



Salud  
y Portavocía del Gobierno

Humanización,  
Prestaciones y Farmacia

Alertas RAPEX mascarillas  
Referencia: SOFM/MJA/fs  
Fecha: 21/12/2020

### ALERTAS AUROPEAS SOBRE MASCARILLAS QUE PRESENTAN RIESGOS PARA LA SALUD DE LOS USUARIOS

RAPEX es un sistema unificado de alerta de productos peligrosos para los consumidores de la Unión Europea. Abarca todo tipo de productos no alimentarios, excepto los farmacéuticos, y pretende asegurar un rápido intercambio de información entre los estados miembros y la Comisión sobre las medidas tomadas para prevenir, restringir o imponer condiciones específicas en el márketing o uso de productos por razones de serio riesgo para la salud y seguridad de los consumidores.

Se adjuntan las últimas alertas RAPEX referentes a mascarillas de filtración para protección frente al contagio por COVID19. Dichas mascarillas tienen la consideración bien de higiénicas, bien de EPI (equipo de protección individual) o bien son falsas mascarillas quirúrgicas (con marcado CE no válido) y ese es el motivo de su inclusión en un sistema de alerta destinado en principio a productos no farmacéuticos.

Le solicitamos que consulten frecuentemente las alertas emitidas por las autoridades europeas sobre MASCARILLAS EPIS 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](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, 21 de diciembre de 2020



P.A. *BOSMA BARRIO*  
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JEFA DE SERVICIO DE ORDENACIÓN  
FARMACÉUTICA Y MEDICAMENTOS



Fecha: 21 DIC. 2020

Hora:  
Número: S-151695



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

Name (on the product or the packaging)  
**3M AURA 9332 +**

Brand (on the product or the packaging)  
• **3M**

**(COUNTERFEIT)**

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

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask labelled as FFP3 NR D with valve.**

Packaging description  
**The product is packed wrapped individually in a transparent plastic bag, and distributed in cardboard boxes with a capacity of 500 pieces. The box is without elements of identification and characterization of the product or other label applied on the box.**

Product Recall

Type/number of model  
• **3M 9332 +**

Batch number  
• **C 20206.1**  
• **TP TC 019/2011**

Bar code  
**Unknown**

Is the product counterfeit?  
**Yes**

Is this notification linked to a Business Gateway case?

Case number  
**INFO/00174/20**

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 fulfil the health and safety requirements and properly protect if not combined with additional protective 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

Retailer

Withdrawal of the product from the market  
**23/11/2020**

Year

Country of origin

Alert submitted by





Case number  
**A12/01572/20**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)  
**The particle/filter retention of the material is insufficient (measured value 61,5% in the penetration test). Consequently, an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection if not combined with additional protective 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  
**Serious**

Product category  
**Protective equipment**

**Measures**

**Voluntary measures**

**Importer**

**Recall of the product from end users**  
**23/09/2020**

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

Product Recall

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

Type/number of model  
• **lug type**

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?  
**Yes - Other**

Is this notification linked to a Business Gateway case?

Professional product?  
**Yes**

Product description  
**White respiratory protective half-face mask of category KN95. The product was also sold online.**

Packaging description  
**The product is sold in a white and green cardboard box, containing 20 pieces.**

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Germany



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

Name (on the product or the packaging)  
**Lucca Care**

Brand (on the product or the packaging)  
**Lucca Light**

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

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

Professional product?  
**No**

Product description  
**Filtering half-face mask, single use, for protection against particles and aerosols, labelled KN95 and FFP2.**

Packaging description  
**The product is sold in a white plastic pouch with black labellings, with ten pieces per pouch.**

Product Recall  
<https://www.hubnet-hamburg.de/>  
**German (de)**

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  
**A12/01730/20**

Type of risk  
**Health risk / other**

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

**(measured value 57,2%).**

**Consequently, an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection if not combined with additional protective 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  
**Serious**

Product category  
**Protective equipment**

Measures

**Voluntary measures    Voluntary measures**

**Retailer**

**Importer**

**Recall of the product  
from end users  
06/11/2020**

**Recall of the product  
from end users  
24/11/2020**

**Year**

**Country of origin**

**Alert submitted by**

**2020**

**People's Republic of China**

**Germany**



Case number  
**INFO/00134/20**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)  
**The product bears a CE marking but is not certified by a relevant body. Consequently, the product might not fulfill the health and safety requirements and thus not properly protect when combined with additional measures. The user expects protection that is possibly not provided by the product. Documents provided by the importer are insufficient.**

Legal provisions (at EU level) and European standards against which the product was tested and did not comply

