

## Présentation de l'offre LANGCI



**GLOBAL**

*Masque FFP2*    **CE**

# Sommaire

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# Introduction 2S Global

La société 2S Global spécialisée dans l'import export propose de guider ses clients dans leurs processus d'approvisionnements avec un accompagnement et des conseils tout au long de la procédure d'achat : de la commande à la livraison finale.

- **Notre objectif** : simplifier l'acquisition d'équipement de protection individuelle pour protéger le plus rapidement possible vos concitoyens ou les collaborateurs de vos entreprises.
- **Un service client réactif** : Notre équipe a plus de 10 ans d'expérience dans l'Import Export entre l'Asie du Sud-Est et l'Europe. Notre obsession : vous accompagner durant chaque étape de votre commande.



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## Nos offres

Nous vous proposons plusieurs types d'équipement de protection individuelle afin de protéger efficacement vos collaborateurs. Nous sommes notamment spécialisés dans les masques de protection individuelle et masques médicaux.



### CONTACT 10H/24 - 6J/7

Nous sommes à votre disposition par téléphone ou par messagerie instantanée.



### + DE 300 CLIENTS

Plus de 300 collectivités locales et entreprises nous font confiance afin de protéger efficacement leurs concitoyens et leurs salariés.



### EQUIPES À VOTRE SERVICE

Nos équipes sont à votre disposition et sont basées en France et en Chine



### LIVRAISON SÉCURISÉE

Nos livraisons sont express, gratuites et sécurisées

# Fiche technique

## Masque FFP2 – LANGCI (Model 5001)



### Caractéristiques

- Masque respiratoire à épuration d'air
- Equipement de Protection Individuelle
- Lanières élastiques aux oreilles
- Masque blanc avec barrette nasale
- Masque avec marquage **CE**

### Normes

Standard : EN 149:2001+A1:2009  
Notify Body CE : 2163  
Classification : FFP2 NR

Conditions de stockages : espace propre, ventilé, sec,  
Date Limite d'utilisation: 5 ans sous conditions de stockage  
Pays de fabrication: Chine

### Description

1/ Polypropylène doux non tissé  
Doux, agréable pour la peau, filtration grosses particules

3/ Filtre en Melt-blown  
Couche filtrante, absorption des micro-germe



2/ Coton à air chaud antibactérien  
antibactérien, anti-odeur et anti-mildiou

4/ Polypropylène doux non tissé  
Doux, agréable pour la peau, filtration grosses particules

### Protection 4 couches

- Antibactérien
- Anti-pollen
- PM2.5
- Anti-postillon
- Anti-poussière
- Anti-cheveux

### Packing



Emballage individuel



### Caractéristiques logistiques

Poids brute carton : 9,4 kg  
Poids volumétrique : 0,086 CBM

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# Conditionnement & Stockage

## 1. Conditionnement



Emballage individuel



50 sachets par boîte



50 sachets  
individuel masques  
par boîte  
(50 masques)



X20  
20 boîtes par carton  
(1000 masques)

### Caractéristiques logistiques

Poids brute carton : 9,4 kg

Poids volumétrique: 0,086 CBM

Poids taxable: nc

## 2. Conditions de stockage



Conditions de stockages:  
Espace propre, ventilé, sec  
Maintenir à l'abri du soleil

Durée de conservation :  
5 ans  
sous conditions de stockage

Date limite de conservation :  
25 janvier 2026

Photos des entrepôts de stockage de Lyon

# Copie du pack - BAT

Le BAT de la boîte est donné à titre indicatif. Il pourra faire l'objet de modification selon vos remarques et besoins. Le design est également susceptible d'évoluer pour rester en ligne avec la législation douanière en vigueur en Europe et en Chine.

