |
| Creation date | 09/06/2021 |
| Validation/distribution date | 10/06/2021 |
| Notification type* | Article 12 GPSD/Article 22 Regulation 765/2008 |
| Notifying country | Slovenia |

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 | Filtering half mask |

packaging)*

Brand (on the product or the packaging)*

CLEANAIR

Type/number of model *

10300

Is the product counterfeit?*

No

Batch number *

Batch 20130, manufacturing date 2020-05

Bar code *

(241)00001016(37)20

Customs code*

63079093

Product description*

Protective respiratory filtration half-face mask, was of uniform white material and without valve. The mask had light blue straps that fit around the head.

Packaging description*

The product is sold in white/blue cardboard boxes, containing a total of 20 masks, reference: article 10300, EN 149:2001+A1:2009, FFP2 NR D, CE 2797.

Total number of items covered by the notification*

**120 Unit
National**

Photos (products, packaging and label)*



*Photo packaging mask Cleanair-1.jpg
Main picture*



Photo mask Cleanair-2.jpg



Photo mask Cleanair-3.JPG

3| Regulations and standards applicable

Legal provisions at EU level applicable? (directive, decision,

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and

regulation, etc.)*

repealing Council Directive 89/686/EEC

EU or national standards applied?*

Yes

EN 149:2001+A1:2009

Is the product CE marked?*

Yes

2797 NB

Declaration of conformity available?*

Yes

 [EU Declaration of conformity-CleanAir.pdf](#)

Certificates

 [EU Type Examination Certificate.pdf](#)

4| Risk description

Type of risk*

Health risk / other

(Overall) risk level*

Serious

Summary of test results*

The mask was tested Total Inward Leakage and failed. The mask does not fulfill the requirements for protection masks, with the EN 149:2001+A1:2009, section 7.9.1 (accordance with section 8.5).

Risk description (technical defect and consequences)*

The total filtration capacity of the mask is insufficient (measured mean values: as low as 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 Regulation and with the relevant European standard EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking.

Are you aware of accidents/incidents linked to the product in question?*

No

Test report

 [Report 121-23345 02.pdf](#)

Risk assessment

 [RA FM SI 4.pdf](#)

5| Traceability

Country of origin* **People's Republic of China**

Country(-ies) of destination* **Italy**

Contact details of the
manufacturer(s)*

Company name* **Eleco S.r.l.**

Address* **Via Verdi 11**

Zip code* **24121**

City* **Bergamo**

Country* **Italy**

Contact details of the exporter(s)* **Unknown**

Contact details of the importer(s)*

Company name* **Eleco S.r.l.**

Address* **Via Verdi 11**

Zip code* **24121**

City* **Bergamo**

Country* **Italy**

Contact details of the
distributor(s)*

Company name* **Univet S.r.l.**

Address* **Via Verdi 11**

Zip code* **24121**

City* **Bergamo**

Country* **Italy**

Company name* **Mega d.o.o.**

Address* **Sermin 71E**

Zip code* **6000**

City* **Koper**

Country* **Slovenia**

Contact details of the retailer(s)*

Company name* **Mega d.o.o.**

Address* **Sermin 71E**

Zip code* **6000**

City* **Koper**

Country* **Slovenia**

Is the product (also) sold online?* **No**

6| Measures

Type of measure(s)* **Voluntary measures**

Name of economic operator taking notified measure(s)* **Mega d.o.o., Sermin 71E,6000 Koper, Slovenia**

Type of economic operator taking notified measure(s)* **Distributor**

Category of measure(s)* **Withdrawal of the product from the market**

Date of entry into force* **Known**

10/05/2021

Duration* **Permanent**

Scope* **National**

Is this notification linked to a Business Gateway case?*

No

Measure(s) adopted

Has the economic operator published product recall information online?*

Unknown

7| Confidentiality

Is there any section of the notification form that you wish to mark as confidential?

