Présentation de l’offre LANGCI

GLOBAL

Masque FFP2 CE

Sommaire

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.

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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, absorbation desmicro-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

X50
50 sachets par boite (50 masques)

X20
20 boîtes par carton (1000 masques)

Caractéristiques logistiques

Poids brute carton : 9,4 kg

Poids volumétrique: 0,086 CBM

2S GLOBAL

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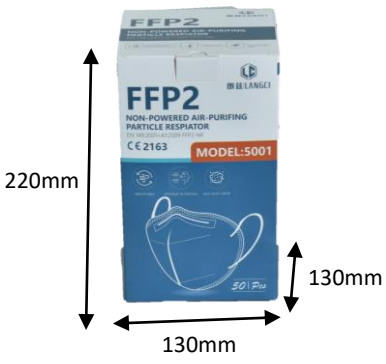
Conditionnement & Stockage

1. Conditionnement

Emballage individuel

50 sachets par boite



50 sachets individuel masques par boite (50 masques)

X20
20 boites par carton (1000 masques)

Caractéristiques logistiques

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

2. Conditions de stockage

Photos des entrepôts de stockage de Lyon

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

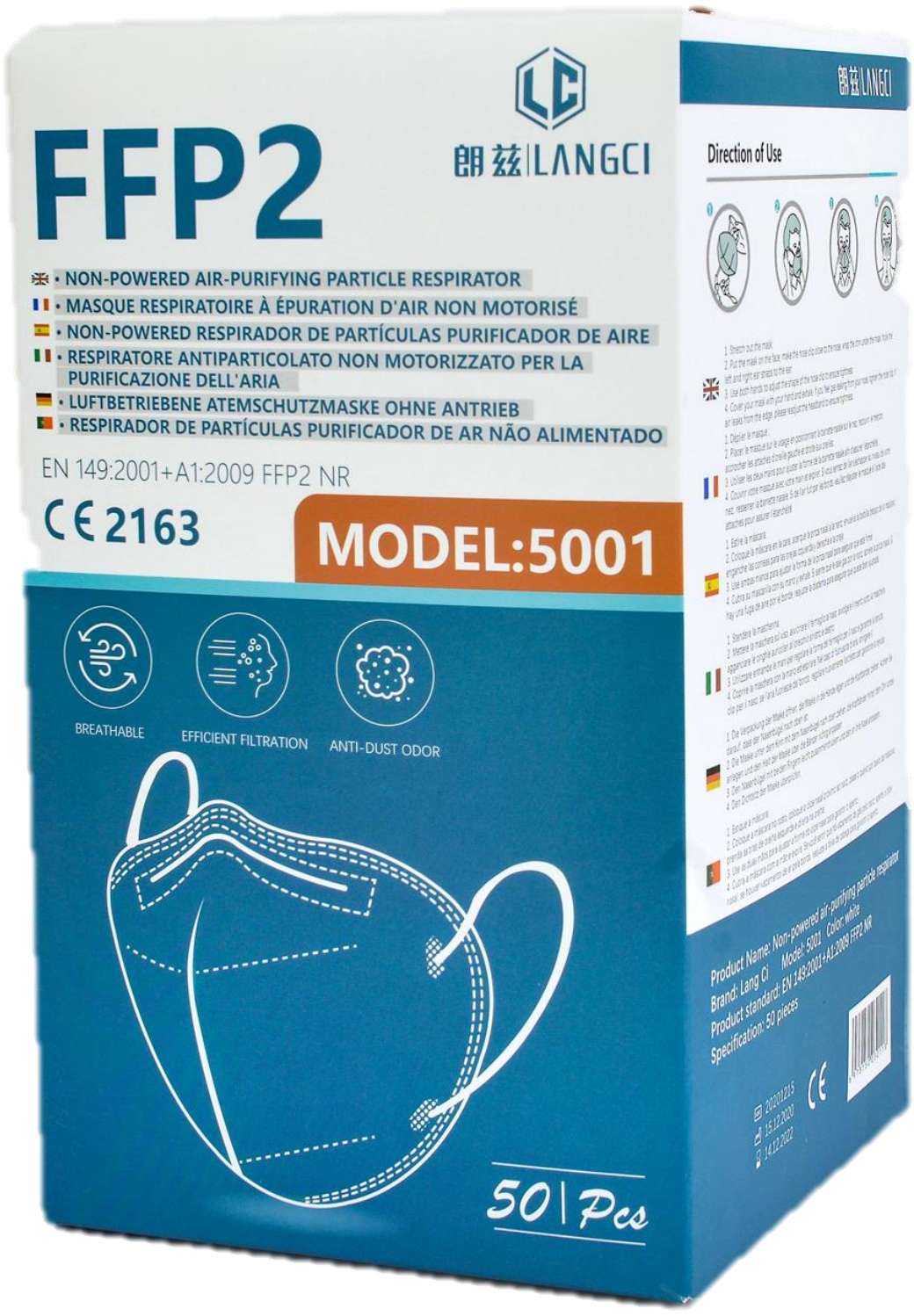
<u>Durée de conservation</u> :
5 ans
sous conditions de stockage

