

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-730

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

Brand Name: LUYAO Model: LY-N900-N909 Filtering half mask

Classification: Class - 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

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163 - PPE -730/01

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

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

Madal	Class	EU Type Examination Certificate			
Model		Serial No.	Date	Issuing NB No.	
LUYAO / LY-N900-N909	FFP2 NR	2163-PPE-730	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 09/06/2020 and will be valid for one year, until 08/06/2021 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

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 09.06.2020 / 2163-KKD-730

Manufacturer: Zhejiang Luyao Electronic Technology Co., Ltd.

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

This report is for the, given above, manufacturer prepared according to the test results obtained from BEFITLAB Test Technology Shanghai Co., Ltd. accredited by IAS (International Accreditation Service), signatory to ILAC MRA, with number TL-787 for the product identified below, dated 30.05.2020 with Serial Id BT20200669T based on EN 149: 2001 + A1: 2009 standard and the technical file dated 31 May 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: LUYAO Model: LY-N900-N909





UFR-383 12.12.2018 Rev.01



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 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
- 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)
- 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





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 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.





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

	C	omorming to EN	149:2001 + A1:2009 Stan	dard Requirements	MARIE REPORT	i 4 Et				
	Classification: Part	icle Filtering Half Ma	sk							
Article	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									
5	Filtering Efficiency	Filtering Efficiency and maximum Total Inward Leakage: Classified as FFP2 Mask is classified for single shift use, NR								
	Mask is classified for	or single shift use, NR								
ements.	Packing: Particle f	filtering half masks a	are packaged to protect them fro	un contamination before us	e and with cardboard boxes to	prever				
Article	mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on inspection results given in the test report.									
7.4										
			ing half macks according to the	imulated wearing treatment a	and temperature conditioning rec	ndte: It i				
		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								
Article		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 o								
7.5		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		. w	13 F 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	P. 1. N. 1. 1.	3 172				
			not collapse when subject to sim	alated wearing and temaratur	re conditioning. No nuisance sit	tuation				
	reported during the	practical performance	tests by human subjects.							
Article	Cleaning and Disir	fection: Particle filter	ring half mask is not designed to	be as re-usable. No cleaning of	or disinfection procedure provide	ed by th				
7.6	manufacturer.									
	Practical Performa	nce :								
Irticle .7			on tests. The wearers did not rep Also no imperfactions reported di	ring total inward tests about	the comfort, field of vision and					
2.0	A	ssessed Elements	Positive No		nts in accordance with EN 1 + A1:2009 and Result					
	2.Head	harness comfort	2	0 Positive resul	Its are obtained from the test					
	3.Secu	rity of fastenings	2	0	subjects					
	5.Field	of vision	2	0 N	o imperfections					
	Conditioning : (A.I	R.) As Received, origin	nal							
Article 7.8	edges and do not co	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 share edges and do not contain burrs.								
	Total Inward Leak	A-100								
Article 7.9.1	condcution of the e Temperature condit	xcercises defined in the ioning and as received re available in the test	ted by 10 individual in an aeros he standard. The samples used in d. The face dimensions of the sub report.	the test are subjected to the	conditioning required in the sta	andard a				
			maller or equal to 11% the values aller or equal to 8% the values var		%.					
	an it marriada sa									
	Panetration of file	According to the re r material: Sodium C	eported results, the product mee	ts the limits for FFP1 and F	FP2 classification.					
	Tenetration of fine	. materials occurring C	monds rooms							
	Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accord EN 149:2001 + A1						
	(A.R.)	11	2,3							
	(A.R.)	12	1,3							
	(A,R.)	13	0,5	FFP1 ≤ 20 %	Filtering half masks t					
		14	1,7		requirements of the	fulfill th				
10001	(S.W.)			ETTER - C C C						
	(S.W.)	15	2,5	FFP2 ≤ 6 %	EN EN 149:2001 +	standar				
Article		15	2,5 1,4	FFP2 ≤ 6 %	EN EN 149:2001 + a	standar A1:200				
	(S.W.)			FFP2 ≤ 6 % FFP3 ≤ 1 %	given in 7.9.2 in rang	standar A1:200 ge of th				
	(S.W.) (S.W.)	16	1,4	- Control of the Cont	given in 7.9.2 in rang	standar A1:200 ge of th				
	(S.W.) (S.W.) (M.S. T.C.)	16 17	1,4 1,8	- Control of the Cont	given in 7.9.2 in rang	standar A1:200 ge of th				
	(S.W.) (S.W.) (M.S. T.C.) (M.S. T.C.) (M.S. T.C.)	16 17 18	1,4 1,8 1,8 1,6	- Control of the Cont	given in 7.9.2 in rang	standard A1:200 ge of the sses.				
	(S.W.) (S.W.) (M.S. T.C.) (M.S. T.C.) (M.S. T.C.) Conditioning : (M.	16 17 18 19	1,4 1,8 1,8 1,6	- Control of the Cont	given in 7.9.2 in rang FFP1, FFP2 clas	standar A1:200 ge of th sses.				
	(S.W.) (S.W.) (M.S. T.C.) (M.S. T.C.) (M.S. T.C.) Conditioning : (M.	16 17 18 19 S.) Mechanical Streng	1,4 1,8 1,8 1,6 th	- Control of the Cont	given in 7.9.2 in rang FFP1, FFP2 clas	standard A1:200 ge of the sses.				