No

8| Other

Additional information

Project CASP Corona2020 (mask) ICSMS PI 210200172979

Other attachments

Reason for investigating the notified product

European coordinated market surveillance project



Submission number **IT/03310/21**

Case number **A12/00916/21**

Version **1**

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1| General information

Submission number **IT/03310/21**

Case number **A12/00916/21**

Creation date **07/06/2021**

Validation/distribution date **17/06/2021**

Notification type* **Article 12 GPSD/Article 22 Regulation 765/2008**

Notifying country **Italy**

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 **FACE MASK KN 95**

packaging)*

Brand (on the product or the packaging)*

WENZHOU XILIAN

Type/number of model *

KN95

Is the product counterfeit?*

Unknown

Batch number *

Unknown

Bar code *

Unknown

Customs code*

Unknown

Product description*

Protective respiratory filtration half-face mask.

Packaging description*

The product is sold in a cardboard box containing 30 items, marked with "KN95", and claiming compliancy to the European standard EN 149. The product also claims protection against droplets, dust, smog and pollen.

Total number of items covered by the notification*

2,586,890 Unit
National

Photos (products, packaging and label)*

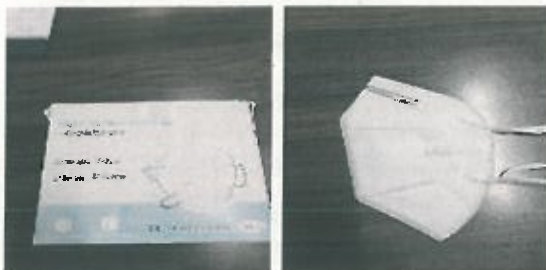


foto 1.jpg
Main picture

foto 2.jpg

3) Regulations and standards applicable

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

Regulation (EU) 2016/425 — Directive 89/686/EEC

EU or national standards applied?* **Yes**

Legislative Decree No 475/92 — EN 149/2009

Is the product CE marked?* **Yes**

The external packaging bears a CE mark, with no indication of the notified body.

Declaration of conformity available?* **No**

Certificates

4| Risk description

Type of risk* **Health risk / other**

(Overall) risk level* **Serious**

Summary of test results* **Laboratory tests carried out showed that the masks in question did not comply with the rules in force for FFP2 devices. According to the laboratory results, the limit values laid down in standard UNI EN 149:2001+A1:2009 were NOT met with respect to those applicable to filtering half masks of any class. The laboratory tests carried out showed a lower filtration level than that provided for in the standard. These products are therefore dangerous to users, who could be lulled into a false sense of security, thus making them even more vulnerable to exposure to hazardous agents.**

Risk description (technical defect and consequences)*

The particle/filter retention of the material is insufficient (measured values: as low as 68%). 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.

Are you aware of accidents/incidents linked to the product in question?*

No

Test report

 [Allegato 1 - Rapporto di Prova.pdf](#)

Risk assessment

5| Traceability

Country of origin* **People's Republic of China**

Country(-ies) of destination* **Unknown
Italy**

Contact details of the manufacturer(s)*

Company name* **WENZHOU XILIAN ELECTRICAL TECHNOLOGY CO. LTD**

Address* **4th Floor,Building No.4, Xinye Road,Binhai New Area, Pingyang County**

Zip code*

City* **Wenzhou City**

Country* **People's Republic of China**

Contact details of the exporter(s)* **Unknown**

Contact details of the importer(s)* **Unknown**

Contact details of the distributor(s)* **Unknown**

Contact details of the retailer(s)* **Unknown**

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

Please give details*

No research has been carried out to ascertain whether there have been any online sales.

6| Measures

Type of measure(s)* **Compulsory measures**

Name of authority ordering the notified measure(s)* **Guardia di Finanza - Compagnia di Gorizia - Procura della Repubblica di Gorizia.**

Type of economic operator to whom the measure(s) were ordered* **Other**

Category of measure(s)* **Withdrawal of the product from the market**

Date of entry into force* **Known**

03/03/2021

Duration* **Permanent**

Scope* **National**

Is this notification linked to a Business Gateway case?* **No**

Measure(s) adopted

Has the economic operator published product recall information online?* **Unknown**

7| Confidentiality

Is there any section of the notification form that you wish to mark as confidential? **No**

8| Other

Additional information

On 3, 10 and 30 March 2021, the financial and economic police unit and the Compagnia di Gorizia of the Guardia di Finanza carried out seizures of face masks found not to meet the requirements necessary to be considered as PPE in specific tests in accredited laboratories. These seizures were ordered by the Public Prosecutor of Gorizia, in the regions of Friuli Venezia Giulia, Lombardy, Piedmont and Lazio. The magistrate granted permission for the information to be placed on the GRAS RAPEX platform. See point 9 of the file annexed to point 4 of this document for the results of the tests on the masks in question.

