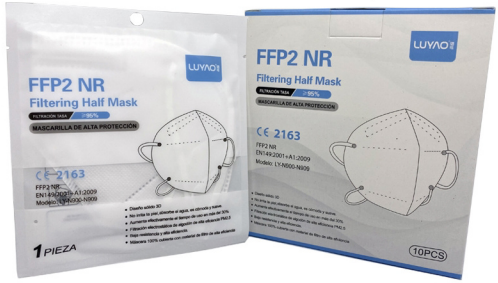
Mascarillas FFP2 con certificado europeo CE - Con eficacia FFP3 certificada por la SGS (embolsadas individualmente - caja de 10 unidades)



Características técnicas:

- Cumplen con la normativa EN 149:2001+A1:2009
- Eficiencia de filtrado >95%
- Eficacia FFP3 certificada por la SGS.
- Certificado europeo CE 2163. Las mascarillas cuentan con certificado CE para los productos de la categoría III. Las mascarillas han superado con éxito los tests que se han llevado a cabo y cumple con los requisitos establecidos en el Reglamento sobre equipos de protección personal (UE) 2016/425 y normas armonizadas, garantizadas por evaluaciones basadas en el anexo 7 (módulo C) o el anexo 8 (módulo d).
- Diseño de cinco capas: Agradable para la piel. El exterior está elaborado con tela no tejida, dos capas de tela fundida envuelta con capa de relleno
- Filtro medio de mayor eficiencia para la más alta protección contra partículas
- Aumenta su tiempo de uso efectivo en un 50% en relación con las mascarillas quirúrgicas.
- No irrita la piel, absorbe el agua, es cómoda y suave.
- Puente nasal interior de alta estabilidad.
- Testeada y probada su eficacia en laboratorios. Este certificado de cumplimiento se ha otorgado en función de los resultados de las pruebas realizadas por BEFTILAT Test Technology Shangay., Ltd. Acreditada por IAS (International Accreditation Service). La mascarilla cuenta con las disposiciones de las normas específicas de la UEy cuenta con el certificado EN 149:2001+A1:2009.
- Medios filtrantes de alto rendimiento con baja resistencia a la respiración.
- Excepcional comodidad y ajuste de la mascarilla para los usuarios.
- Mascarillas libres de grafeno.

Calle Sierra Filabres 1. Polígono Industrial La Olivilla. CP:28946. Fuenlabrada (Madrid).
91 632 77 40
tienda@fisaude.com

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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-730/R1

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

Zhejiang Luyao Electronic Technology Co., Ltd.
Wei 1st Road Mechanical Park, Wanquan Light Industrial Base Pingyang, Wenzhou, Zhejiang, 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

Single shift use particle filtering half face mask for protection against solid and liquid aerosols, is a cup shape, 5 layers polypropylene nonwoven fabrics, without valve, fitted with ear loops and internal nose clip. The model have colored ones (black, blue, gray, green, pink, red, white, orange) manufactured by use of colored spunbound fabrics in the most outer layer of the mask, with the earloops as well.

Brandname: LUYAO **Model:** LY-N900-N909
Classification: FFP2 NR

For more details, refer technical evaluation report provided to the manufacturer, dated 23.04.2021 and number 2163-KKD-730-R2.

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.

This certificate is initially issued on **09/06/2020** and updated on **23/04/2021**, will be valid for 5 years from the issue date, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 23.04.2021 / 2163-KKD-730-R2

Initial report date and number: 09.06.2020 / 2163- KKD-730

Revision Report date and number: 17.01.2021 / 2163-KKD-730-R1

This technical evaluation report is updated with the use of the same fabric as defined in the initial technical file with colored versions in the outer most layer of the mask and earloops. There is no other design or material change in the colored versions of the model. See relevant test reports on the material innocousness of the material.

Manufacturer: Zhejiang Luyao Electronics Technology Co., Ltd.

Address: Wei 1st Road Mechanical Park, Wanquan Light Industrial Base, Pingyang, Wenzhou , Zhejiang, China

Introduction

This report is prepared for the, given above, manufacturer according to the test results obtained from Jiangsu Guojian Testing Technology Co., Ltd. accredited by CNAS (Chinese Accreditation Service), signatory to ILAC MRA, with number L10118 for the product identified below, dated 04.09.2020 with Serial ID (2020) WSZ FHL No.7734 based on EN 149 : 2001 + A1: 2009 standard and *test reports on the material safety by means of toxic, carcinogen, irritationg and sensitivity evaluation.*

The revised technical file dated 25 March, 2021 Version 02 provided by 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 No. 2163-PPE-730/R1 issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 7 pages.

Product Description: Single shift use particle filtering half face mask for protection against solid and liquid aerosols, is a cup shape, 5 layers polypropylene nonwoven fabrics, without valve, fitted with ear loops and internal nose clip. The model have colored ones (black, blue, gray, green, pink, red, white, orange) manufactured by use of colored spunbound fabrics in the most outer layer of the mask, with the earloops as well.