**NON-POWERED AIR-PURIFYING PARTICLE RESPIRATOR**  
**EN 149:2001+A1:2009 FFP2 NR**  
**FFP2**

**FFP2**  
**MODEL:5001**  
**CE 2163**  
**EN 149:2001+A1:2009 FFP2 NR**  
**50 | Pcs**

**Direction of Use**

1. Before use, check the expiration date, the model, the size and the weight of the mask. Do not use the mask if the expiration date has expired.
2. Before use, check the fit of the mask on your face. The mask should fit snugly against your face. Do not use the mask if it does not fit properly.
3. Do not touch the mask with your hands. If you touch the mask, wash your hands with soap and water.
4. Do not touch the mask with your hands. If you touch the mask, wash your hands with soap and water.
5. Do not touch the mask with your hands. If you touch the mask, wash your hands with soap and water.
6. Do not touch the mask with your hands. If you touch the mask, wash your hands with soap and water.
7. Do not touch the mask with your hands. If you touch the mask, wash your hands with soap and water.
8. Do not touch the mask with your hands. If you touch the mask, wash your hands with soap and water.
9. Do not touch the mask with your hands. If you touch the mask, wash your hands with soap and water.
10. Do not touch the mask with your hands. If you touch the mask, wash your hands with soap and water.

**Product Name: Non-powered air-purifying particle respirator**  
**Brand: Lang Ci**  
**Model: EN 149:2001+A1:2009 FFP2 NR**  
**Specification: 50 pieces**

**Warning**

1. This product is a self-priming filter type air-purifying respirator.
2. Do not use when the environmental oxygen concentration is less than 17.5%.
3. Do not use when the temperature is above 40°C or below 5°C.
4. Do not use when the relative humidity is above 95% or below 5%.
5. Do not use when the atmospheric pressure is above 1013 hPa or below 960 hPa.
6. Do not use when the atmospheric pressure is above 1013 hPa or below 960 hPa.
7. Do not use when the atmospheric pressure is above 1013 hPa or below 960 hPa.
8. Do not use when the atmospheric pressure is above 1013 hPa or below 960 hPa.
9. Do not use when the atmospheric pressure is above 1013 hPa or below 960 hPa.
10. Do not use when the atmospheric pressure is above 1013 hPa or below 960 hPa.

**Manufacturer: Zhejiang Langci Medical Equipment Co., Ltd.**  
**Add.: Building No. 2, Chengnan Industrial Park,**  
**Meicheng Town, Jiande City, Zhejiang Province, P.R. China**  
**Made in China**

# Copie du pack – Photos 1/2



# Copie du pack – Photos 2/2

**朗兹 | LANGCI**

**Warning**

1. This product is a self-priming filter type anti-particulate respirator  
 2. Don't use in environments with an ambient temperature above 50 degrees  
 3. Don't use when the environmental oxygen rate is less than 19.5%  
 4. Don't use under toxic gas environment (can't replace gas mask)  
 5. Only suitable for respiratory protection of particulate matter.  
 6. It is not recommended for children, pregnant women and elderly because of the breathing resistance of the masks.

1. Ce produit est un respirateur anti-particules de type filtre auto-amorçant  
 2. Ne pas utiliser dans des environnements avec une température ambiante supérieure à 50 degrés  
 3. Ne pas utiliser lorsque le taux d'oxygène dans l'environnement est inférieur à 19.5%  
 4. Ne pas utiliser dans un environnement gazeux toxique (ne peut pas remplacer le masque à gaz)  
 5. Convient uniquement pour la protection respiratoire des particules.  
 6. Il n'est pas recommandé pour les enfants, les femmes enceintes et les personnes âgées en raison de la résistance respiratoire des masques.

1. Este producto es un respirador anti-partículas de tipo filtro autocebante  
 2. No lo use en entornos con una temperatura ambiente superior a 50 grados  
 3. No lo use cuando la tasa de oxígeno ambiental sea inferior al 19.5%  
 4. No lo use en un ambiente de gas tóxico (no puede reemplazar la máscara de gas)  
 5. Solo apto para protección respiratoria de material particulado.  
 6. No se recomienda para niños, mujeres embarazadas y ancianos debido a la resistencia respiratoria de las máscaras.

1. Questo prodotto è un respiratore antiparticolato con filtro autoadescante  
 2. Non utilizzare in ambienti con una temperatura ambiente superiore a 50 gradi  
 3. Non utilizzare quando il tasso di ossigeno ambientale è inferiore al 19.5%  
 4. Non utilizzare in ambienti con gas tossico (non può sostituire la maschera antigas)  
 5. Adatto solo per la protezione respiratoria del particolato.  
 6. Non è raccomandato per bambini, donne in gravidanza e anziani a causa della resistenza respiratoria delle maschere.