Other attachments

Reason for investigating the notified product



Case number
A12/00835/21

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 7,5%). 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
31/05/2021

Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Sunqomo

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

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

Is the product (also) sold online?
Unknown

Professional product?
No

Product description
Protective respiratory filtration half-face mask, procured by North Rhine-Westphalia in the context of the pandemic.

Packaging description
The product is sold in a white cardboard box with the markings "KN95" or "KN95 GB2626-2006"

Product Recall

Type/number of model
• **Disposable protective Mask KN95**

Batch number
Unknown

Bar code
• **6973079891425**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany



Case number
A12/00836/21

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 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.

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
31/05/2021

Product (what the product is)
Particle filter mask

Product Recall

Type/number of model
• KN95 Respirator

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

Batch number
Unknown

Bar code
• 6972144532652
• 6972144532645

Brand (on the product or the packaging)
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?
Unknown - -

Professional product?
No

Product description
Protective respiratory filtration half-face mask, procured by North Rhine-Westphalia in the context of the pandemic.

Packaging description
White cardboard box, marked with "KN95", containing 30 units.

Year

Country of origin

Alert submitted by

Confidential



Case number
A12/00837/21

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 82%). 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
31/05/2021

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)
Everise

Type/number of model
• WSX-KN-1

Brand (on the product or the packaging)
• Everise

Batch number
Unknown

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

Bar code
Unknown

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

Is the product counterfeit?
Unknown

Professional product?
No

Is this notification linked to a Business Gateway case?

Product description
Protective respiratory filtration half-face mask, procured by North Rhine-Westphalia in the context of the pandemic.

Packaging description
Blue/white outer packaging, marked with 'KN95', containing 50 units.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany



Case number
A12/00912/21

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 22%). 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

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

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)

Type/number of model
Unknown

Brand (on the product or the packaging)
• SCYFKZ

Batch number
Unknown

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

Is the product counterfeit?
Unknown

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

Is this notification linked to a Business Gateway case?

Professional product?
No

Product description
Protective respiratory filtration half-face mask, without valve, for single use.

Packaging description
The product is sold in a blue and white plastic pouch containing 5 masks, marked with "KN95" and "GB2626-2006".

Year

Country of origin

Alert submitted by



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Folding Respirator

Brand (on the product or the packaging)
• UNECH

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 respiratory filtration half-face mask, without valve, for single use.

Packaging description
The product is sold in a blue and white plastic pouch containing 5 masks, marked with "KN95=FFP2" on one side and "3D MASK Pharmacy" on the other. The product

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
A12/00913/21

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 38%). 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

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

claims protection against PM2.5, dust and viruses.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Italy



Case number
A12/00914/21

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 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

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

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)
KN 95 PROTECTIVE MASK

Type/number of model
Unknown

Brand (on the product or the packaging)
**• ANHUI
ZHONGNAN**

Batch number
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?
Unknown - No research has been carried out to ascertain whether there have been any online sales.

Professional product?
No

Product description
Protective respiratory filtration half-face mask, without valve, for single use.

Packaging description
The product is sold, packed in a transparent plastic pouch, in a cardboard box

containing 50 items, marked with "KN95",
and claiming compliancy to the European
standard EN 149.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Italy



Case number
A12/00915/21

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 34%). 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

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

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)
KN 95 FACE MASK

Type/number of model
Unknown

Brand (on the product or the packaging)
JY-JUNYUE

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 - No research has been carried out to ascertain whether there have been any online sales.

Is this notification linked to a Business Gateway case?

Professional product?
No

Product description
Protective respiratory filtration half-face mask.

Packaging description
The product is sold in a blue and white plastic pouch containing 10 items, marked with both "KN95" and "FFP2", and claiming compliancy to the European standard EN

149.