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	Penetration of fi	lter material:	: : Paraffin Oil Tes	100					
	Co	Condition (A.R.)		Paraffin Oil 1 95 L/min ma		Requirements in accordance with EN 149:2001 + A1:2009		Result	
		(A.R.)	Sample 20	1,7					
		(A.R.)		2,7					
	(A.R.) (S.W.) (S.W.)		22	22 2,2 23 2,0 24 1,9		FFP1 ≤ 20 %		alf masks fulfill the	
70-1076			23					requirements of the standard	
Article			24					9:2001 + A1:2009	
7.9.2		(S.W.) (M.S. T.C.) (M.S. T.C.)		3,1			given in 7.9.2 in range of the		
				2,9			FFP1, FFP2 classes.		
				2,5		1.00			
	and the state of t			2,0					
	The second secon	(M.S. T.C.) 28 2,0 Conditioning: (M.S.) Mechanical Strength							
	(T.C.) Tempera A.R.) As Rece	ature Conditioning gived, original ed wearing treatm						
Article 7.10	adverse effect on			ce report, the likel	hood of mask ma	iterials in contact with the	skin causii	ng irritation or other	
	Flammability:					180			
	Condition No. Sam		le Vis	Visual inspection		Requirements in accordance with E 149:2001 + A1:2009		Result	
Article	(A.R.)	29		Burn for 0s		Filtering half mask		Passed	
7.11	(A R.)	30		Burn for 0s		hall not burn or not	Grand Communication and Communication Commun		
7.11	(T.C.)	31		Burn for 0s		continue to burn for		ing half masks fulfill	
	(T.C.)	(T.C.) 32		Burn for 0s				requirements of the	
	removal from the l					noval from the flame	standard		
	Conditioning: (A.R.) As Received, original (T.C.) Temperature Conditioning								
	Carbon dioxide o	Charles - Control of the Land	The state of the s						
		Tourient or the	· mananton ant		An average				
Article	Condition	No. of Sample		the inhalation air volume	CO ₂ content of the inhalation air	Requirements in accord EN 149;2001 + A1		Result	
7.12	(A.R.)	33	0,69)				Passed	
	(A.R.)	34	0,68		0,69			Filtering half mask fulfil requirements	
	Conditioning: (/	the sta anditioning : (A.R.) As Received, original					the standard		
Article 7.13	Head harness: In	Practical Per	formance and TIL			been reported for donnir the mask firmly enough.	g and remo	ove of the mask also t	
Article 7.14	Field of vision: In	Practical Per	rformance report, i	no adverse effects	were reported for	the field of vision availab	ility when	the mask is weared.	
Article 7.15	Exhalation Valve	e(s): The mod	el under inspection	n have no valves.					
Article 7.16	treatment complie	nation of the es with the lin	results gathered f nits given in the s	tandard for FFP1,	FFP2 and FFP3	red, 3 with temparature classes. This is valid for sted are available in the te	inhalation i	Action and the second s	





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 LY-N900-N909. The mask template (drawing) indicates that the mask will carry information about the manufacturer / trademark (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. 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 LY-N900-N9091exists 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
Osman CAMCI PPE Expert	Suat KAÇMAZ General Manager