1. Dieses Produkt ist ein selbstansaugender Filter-Atemschutz mit Filter  
 2. Nicht in Umgebungen mit Umgebungstemperaturen über 50 Grad verwenden  
 3. Nicht verwenden, wenn die Umweltsauerstoffrate weniger als 19.5% beträgt  
 4. Nicht in Umgebungen mit giftigen Gasen verwenden (Gasmasken kann nicht ersetzt werden)  
 5. Nur zum Atemschutz von Partikeln geeignet.  
 6. Es wird wegen des Atemwiderstands der Masken nicht für Kinder, schwangere Frauen und ältere Menschen empfohlen.

1. Este produto é um respirador anti-particulado do tipo filtro de escorvamento automático  
 2. Não use em ambientes com temperatura ambiente acima de 50 graus  
 3. Não use quando a taxa de oxigênio ambiental for inferior a 19.5%  
 4. Não use em ambiente de gás tóxico (não pode substituir a máscara de gás)  
 5. Adequado apenas para proteção respiratória de partículas.  
 6. Não é recomendado para crianças, gestantes e idosos devido à resistência respiratória das máscaras.

**Manufacturer: Zhejiang Langci Medical Equipment Co., Ltd.**  
**Add.: Building No. 2, Chengnan Industrial Park,**  
**Meicheng Town, Jiande City, Zhejiang Province, P.R. China**

**Made in China**

See the information provided by the Zhejiang Langci Medical Equipment Co., Ltd.

Storage temperature: -20°C and +35 °C

Max ambient relative humidity: storage < 80%



**朗兹 | LANGCI**

**Direction of Use**

1. Stretch out the mask.  
 2. Put the mask on the face, make the nose clip close to the nose, wrap the chin under the mask; hook the left and right ear straps to the ear.  
 3. Use both hands to adjust the shape of the nose clip to ensure tightness.  
 4. Cover your mask with your hand and exhale. If you feel gas leaking from your nose, tighten the nose clip, if air leaks from the edge, please readjust the headband to ensure tightness.

1. Déplier le masque ;  
 2. Placer le masque sur le visage en positionnant la barrette nasale sur le nez, recouvrir le menton, accrocher les attaches d'oreille gauche et droite aux oreilles ;  
 3. Utiliser les deux mains pour ajuster la forme de la barrette nasale afin d'assurer l'étanchéité ;<
 4. Couvrir votre masque avec votre main et expirer. Si vous sentez de l'air s'échapper au niveau de votre nez, resserrer la barrette nasale. Si de l'air fuit par les bords, veuillez réajuster le masque à l'aide des attaches pour assurer l'étanchéité.

1. Estirer la máscara.  
 2. Coloque la máscara en la cara, acerque la pinza nasal a la nariz, envuelva la barbilla debajo de la máscara, enganche las correas para las orejas izquierda y derecha a la oreja.  
 3. Use ambas manos para ajustar la forma de la pinza nasal para asegurar que esté firme.  
 4. Cubra su mascarilla con su mano y exhale. Si siente que le sale gas por la nariz, apriete la pinza nasal. Si hay una fuga de aire por el borde, reajuste la diadema para asegurar que quede bien ajustada.

1. Stendere la mascherina;  
 2. Mettere la maschera sul viso, avvicinare il fermaglio al naso, avvolgere il mento sotto la maschera agganciare le cinghie auricolari all'orecchio sinistro e destro.  
 3. Utilizzare entrambe le mani per regolare la forma del fermaglio per il naso e garantire la tenuta;  
 4. Coprire la maschera con la mano ed espirare. Nel caso di fuoriuscita di aria, stringere il fermaglio per il naso; se l'aria fuoriesce dai bordi, regolare nuovamente l'archetto per garantire la tenuta.

1. Die Verpackung der Maske öffnen, die Maske in die Hände legen und die Kopfbänder ziehen. Achten Sie darauf, dass der Nasenbügel nach oben ist.  
 2. Die Maske unter dem Kinn mit dem Nasenbügel nach oben ziehen, die Kopfbänder hinter dem Ohr vorbei anlegen und den Halt der Maske über die Bänder richtig anpassen.  
 3. Den Nasenbügel mit beiden Fingern leicht zusammendrücken und den an Ihre Nase anpassen.  
 4. Den Dichtstreifen der Maske überprüfen.