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)
3D PROTECTIVE MASK

Brand (on the product or the packaging)
• **WENZHOU HUASAI**

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 respiratory filtration half-face mask.

Packaging description
The product is sold in a cardboard box containing 50 items, marked with "KN95",

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
A12/00917/21

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 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

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

and claiming compliancy to the European standard EN 149.

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)
KN 95 - EAR MOUNTED MASK

Brand (on the product or the packaging)
• ZHONGKANG

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 respiratory filtration half-face mask.

Packaging description
The product is sold in a cardboard box containing 50 items, marked with "KN95", "FFP2" and "FDA".

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
A12/00918/21

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 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

**Ban on the marketing of the product and any accompanying measures
03/03/2021**

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)
WENXIN

Brand (on the product or the packaging)
• **TONGCHENG**
• **WENXIN**

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 respiratory filtration half-face mask.

Packaging description
The product is sold in a cardboard box containing 10 items, marked with "KN95" and "FFP2", and claiming compliancy to the

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
A12/00919/21

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%). 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

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

European standard EN 149.

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)
Mascherina FFP2 5 strati

Brand (on the product or the packaging)
• **Safemed Saglik**
Urunleri Haydar Bozdemir

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 protective respiratory filtration half-face mask, with transverse orientation and printing, claiming compliance to the relevant European standard EN 149.

Product Recall

Type/number of model
• **P0102**

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00927/21

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 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 with the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Compulsory measures

Importer

Withdrawal of the product from the market
04/05/2021

Packaging description

The product is sold in a transparent cellophane pouch containing three items and an information leaflet in Italian containing instructions for use, the dates of production, and the names and addresses of the manufacturer and of the distributor.

Year

Country of origin

Alert submitted by

| | | |
|------|--------|-------|
| 2021 | Turkey | Italy |
|------|--------|-------|

Confidential



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
FFP2 QIBU

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

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

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

Professional product?
No

Product description
White protective respiratory filtration half-face mask.

Packaging description

Product Recall

Type/number of model
• **QB 001**

Batch number
• **20210120**

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00928/21

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 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.

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

Withdrawal of the product from the market
07/05/2021

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)
FILTER RESPIRATOR

Brand (on the product or the packaging)
• BI WEI KANG

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 protective respiratory filtration half-face mask, with the brand and the mark "KN95" printed on the side.

Packaging description
The product is sold in a non-transparent plastic pouch containing 10 items, and

Product Recall

Type/number of model
**• 9600 TYPE
FILTER RESPIRATOR**

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00929/21

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 81%). 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

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

claiming compliancy to the European standard EN 149.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Italy

Confidential



Product (what the product is)
Particle filter mask

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

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

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 is also sold online.

Packaging description

Product Recall

Type/number of model
• **518902-01**
• **1/BC11.5/12**

Batch number
• **CA/AE**

Bar code
Unknown

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/00931/21

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 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 and the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures

Importer

Removal of this product listing by the online marketplace

Year

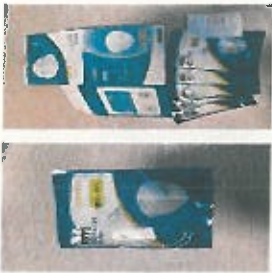
Country of origin

Alert submitted by

2021

People's Republic of China

Belgium



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
LEIKANG

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

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 respiratory filtration half-face mask, with the brand and the claims "FFP3" and "EN 149" printed on the side of the product.

Packaging description
The product is sold, packed individually in a transparent and blue plastic pouch, in a

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
A12/00932/21

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 86%). 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

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

blue and white cardboard box containing 30 items, with the claims "FFP3" and "BFE>99%".

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Italy

Confidential



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
FFP3 protective mask

Brand (on the product or the packaging)
• XINNUOZI

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 respiratory filtration half-face mask, with the brand.