(Overall) risk level  
**Serious**

Product category  
**Protective equipment**

**Measures**

**Voluntary measures**

**Distributor**

**Withdrawal of the product from the market**  
**01/09/2020**

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

Product Recall

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

Type/number of model  
**Unknown**

Brand (on the product or the packaging)  
**Unknown**

Batch number  
**Unknown**

Bar code  
**Unknown**

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?  
**Yes**

Product description  
**Protective respiratory filtration half-face mask.**

Packaging description  
**Sold in cardboard boxes, 50 units in each box.**

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Iceland



Case number  
**INFO/00135/20**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)

**The mask is presented as providing a high protective function (“high filtration capacity”, “help filter up to 90% of bacteria”, “ideal for home healthcare use”). However these claims are not backed by evidence. In the absence of proof of the efficiency of these masks, this could create a false sense of safety to the wearer of the mask” 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

(Overall) risk level  
**Unknown**

Product category  
**Protective equipment**

**Measures**

**Compulsory measures.**

**Importer**

**Import rejected at border  
01/10/2020**

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

Product Recall

Type/number of model  
• **GB/T 32610-2016**

Name (on the product or the packaging)  
**Disposable Masks**

Batch number  
**Unknown**

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

Bar code  
**Unknown**

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

Is the product counterfeit?  
**Unknown**

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

Is this notification linked to a Business Gateway case?

Professional product?  
**No**

Product description  
**Respiratory filtration half-face mask.**

Packaging description  
**White and blue cardboard box containing 50 disposable masks.**

Year

Country of origin

Alert submitted by

**2020**

**People's Republic of China**

**Luxembourg**





Case number  
**INFO/00140/20**

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**

**Retailer**

**Withdrawal of the product from the market**  
**02/11/2020**

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

Product Recall

Type/number of models  
**Unknown**

Name (on the product or the packaging)  
**Disposable Protective Mask**

Batch number  
**Unknown**

Brand (on the product or the packaging)  
**Unknown**

Bar code  
**6025452157500**

Is the product counterfeit?  
**No**

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

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

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask.**

Packaging description  
**The product is sold in a white cardboard box with blue highlights containing 50 pieces. It claims conformity to standard EN 149 on the box.**

Year

Country of origin

Alert submitted by

DRAFT



Case number  
**INFO/00141/20**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)  
**The product is not provided with information about the manufacturer and no documentation has been provided that the product has been certified as protective equipment by the relevant body. Consequently, the product might not fulfil the health and safety requirements.**

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  
**10/09/2020**

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

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

Brand (on the product or the packaging)  
**Unknown**

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

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask. The standard EN 149 is printed on the product.**

Packaging description  
**The product is sold in a transparent plastic bag with printed instructions. The barcode is stuck on the packaging.**

Product Recall

Type/number of models  

- **DM019**
- **LEI.SHI.DE**
- **2792**
- **2834**

Batch number  
**Unknown**

Bar code  
• **4751028392535**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Latvia



Case number  
**INFO/00143/20**

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**  
**29/09/2020**

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

Product Recall

Type/number of models  
**• ZT-6088**

Name (on the product or the packaging)  
**KN95**  
**Respirator/FFP2**

Batch number  
**Unknown**

Bar code  
**• 691900356947**

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?  
**Unknown**

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

Professional product?  
**No**

Product description  
**White respiratory protective half-face mask, with the mentions "KN95" and EN 149:2001+A1:2009 printed on it.**

Packaging description  
**The product is packaged in a transparent plastic bag. The product's barcode has been stuck on the package.**

Year

Country of origin

Alert submitted by



DRAFT



Case number  
**INFO/00144/20**

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**

**Retailer**

**Withdrawal of the product from the market**  
**02/11/2020**

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

Product Recall

Name (on the product or the packaging)  
**Disposable Protective Mask**

Type/number of model  
**Unknown**

Batch number  
**• 2003001**

Bar code  
**• 5019096544627**

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 - unknown**

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask with 3 ply.**

Packaging description  
**The product is sold in a transparent and green plastic bag with zip closure containing 10 pieces. It claims conformity to standard EN 149 on the box.**

Year

Country of origin

Alert submitted by



DRAFT



Case number  
**INFO/00145/20**

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**

**Retailer**

**Withdrawal of the product from the market**  
**26/10/2020**

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

Product Recall

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

Type/number of models  
**• 1500**

Batch number  
**• 20200601**

Bar code  
**• 5079072716202**

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

Is the product counterfeit?  
**Unknown**

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

Is this notification linked to a Business Gateway case?  
**Unknown**

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask.**

Packaging description  
**The product is sold in a white and green cardboard box containing 50 pieces. On the package is written BFE > 95.**