<u>Date limite de conservation :</u>
25 janvier 2026

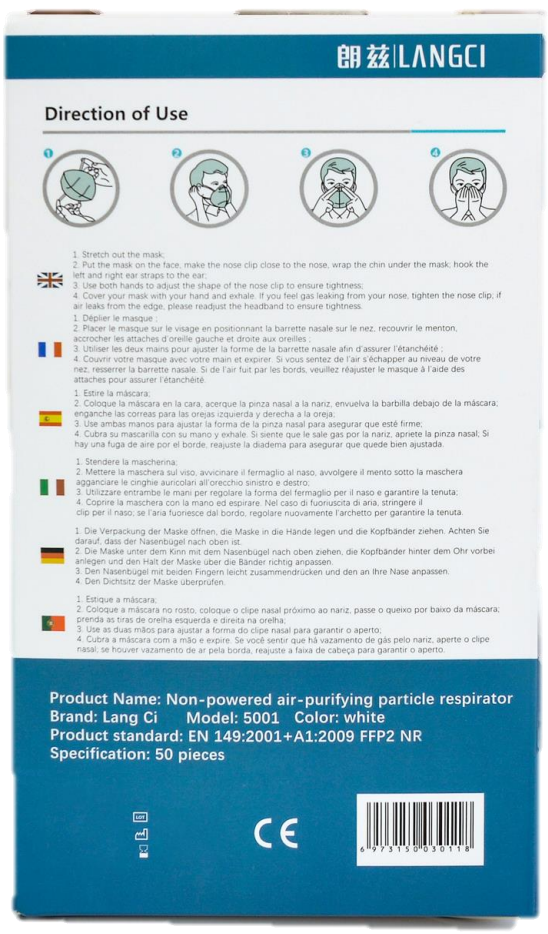
Copie du pack - BAT

Le BAT de la boite 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.

Copie du pack – Photos 1/2



Copie du pack – Photos 2/2



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

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CERTIFICATION

NB 2163

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.

CE
2163

Suat KAÇMAZ
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Director

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Déclaration de conformité du fabricant

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Verify the validity with the QR code

UNIVERSAL
CERTIFICATION
NB 2163

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, Jiande 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.