1. Estique a máscara.  
 2. Coloque a máscara no rosto, coloque o clipe nasal próximo ao nariz, passe o queixo por baixo da máscara, prende as tiras de orelha esquerda e direita na orelha.  
 3. Use as duas mãos para ajustar a forma do clipe nasal para garantir o aperto.  
 4. Cubra a máscara com a mão e expire. Se você sentir que há vazamento de gás pelo nariz, aperte o clipe nasal; se houver vazamento de ar pela borda, reajuste a faixa de cabeça para garantir o aperto.

**Product Name: Non-powered air-purifying particle respirator**  
**Brand: Lang Ci Model: 5001 Color: white**  
**Product standard: EN 149:2001+A1:2009 FFP2 NR**  
**Specification: 50 pieces**

CE

6 973150 30118

# Photos du produit



Photo 1  
Masque emballé



Photo 2  
Masque fermé



Photo 3  
Masque ouvert

# Déclaration CE

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Verify the validity with the QR code



## CERTIFICATE OF CONFORMANCE

**Certificate No: 2163-PPE-726/01**

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**Zhejiang Langci Medical Equipment Co., Ltd.**

Building No. 2, Chengnan Industrial Park, Meicheng Town, Jiande City 311600, Zhejiang Province, P. R. China

Continues to fulfil the requirements of

### **EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

#### Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
LANGCI / 5001	FFP2 NR	2163-PPE-726	09.06.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with:

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **22/07/2020** and will be valid for one year, until **21/07/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.



  
Suat KACMAZ  
UNIVERSAL CERTIFICATION  
Director

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80

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# Déclaration de conformité du fabricant

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## EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-726

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**Zhejiang Langci Medical Equipment Co., Ltd.**  
Building No. 2, Chengnan Industrial Park, Meicheng Town, Jiaode City 311600, Zhejiang Province, P.R. CHINA

are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

### Product Definition

Brand Name: LANGCI Model: 5001

Filtering half mask

Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with:

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2)** or **Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **09/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



SERIL KACMAZ  
UNIVERSAL CERTIFICATION  
Director

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# Rapports de tests selon la norme EN 149:2001 +A1 : 2019 1/6



## TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 09.06.2020 / 2163-KKD-726

**Manufacturer:** Zhejiang Langci Medical Equipment Co., Ltd.

**Adress:** Building No. 2, Chengnan Industrial Park, Meicheng Town, Jiande City 311600, Zhejiang Province, P.R. China

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Quality Supervision and Inspection Center for Special Safety Protection Products accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-7901 for the product identified below, dated 21.05.2020 with Serial Id STFWT202011880 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 01 June 2020 Version 01 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the client.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personal Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

**Product Description:** Particle Filtering Half Mask

**Classification:** FFP2 NR

**Trademark:** LANGCI Model: 5001



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# Rapports de tests selon la norme EN 149:2001 +A1 : 2019 2/6



## THE CLAUSES OF EN 149: 2001 + A1: 2009 STANDARD RELATED TO EUROPEAN UNION DIRECTIVE EU 2016/425 REQUIREMENTS

### 1.1. Design principles

#### 1.1.1. Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level.

#### 1.1.2. Levels and classes of protection

##### 1.1.2.1. Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

##### 1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

### 1.2. Innocuousness of PPE

#### 1.2.1. Absence of risks and other inherent nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

##### 1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

##### 1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

##### 1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

### 1.3. Comfort and effectiveness

#### 1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

#### 1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

### 1.4. Information supplied by the manufacturer

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

- a) In addition to the name and address of the manufacturer and/or his authorized representative established in the Community
- b) Storage, use, cleaning, maintenance, servicing and disinfection, cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
- c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
- d) Suitable PPE accessories and the characteristics of appropriate spare parts;
- e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
- f) The obsolescence deadline or period of obsolescence of PPE or certain of its components;
- g) The type of packaging suitable for transport;
- h) The significance of any markings (see 2.12)
- i) Where appropriate the references of the Directives applied in accordance with Article 5(6) (b);
- j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination

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# Rapports de tests selon la norme EN 149:2001 +A1 : 2019 3/6



## 2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

### 2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

### 2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

### 2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

### 2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

### 2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

### 2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

### 2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must remain perfectly legible throughout the foreseeable useful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.