Year

Country of origin

Alert submitted by

**2020**

**People's Republic of China**

**Romania**





Case number  
**INFO/00146/20**

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.**

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

Product Recall

Name (on the product or the packaging)  
**Disposable protective mask with 3 layers with 3 folds, with elastic**

Type/number of model  
**Unknown**

Batch number  
**• 202007**

Bar code  
**• 4205170326023**

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.**

Brand (on the product or the packaging)  
**Unknown**

Is the product counterfeit?  
**Unknown**

(Overall) risk level  
**Unknown**

Product category  
**Protective equipment**

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

Is this notification linked to a Business Gateway case?  
**Unknown**

Measures

**Compulsory measures**

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

Retailer

Professional product?  
**No**

Withdrawal of the product from the market  
**03/11/2020**

Product description  
**Protective respiratory filtration half-face mask.**

Packaging description  
**The product is sold in cardboard boxes, with 50 units in each box. On the package is written BFE > 95.**

Year

Country of origin

Alert submitted by

DRAFT



# Safety Gate RAPEX



Case number  
**INFO/00147/20**

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**

**Retailer**

**Withdrawal of the product from the market**  
**03/11/2020**

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

Name (on the product or the packaging)  
**Disposable protective mask for children**

Brand (on the product or the packaging)  
**#BacktoSchool  
Meli Melo**

OECD Portal category (if known)  
**85000000 - Safety / Protection - D13**

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask.**

Packaging description  
**The product is sold in a transparent plastic bag containing 10 units with a self-adhesive tape fastening system.**

Product Recall

Type/number of model  
**• EO7TTNDMJCH - SET 10**

Batch number  
**• JAX-Y20-M05-D07**

Bar code  
**• 594907480167**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Year

Country of origin

Alert submitted by

DRAFT



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

Name (on the product or the packaging)  
**KN95  
Respirator/FFP2**

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

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, with the mentions "KN95" and "GB2626-2006" printed on it. The mention of the European standard "EN 149" is also printed on the product.**

Packaging description  
**The product is packaged in a transparent plastic bag, placed in a white cardboard box containing 50 pieces. On the package is written "EN 14683:2019", both on the bottom left side and on the product's**

Product Recall

Type/number of model  
**• HT9210**

Batch number  
**Unknown**

Bar code  
**Unknown**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**INFO/00148/20**

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  
**28/08/2020**

picture.

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Latvia

DRAFT



Case number  
**INFO/00149/20**

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**

**Compulsory measures**

**Importer**

**Import rejected at border**

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

Product Recall

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

Type/number of models  
**Unknown**

Batch number  
**• 2020-5**

Brand (on the product or the packaging)  
**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 information available**

Professional product?  
**No**

Product description  
**KN95 Protective Face Mask (non - medical)**

Packaging description  
**The product is sold in printed cardboard packaging containing 50 pieces. The cardboard packaging is red, white and black in colour.**

Year

Country of origin

Alert submitted by

DRAFT





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

Name (on the product or the packaging)  
**3D Folding Mask**

Brand (on the product or the packaging)  
**BEKANG**

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

Is the product (also) sold online?  
**Unknown - No**  
further investigation has been carried out in that respect.

Professional product?  
**No**

Product description  
**White protective respiratory filtration half-face mask. Various standards, including EN 149, are printed on the product, together with the CE marking.**

Packaging description  
**The product is sold in a plastic pouch, containing 1 piece only. Standards and instructions are printed on the packaging.**

Product Recall

Type/number of model  
**9501**

Batch number  
**Unknown**

Bar code  
**Unknown**

Is the product counterfeit?

Is this notification linked to a Business Gateway case?