CE
2163

Sinat KAÇMAZ
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Director

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TECHNICAL ASSESSMENT REPORT

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

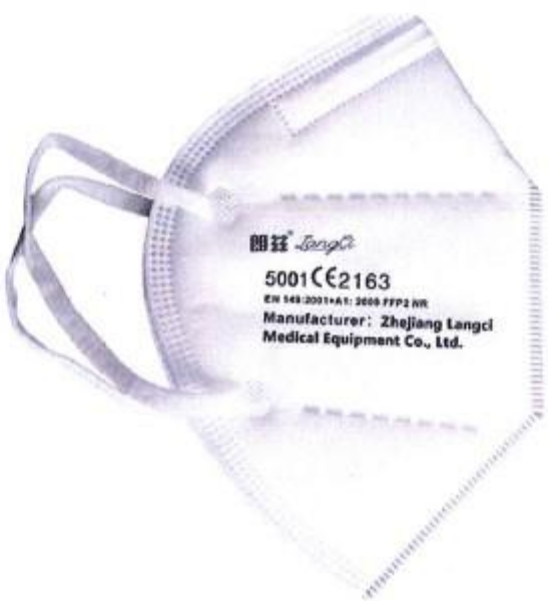
Manufacturer: Zhejiang Langci Medical Equipment Co., Ltd.
Adress: Building No. 2, Chengnan Industrial Park, Meicheng Town, Jiande City 311600, Zhejiang Province, P.R. China

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 Proteciton 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 cient.

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 Personel 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*

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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 foreseenble conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest prossible 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 fore seeable 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 permessible user impediment
Any inpediment 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 foreseenble 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 addressof 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 guestion;
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 deadlineor period of obsolescence of PPEor 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 inaccordance with Article5(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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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 rem ain perfectly legible throughout the foreseeableuseful 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 al lor 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*

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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	**Classification:** Particle Filtering Half Mask The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as: Filtering Efficiency and maximum Total Inward Leakage: Classified as FFP2 Mask is classified for single shift use, NR
Article 7.4	**Packing:** 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.
Article 7.5	**Material:** 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 declines that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users. Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.
Article 7.6	**Cleaning and Disinfection:** Particle filtering half mask **is not** designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.
Article 7.7	**Practical Performance :** The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared 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.

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 **No imperfections**
3.Security of fastenings	2	0	
5.Field of vision	2	0	

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

Article 7.8	**Finish of Parts:** 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.
Article 7.9.1	**Total Inward Leakage:** 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 excercises 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 excersize are available in the test report. It was reported that; 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%. **According to the reported results, the product meets the limits for FFP1 and FFP2 classification.**
Article 7.9.2	**Penetration of filter material:** Sodium Chloride Testing

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		
(A.R.)	20#	1,87		
(A.R.)	21#	1,94	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.
(S.W.)	22#	2,02		
(S.W.)	23#	2,09	FFP2 ≤ 6 %	
(S.W.)	24#	2,18		
(M.S. T.C.)	25#	2,27	FFP3 ≤ 1 %	
(M.S. T.C.)	26#	2,43		
(M.S. T.C.)	27#	2,39		

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

95 L/min = 1,6 dm^3/s

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Rapports de tests selon la norme EN 149:2001 +A1 : 2019 *5/6*

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Article 7.9.2

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		
(A.R.)	29#	4,29		
(A.R.)	30#	4,35	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 gives in 7.9.2 in range of the FFP1, FFP2 classes.
(S.W.)	31#	4,53		
(S.W.)	32#	4,48	FFP2 ≤ 6 %	
(S.W.)	33#	4,65		
(M.S. T.C.)	34#	4,77	FFP3 ≤ 1 %	
(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 7.10

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
(A.R.)	38#	Didn't burn		
(T.C.)	39#	Didn't burn		Filtering half masks fulfill requirements of the standard
(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_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	41#	0,55	0,55	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed
(A.R.)	42#	0,56			
(A.R.)	43#	0,54			Filtering half masks fulfil requirements of the standard

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 weared.

Article 7.15

Exhalation Valve(s): 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.

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Article 7.17	**Clogging: This test is not applied to Particle Filtering Half Mask which is not reusable.** *(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)*
Article 7.18	**Demountable Parts:** There are no demountable parts of the mask.
Article 8	**Testing:** 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	**Marking – Packaging:** 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	**Information to be supplied by the manufacturer:** 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
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