

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1098

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

Wenzhou Junyue Bag Making Co., Ltd.

Building 5, Yellow River industrial park, no. 4699 century avenue, longgang city, wenzhou city, zhejiang province, 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

Model: JY-2018-1 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 20/07/2020 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

UNIVERSAL CERTIFICATION
Director



TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 20.07.2020 / 2163-KKD-1098

Manufacturer: Wenzhou Junyue Bag Making Co., Ltd.

Address: Building 5, Yellow River industrial park, no. 4699 century avenue, longgang city, wenzhou city, zhejiang

province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Ningbo Customs District Technology Center accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-0317 for the product identified below, dated 03.07.2020 with Serial Id KZ2020372 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 18 July, 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 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

Model: JY-2018-1

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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 foresceable 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 foresceable 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:

- 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;
- The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
- g) The type of packaging suitable for transport;
- The significance of any markings(see 2.12)
- i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
- 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 unione 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 are 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

3.10.1. 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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UFR-383 12.12.2018 Rev.01



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

	Cont	forming to EN	149:2001 + A1:2009 S	andard Re	quirements									
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Article	The mask subject to e	valuation based on	the test results and technical fil	e provided by	the manufacturer is classifie	ed as;								
5			Inward Leokage: Classified as	FFP2										
X-701	Mask is classified for													
Article	Packing: Particle file	tering half masks	are packaged to protect their	from contam	ination before use and wi	ith cardboard boxes to pre-								
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rticle	marks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfor security of fastenings and field of vision. Also no imperfactions reported during total inward tests about the comfort, field of vision and fastenings.													
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	Penetration of filts	er material	: Paraffin Oil Testi	ng					
	Cond	lition	No. of Sample	Paradfin Oil 1 95 L/min ma		equirements in accordance h EN 149:2001 + A1:2009		Result	
	(A	(A.R.)		1.82					
	(A	(A.R.)		1.89					
		(A.R.)		1.96		FFP1 ≤ 20 %	Filterina h	alf masks fulfill the	
Article		W.)	31	2.00				ents of the standard	
7.9.2		W.)	32	1.96		FFP2 ≤ 6 %		19:2001 + A1:2009	
1.7.6	CS.	W.)	33	2.13				.9.2 in range of the	
		T.C.)	34	1.95		FFP3 ≤ 1 %		nd FFP2 classes.	
	(M.S.	T.C.)	35	2.04				20-20-20-20-20-20-20-20-20-20-20-20-20-2	
	(M.S	T.C.)	36	1.98					
	Conditioning: (M.)	 Mechani 	ical Strength						
	(T.)	C.) Temper	sture Conditioning						
	(A.)	R.) As Rece	rived, original						
	(S.1	W.) Simular	ed wearing treatme	ent					
Article 7,10	Compatibility with	skin: In Pr	ractical Performance	e report, the likel	ihood of mask m	aterials in contact with the	skin causi	ng imitation or other	
1,10	adverse effect on he Flammability:	aith was no	t reported.						
	Condition	No. o Samp	Win	Visual inspection Requirements in accordance with		ments in accordance with E 149:2001 + A1:2009	N	Result	
Fred B	(A.R.)	42	В	arm for 0s		Filtering half mask	Passed		
Article	(A.R.)	43	B	um for 0s	-	shall not burn or not			
.11	(T.C.)			Burn for 0s		continue to burn for		ing half masks fulfil	
	(T.C.)	45	n	Burn for 0s		more than 5 s after		requirements of the	
						moval from the flame	standard		
	Conditioning: (A.R								
	The first of the second section of the section of the second section of the section o	and the second second second	sture Conditioning						
	Carbon diexide cor	stent of the	inhalation air:						
Article	Condition	No. of Sample		O _c content of the inhalation air [%] by volume		Requirements in accord EN 149:2001 + A1:		Result	
7.12	(A.R.)	46	0.47		air			Passed	
	(AR.)	47	0.46			COs content of the inha	lation air		
	(A.R.)	48	0.48		0.47 [%]	shall not exceed an ave 1,0% by volume	overage of Filtering half m.		
	Conditioning: (A.R) As Recei	ved, original					the standard	
Article 7.13	Head harness: In P results of these tests	ractical Per indicates th	formance and TIL out the ear loops / h	test reports no ad ead harness are o	verse effects have apable of holding	to been reported for donning the mask firmly enough.	g and remo	we of the mask also t	
trticle 7,14	Field of vision: In F	ractical Per	formance report, n	o adverse effects	were reported fo	r the field of vision availab	lity when	the mask is weared.	
(micle	Exhalation Valvets	to The mod	el anales income tions	hove no values					
7.15	Syramon differ	A TOTAL OF							
	Breathing Resistan	ce: Inhalati	on						
tructe		d complies	with the limits giv			d, 3 with temparature cond FP3 classes. This is valid f			