Case number  
**INFO/00153/20**

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**

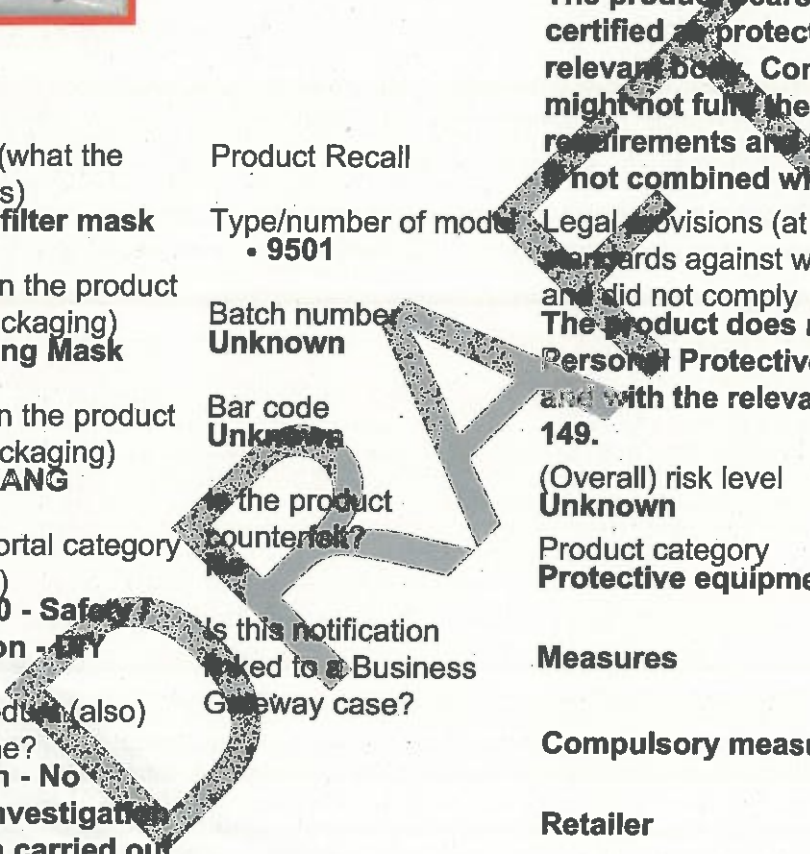
Product category  
**Protective equipment**

Measures

Compulsory measures

Retailer

Ban on the marketing of the product and any accompanying measures



Year

Country of origin

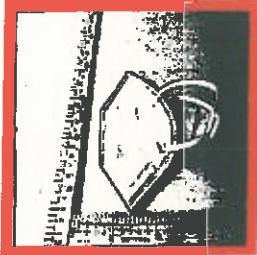
Alert submitted by

2020

People's Republic of China

Italy

DRAFT



Case number  
**INFO/00155/20**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)

**The product is not certified as protective equipment by an authorised notified 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**

### Distributor

**Ban on the marketing of the product and any accompanying measures  
13/05/2020**

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

Product Recall

Type/number of model  
• **JC06**

Name (on the product or the packaging)  
**KN95 PROTECTIVE FACE MASK**

Batch number  
**Unknown**

Brand (on the product or the packaging)  
• **MC CONS**

Bar code  
**Unknown**

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

Is the product counterfeit?  
**No**

Is this notification linked to a Business Gateway case?

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask.**

Packaging description  
**The product is sold in a small cardboard pack of 10 units each.**

Year

Country of origin

Alert submitted by

**2020**

**People's Republic of China**

**Italy**



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

Name (on the product or the packaging)  
**FACE MASK - 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  
**Face mask with three layers of protection.**

Packaging description  
**The product is sold in a white and blue cardboard box containing 50 pieces.**

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/00160/20**

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**

Retailer

**Withdrawal of the product from the market 19/11/2020**

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Romania



Case number  
**INFO/00161/20**

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 Regulation on personal protective equipment and the relevant European Standard EN 149.**

(Overall) risk level  
**Unknown**

Product category  
**Protective equipment**

**Measures**

**Compulsory measures**

**Retailer**

**Withdrawal of the product from the market 19/11/2020**

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  
**• KN 95 (Civil Grade)**

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?  
**No**

Is this notification linked to a Business Gateway case?

Professional product?  
**No**

Product description  
**KN 95 protective mask**

Packaging description  
**The product is sold in a white cardboard box containing 10 pieces. Every mask is wrapped individually in a transparent plastic bag.**

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Romania



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

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

Brand (on the product or the packaging)  
• **Meli Care**

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

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask.**

Packaging description  
**The product is sold in a package containing 10 units packed in a plastic bag closed by heat sealing. Product information is printed on the plastic bag, on a paper label inside the bag and a self-adhesive label applied on the bag.**

Product Recall

Type/number of model  
**Unknown**

Batch number  
• **F20040011**

Bar code  
• **2700300964108**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**INFO/00162/20**

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**

Retailer

Withdrawal of the product from the market  
**03/11/2020**

Year

Country of origin

Alert submitted by





Case number  
**INFO/00163/20**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)  
**The product may not meet the health and safety requirements and therefore may not be adequately protected 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 Regulation on personal protective equipment and with the relevant European standard EN 149:2001 + A1:2009.**

(Overall) risk level  
**Unknown**

Product category  
**Protective equipment**

**Measures**

**Compulsory measures**

**Retailer**

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

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

Product Recall  
Type/number of model  
• **AN-001**

Name (on the product or the packaging)  
**Particle filter mask**

Batch number  
• **2020050420**

Brand (on the product or the packaging)  
• **FEALTER™**

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 respiratory filtration half-face mask. The product is also sold online.**