If PPE (or a PPE component) is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

## 3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

### 3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

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# Rapports de tests selon la norme EN 149:2001 +A1 : 2019 4/6



Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

Conforming to EN 149:2001 + A1:2009 Standard Requirements

Article 5	<p><b>Classification:</b> Particle Filtering Half Mask</p> <p>The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as:  <b>Filtering Efficiency and maximum Total Inward Leakage:</b> Classified as FFP2  <b>Mask is classified for single shift use, NR</b></p>																																						
Article 7.4	<p><b>Packaging:</b> Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report.</p>																																						
Article 7.5	<p><b>Material:</b> Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; it is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users.</p> <p>Based on the test results, the masks did not collapse when subject to simulated wearing and temperature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.</p>																																						
Article 7.6	<p><b>Cleaning and Disinfection:</b> Particle filtering half mask is not designed to be re-usable. No cleaning or disinfection procedure provided by the manufacturer.</p>																																						
Article 7.7	<p><b>Practical Performance :</b></p> <p>The test report indicates that the human subjects did not face any difficulty in performing the exercises while they were wearing by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfections reported during total inward tests about the comfort, field of vision and fastening issues.</p> <table border="1"> <thead> <tr> <th>Assessed Elements</th> <th>Positive</th> <th>Negative</th> <th>Requirements in accordance with EN 149:2001 + A1:2009 and Result</th> </tr> </thead> <tbody> <tr> <td>2 Head harness comfort</td> <td>2</td> <td>0</td> <td rowspan="3">Positive results are obtained from the test subjects <b>No imperfections</b></td> </tr> <tr> <td>3 Security of fastenings</td> <td>2</td> <td>0</td> </tr> <tr> <td>5 Field of vision</td> <td>2</td> <td>0</td> </tr> </tbody> </table> <p><b>Conditioning :</b> (A.R.) As Received, original</p>	Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result	2 Head harness comfort	2	0	Positive results are obtained from the test subjects <b>No imperfections</b>	3 Security of fastenings	2	0	5 Field of vision	2	0																								
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Article 7.8	<p><b>Finish of Parts:</b> The test report states that the particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.</p>																																						
Article 7.9.1	<p><b>Total Inward Leakage:</b></p> <p>The Total Inward Leakage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the conduction of the exercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as Temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each exercise are available in the test report.</p> <p>It was reported that:</p> <p>The 47 out of 50 exercise measurement results are smaller or equal to 11%.          At least 9 of 10 individual's arithmetic mean is smaller or equal to 8%.</p> <p>According to the reported results, the product meets the limits for FFP1 and FFP2 classification.</p>																																						
Article 7.9.2	<p><b>Penetration of filter material: Sodium Chloride Testing</b></p> <table border="1"> <thead> <tr> <th>Condition</th> <th>No. of Sample</th> <th>Sodium Chloride Testing 95 L/min max (%)</th> <th>Requirements in accordance with EN 149:2001 + A1:2009</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>(A.R.)</td> <td>19#</td> <td>1,81</td> <td rowspan="3">FFP1 ≤ 20 %</td> <td rowspan="6">Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the <b>FFP1, FFP2</b> classes.</td> </tr> <tr> <td>(A.R.)</td> <td>20#</td> <td>1,87</td> </tr> <tr> <td>(A.R.)</td> <td>21#</td> <td>1,94</td> </tr> <tr> <td>(S.W.)</td> <td>22#</td> <td>2,02</td> <td rowspan="2">FFP2 ≤ 6 %</td> </tr> <tr> <td>(S.W.)</td> <td>23#</td> <td>2,09</td> </tr> <tr> <td>(S.W.)</td> <td>24#</td> <td>2,18</td> <td rowspan="3">FFP3 ≤ 1 %</td> </tr> <tr> <td>(M.S. T.C.)</td> <td>25#</td> <td>2,27</td> </tr> <tr> <td>(M.S. T.C.)</td> <td>26#</td> <td>2,43</td> </tr> <tr> <td></td> <td>(M.S. T.C.)</td> <td>27#</td> <td>2,39</td> <td></td> </tr> </tbody> </table> <p><b>Conditioning :</b> (M.S.) Mechanical Strength          (T.C.) Temperature Conditioning          (A.R.) As Received, original          (S.W.) Simulated wearing treatment</p> <p>95 L/min = 1,6 dm<sup>3</sup>·m<sup>-3</sup></p>	Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result:	(A.R.)	19#	1,81	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the <b>FFP1, FFP2</b> classes.	(A.R.)	20#	1,87	(A.R.)	21#	1,94	(S.W.)	22#	2,02	FFP2 ≤ 6 %	(S.W.)	23#	2,09	(S.W.)	24#	2,18	FFP3 ≤ 1 %	(M.S. T.C.)	25#	2,27	(M.S. T.C.)	26#	2,43		(M.S. T.C.)	27#	2,39	
Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result:																																			
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# Rapports de tests selon la norme EN 149:2001 +A1 : 2019 5/6