Classification: FFP2 NR

Brandname: LUYAO

Model: LY-N900-N909

Component and Materials:

Component	Material	Grade / Size
Layer 1	Polyester Fiber Non-wovens	70gsm(±2)
Layer 2	ES Fiber	40gsm(±2)
Layer 3	Poly tetra fluoroethylene	25gsm(±2)
Layer 4	Polypropylene	25gsm(±2)
Layer 5	Polyester Fiber Non-wovens	28gsm(±2)
Ear straps	Polyester and spandex	Width:4mm±0.5mm Length:185mm±5mm
Nose clip	Plastic + Iron	Width:5mm±0.5mm Length:75mm±5mm

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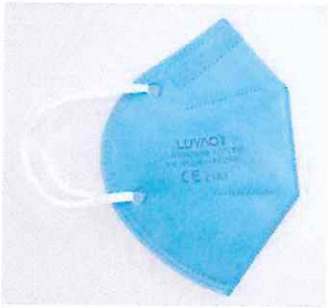
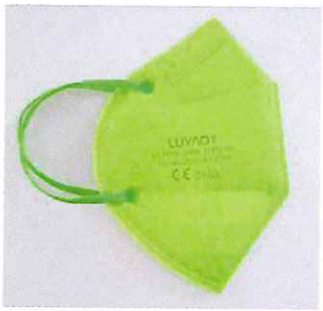
Sample Photos

Black

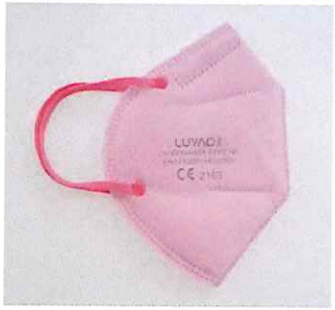


Blue

Gray

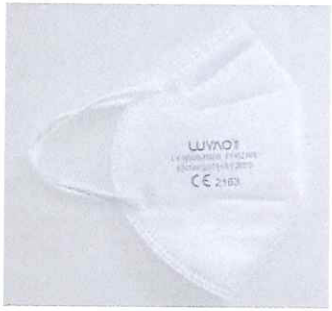


Green

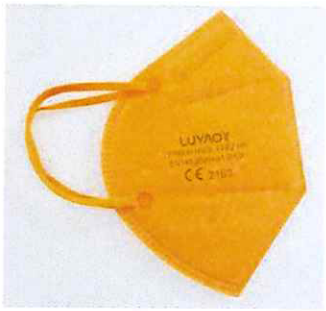


Pink

Red



White



Orange

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ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT

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 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 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 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

3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.
The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.
The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.
The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.
In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.

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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. Details given in Annex 9.1 of Technical File.
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 declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users. Manufacturer declares that the material do not have any adverse effect for the wearers health in Section 7 of the Technical File. 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. *The model have colored ones manufactured by use of colored spunbond fabrics in the most outer layer of the mask. Based on the test results in the test report of TUV THURINGEN (SHANGHAI) CO., LTD. (Report numbers 8621.SH.2103.0122R1 (Black), 8621.SH.2103.0123R1(Gray), 8621.SH.2103.0124R1(Red),8621.SH.2103.0125R1(Pink),8621.SH.2103.0126R1(Orange),8621.SH.2103.0128R1(Blue),8621.SH.2103.0129R1(Green), (2020)WSZ FHL NO.7734(White) – prepared by TUV THURINGEN (SHANGHAI) CO., LTD., the colored materials (spunbond fabric) used in the outer most layer of the mask is considered to be safe for use on the mask.*
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 imperfactions 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
Head harness comfort	2	0	Positive results are obtained from the test subjects **No imperfections**
Security of fastenings	2	0	
Field of vision	2	0	

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

Article 7.8	**Finish of Parts:** 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: All 50 individual exercise results are smaller or equal to 11 %, the values varies between 1,0% and 8,1%. All 10 individual arithmetic mean is smaller or equal to 8 %, the values varies between 2,2% and 5,6%. **According to the reported results, the product meets the limits for FFP2 classification.**

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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.)	-	0,4	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2 and FFP3** classes.
(A.R.)	-	0,4		
(A.R.)	-	0,5		
(S.W.)	-	0,4		
(S.W.)	-	0,5		
(S.W.)	-	0,4		
(M.S. T.C.)	-	0,5		
(M.S. T.C.)	-	0,6		
(M.S. T.C.)	-	0,7		

95 L/min = 1,6 $dm^3.sn^{-1}$

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

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.)	-	1,0	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1 and FFP2** classes.
(A.R.)	-	1,1		
(A.R.)	-	1,0		
(S.W.)	-	1,1		
(S.W.)	-	1,1		
(S.W.)	-	1,2		
(M.S. T.C.)	-	2,5		
(M.S. T.C.)	-	3,0		
(M.S. T.C.)	-	3,8		

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.)	-	Burn for 0,5 s	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.)	-	Burn for 0,4 s		
(T.C.)	-	Burn for 0,5 s		
(T.C.)	-	Burn for 0,4 s		

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.)	-	0,7067	0,70 [%]	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	**Passed** Filtering half masks fulfil requirements of the standard
(A.R.)	-	0,7053			
(A.R.)	-	0,7049			

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 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):
No exhalation valve exists.

Article 7.16

Breathing Resistance: Inhalation

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 simulated wearing treatment conditioned samples complies with the limits given in the standard for FFP2 class. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.

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 on the product.
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 name and trademark of the manufacturer is stated to exist on the carton boxes. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the year of end 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 LY-N900-N909. The mask template (drawing) indicates that the mask will carry information about the brandname (LUYAO) 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. The tested sample by the laboratory carry necessary marking information as stated in the technical documentation, the manufacturer shall also follow marking instructions for serial production. Model drawing LY-N900-N909 exists in the technical file of the manufacturer, Annex 6 of technical file. *The manufacturer shall pay attention on the colored samples that the markings shall be easily readable on the mask.*
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 of technical file. The manufacturer shall include this documented user information text in every smallest commertially available package.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert	**Suat KAÇMAZ** Director UNIVERSAL CERTIFICATION CE 2163 Notified Body

UNIVERSAL SERTİFİKASYON UYGUNLUK DEĞERLENDİRME A.Ş Tatlısu Mh. Arif Ay Sk. No:16 Ümraniye / İSTANBUL T:+90 216 455 80 80 F: +90 216 455 80 08 info@universalcert.com