Packaging description  
**The product is sold in a white and green cardboard box containing 20 pieces. Every mask is wrapped individually in a transparent plastic bag.**

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Romania





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  
**Protective respiratory filtration half-face mask with 3 ply.**

Packaging description  
**The product is sold in a white and green cardboard box containing 50 pieces. It claims BFE > 95 and to be "non-medical".**

Product Recall

Type/number of model  
• **1620**

Batch number  
• **20200605**

Bar code  
• **5949072716202**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**INFO/00164/20**

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**

Retailer

Withdrawal of the product from the market  
**26/10/2020**

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Romania



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)  
• **BSPGUARD**

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

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask.**

Packaging description  
**The product is sold in a white and blue plastic bag with zip closure containing 10 pieces. It claims BFE > 95.**

Product Recall

Type/number of model  
• **1599**

Batch number  
• **20200605**

Bar code  
• **5949072715991**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**INFO/00165/20**

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**

**Retailer**

**Withdrawal of the product from the market  
26/10/2020**

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Romania



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

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

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

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

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask, with 5 layers.**

Packaging description  
**The product is sold in a white and blue cardboard box containing 5 pieces.**

Product Recall

Type/number of model  
• **1541**

Batch number  
• **20200605**

Bar code  
• **5949072715410**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**INFO/00166/20**

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 149:2011 + A1:2009 FFP2.**

(Overall) risk level  
**Unknown**

Product category  
**Protective equipment**

Measures

Compulsory measures

Retailer

Withdrawal of the product from the market  
**29/10/2020**

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Romania



Case number  
**INFO/00168/20**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)

**The product 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**

**Recall of the product from end users  
15/09/2020**

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

Product Recall

Type/number of model  
**Unknown**

Name (on the product or the packaging)

Batch number  
**Unknown**

Brand (on the product or the packaging)  
**Unknown**

Bar code  
**• 7 805070 003660**

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

Is the product counterfeit?  
**Unknown**

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

Is this notification linked to a Business Gateway case?

Professional product?  
**No**

Product description  
**Protective respiratory filtration mask with one layer of the filter.**

Packaging description  
**The packaging of the mask indicates a decades-old product. A sticker on the side has a barcode and description that reads, 3M 100 maskar. The sticker was put on the box by the seller.**

Year

Country of origin

Alert submitted by

**2020**

**Unknown**

**Iceland**



Case number  
**INFO/00169/20**

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**

**Retailer**

**Withdrawal of the product from the market  
23/11/2020**

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)  
**Unknown**

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

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

Professional product?  
**No**

Product description  
**KN 95 protective mask.**

Packaging description  
**The product is sold in a white and green cardboard box containing 20 pieces. The products are packed in 2 pieces in a transparent bag.**

Product Recall

Type/number of model  
• **FFP2 NR D**

Batch number  
• **20APR2020**

Bar code  
• **6973208700093**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Romania



Case number  
**INFO/00170/20**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)

**The product bears CE mark and 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**

**Compulsory measures**

**Retailer**

**Withdrawal of the product from the market  
05/11/2020**

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

Product Recall

Type/number of model  
**Unknown**

Name (on the product or the packaging)  
**Disposable protective mask with 3 layers**

Batch number  
• **200300102**

Bar code  
• **5949096544010**

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?  
**No**

Professional product?  
**No**

Product description  
**Disposable protective mask with 3 layers.**

Packaging description  
**The product is sold in a white and green cardboard box containing 50 pieces.**

Year

Country of origin

Alert submitted by

**2020**

**People's Republic of China**

**Romania**



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)  
**• DA SHANG REN  
YI**

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

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

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask, 3 layers.**

Packaging description  
**The product is sold in white and blue cardboard box, 50 units in each box. The products are packed in 25 pieces in a transparent bag.**

Product Recall

Type/number of model  
**• BF95-G**

Batch number  
**• 2020031080**

Bar code  
**• 6422115000609**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**INFO/00171/20**

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**

**Retailer**

**Withdrawal of the product from the market  
23/11/2020**

Year

Country of origin

Alert submitted by







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

Name (on the product or the packaging)  
**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. The product does not bear the CE marking. It has the mentions "KN95" and "GB2626-2006" printed on it.**

Packaging description  
**Every mask is wrapped individually in a transparent plastic bag without any identification elements.**

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/00172/20**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)  
**The product has no CE marking and 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

Importer

Withdrawal of the product from the market  
**20/11/2020**

Year

Country of origin

Alert submitted by