Packaging description
The product is sold, packed individually in a transparent and white plastic pouch, in a white cardboard box containing 30 items,

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
A12/00933/21

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 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 with the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Compulsory measures

Other

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

with the claims "FFP3", "BFE>99%" and of compliancy to the European standard EN 149.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Italy

Confidential



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 Self-Priming Filter & Anti Particle Respirator - 5 masks' pack

Brand (on the product or the packaging)
Anysound

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

Is the product (also) sold online?
Unknown - Procured by North Rhine-Westphalia in the context of the pandemic.

Professional product?
No

Product description
White protective respiratory filtration half-face mask.

Packaging description
The product is sold in white-blue plastic pouches containing 5 items each, with the

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
A12/00943/21

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 15%). 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
31/05/2021

claim KN95.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany

Confidential



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 Self-Priming Filter & Anti Particle Respirator - 10 masks' pack

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

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

Is the product (also) sold online?
Unknown - Purchased during the pandemic by the Land North Rhine-Westphalia.

Professional product?
No

Product description
White protective respiratory filtration half-face mask, sold in white-blue plastic pouches containing 10 items each, with the claim KN95.

Packaging description

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
A12/00944/21

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 15%). 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
31/05/2021

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany

Confidential



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Respirator FFP2 respiratory protective mask FFP2

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

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

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

Professional product?
Yes

Product description
Protective respiratory filtration half-face mask. The product was sold online, in particular via Amazon.

Packaging description
The product is sold in transparent plastic pouches.

Product Recall

Type/number of model
• **univent-medical**

Batch number
• **Art-Nr. 1488**

Bar code
• **4250397303499**

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/00962/21

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 72.5%). 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

Ban on the marketing of the product and any accompanying measures
21/05/2021

Year

Country of origin

Alert submitted by

Confidential



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
**FFP2
Atenschutzmaske**

Brand (on the product or the packaging)
• PROPAKS

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 is also sold online.

Packaging description
The product is sold in individual transparent plastic pouches, packed in a white and blue cardboard box containing a total of 10 masks. The smaller packaging unit lacks the declaration of conformity, and the corresponding link or reference.

Product Recall

Type/number of model
**• P-0102
• P0102**

Batch number
Unknown

Bar code
• 8699234662980

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00963/21

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 58%).

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

Importer

Withdrawal of the product from the market

Withdrawal of the product from the market

Compulsory measures

Voluntary measures

Other

Distributor

Withdrawal of the product from the market

Withdrawal of the product from the market

Year

Country of origin

Alert submitted by

2021

Turkey

Germany

Confidential



Case number
A12/00964/21

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

Compulsory measures

Importer

Recall of the product from end users

Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
FFP2 Face mask

Brand (on the product or the packaging)
• YWSH

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

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

Professional product?
No

Product description
Black protective respiratory filtration half-face mask. The product is also sold online.

Packaging description
The product is sold in purple plastic pouches containing 1 item, with a reference to EN 149 and the claims to be FFP2; the product is CE marked.

Product Recall

Type/number of model
• SH-ZK12

Batch number
• 202101A
• Production date: 20210120

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Belgium



Case number
INFO/00122/21

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. 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

Voluntary measures

Retailer

**Removal of this product listing by the online marketplace
31/05/2021**

Product (what the product is)
Particle filter mask

Product Recall

Type/number of model
• **ORKS-01**

Name (on the product or the packaging)
Protective mask

Batch number
• **16.09.2020**

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

Bar code
• **6970639790044**

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?
Yes - Other

Professional product?
No

Product description
**Blue mask with earloops and without valve.
The product is also sold online.**

Packaging description
The product is sold in a white/green cardboard box with 20 masks inside, with the claims FFP2 on it.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Estonia



Case number
INFO/00123/21

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. 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 and with the relevant European standard EN 149.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Voluntary measures

Retailer

**Removal of this product listing by the online marketplace
31/05/2021**

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)
Self-imbibition filter anti particle respirator

Type/number of model
Unknown

Batch number
Unknown

Bar code
Unknown

Brand (on the product or the packaging)
KAYLEINSTER

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?
Yes - Other

Professional product?
No

Product description
Grey filtering half mask with valve and earloops in a transparent plastic bag. The product was also sold online.

Packaging description
White/light blue cardboard box with 10 masks inside.

Year

Country of origin

Alert submitted by

DRAFT