Penetration of filter material : Paraffin Oil Testing					
Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result	
(A.R.)	28#	4,24	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1, FFP2 classes.	
(A.R.)	29#	4,29			
(A.R.)	30#	4,35			
(S.W.)	31#	4,57	FFP2 ≤ 6 %		
(S.W.)	32#	4,48			
(S.W.)	33#	4,65	FFP3 ≤ 1 %		
(M.S. T.C.)	34#	4,77			
(M.S. T.C.)	35#	4,81			
(M.S. T.C.)	36#	4,92			

Conditioning : (M.S.) Mechanical Strength  
(T.C.) Temperature Conditioning  
(A.R.) As Received, original  
(S.W.) Simulated wearing treatment

Article 7.9.3

Article 7.10  
Compatibility with skin: In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

Article 7.11  
Flammability :

Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	37#	Didn't burn	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed Filtering half masks fulfill requirements of the standard
(A.R.)	38#	Didn't burn		
(T.C.)	39#	Didn't burn		
(T.C.)	40#	Didn't burn		

Conditioning : (A.R.) As Received, original  
(T.C.) Temperature Conditioning

Article 7.12  
Carbon dioxide content of the inhalation air:

Condition	No. of Sample	CO <sub>2</sub> content of the inhalation air [%] by volume	An average CO <sub>2</sub> content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	41#	0,55	0,55	CO <sub>2</sub> content of the inhalation air shall not exceed an average of 1,0% by volume	Passed Filtering half masks fulfill requirements of the standard
(A.R.)	42#	0,56			
(A.R.)	43#	0,54			

Conditioning : (A.R.) As Received, original

Article 7.13  
Head harness: In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.

Article 7.14  
Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is worn.

Article 7.15  
Exhalation Valves: The model under inspection have no valves.

Article 7.16  
Breathing Resistance: Inhalation  
The overall evaluation of the results gathered for 9 different samples 3 as received, 3 with temperature conditioning, 3 simulated wearing treatment complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min. The measurement details for each single mask tested are available in the test report.  
**Passed.**

# Rapports de tests selon la norme EN 149:2001 +A1 : 2019 6/6



Article 7.17	<b>Clogging:</b> This test is not applied to Particle Filtering Half Mask which is not reusable. <i>(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)</i>
Article 7.18	<b>Demountable Parts:</b> There are no demountable parts of the mask.
Article 8	<b>Testing:</b> All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask.
Article 9	<b>Marking – Packaging:</b> Necessary markings are available on the product package (box). The manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the end date of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 9.1 of the technical file.  The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing 5001. The mask template (drawing) indicates that the mask will carry information about the manufacturer / trademark (LANGCI) of the manufacturer, Type of mask; the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. Even the tested sample by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model drawing 5001 exists in the technical file of the manufacturer, Annex 6 of technical file.
Article 10	<b>Information to be supplied by the manufacturer:</b> In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate. Annex 8. The manufacturer shall include this documented user information text in every smallest commercially available package.

PREPARED BY	APPROVED BY
<b>Osman CAMCI</b> PPE Expert 	 <b>Suat KAÇMAZ</b> General Manager 

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