Article 7.17	Clogging: This test is not applied to Particle Filtering Half Mark which is not reusable.
777	(For single shift use devices, the cingging true is optional test. For re-analyte devices test is mandatury.)
Article 7.18	Demountable Parts: There are no demountable parts on the product.
Article B	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.
	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-asability, 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.
Arricle 9	The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing JY-2018-1. The mask template (drawing) indicates that the mask will carry information about the name / trademark (Wenzhou Junyue Bag Making Co., Ltd. / JunYue) 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 JY-2018-1 drawing exists in the technical file of the manufacturer, Asnex 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. Amex 8. The manufacturer shall include this documented user information text in every smallest commercially available package.

PREPARED BY	APPROVED BY	V.DEAN
Osman CAMCI PPE Expert	Sunt KAÇMAZ Director	Och King



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The Testing Center is accredited for compliance with ISO/IEC17025:2017.

The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.

CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT

Selected test items from EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirements, testing, marking

According to supervised product checks procedure at random intervals (C2)

The following samples were submitted and identified on behalf of the client as:

Product : Particle Filtering Half Mask

Report No. : **KZ2021841**

Client : Universal Certification and Surveillance Service Trade Ltd.Co.

Model(s) : JW078

Number of samples : 20

Received date : 2020.07.28

Date(s) of tests : 2020.07.28-2020.08.18

DESCRIPTION OF SAMPLES

General information

Classification Main components
White folding mask

Manufacturer WENZHOU JUNYUE BAG MAKING CO., LTD.

Manufacturer address Building 5, Yellow River industrial park, No. 4699 century avenue,

Longgang city, Wenzhou city, Zhejiang province, China

Approve: 傳承本, Fu Kejie

Authorized Signatory, Lab Director

Reviewer:

Fu Danhua

Chief Tester:

Eona Viii

Feng Yun

Issued: 2020.08.18

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Test Report No.KZ2021841

Conditions:

The test results presented in this report relate to the samples tested only.

This report may be reproduced and distributed to your clients, provided that it is reproduced and distributed in full.

The authenticity of this test report and its contents can be verified by contacting the laboratory.

Conclusion

Test Items

Clause 7.	9.2 Penetra	ation of filter ma	iterial	OCT CELL OF	III	ON MEDIE	(TECHII GOLCE)	All Ci I	Pass
Clause 7.	.16 Breath	ing resistance	DETRIE CHIN	OL CHAIR	IIIACBO AIII	CUSTO DESTRI	CHROLE	It. MAGBO A	Pass

Remarks: Pass = Meet EN 149:2001+A1:2009 FFP3 Requirement

Fail = Below EN 149:2001+A1:2009 FFP3 Requirement

N/A = Not Applicable

Disclaimer Measurement Uncertainty:

Unless otherwise agreed upon, Pass or Fail verdicts are given based on the measured values without any considerations of measurement uncertainties. Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according to ISO/IEC 17025 requirements.

By taking measurement uncertainties into account it might happen that measured values can neither be assessed as Pass nor as Fail.

Test Results

7.9.2 Penetration of filter material

Pass1

The penetration of the filter of the particle filtering half mask shall meet the following requirements.

Sodium chloride test 95 L/min

Paraffin oil test 95 L/min

90	FFP1	380 1510MS	MEBO MINEBC	≤20%	INGBC	STOWN INGE	MINGBO	-III-GBO	IINGBO	€20%	, MGBO	IINGBO	-III/GBO	117
	FFP2		O NGBO	≤6%	MOL	HILL TEBO	NEBO	SION	TRIC I	≤6%	(680)	NCBO.	STOWN X	81C
9	FFP3	31 CHE WITH	CICKERO	≤1%	, oct	165 TO	S. C. BOC	MSDI		≤1%	- Circular	1680 C	MSDE	

Note 1: FFP3 respirator. Test results are shown in Annex A Table 7.9.2.

7.16 Breathing resistance

Pass

OSTRIC CHADLO CHATE	THE OF THE CITY OF THE WAY	Maximum permitted resistance (mba	ar) Extra Mark Mark Detro		
Classification	Inha Inha	Exhalation			
SOLVERY OF CEL	30 L/min	95 L/min	160 L/min		
FFP1	0.6	2.125	3.0		
FFP2	0.7	2.4	3.0		
FFP3	1.0 5 N	3.0	3.0		

Note 2: FFP3 respirator. Test results are shown in Annex A Table 7.16.

End of Test Results

Test Report No.KZ2021841

Annex A: Summarization of Test Data

Test specification: EN 149:2001+A1:2009 Clause 8.11

Condition	Sample No.	Penetration (%)	Assessment
Registration of the state of th	01	0.42	PEDIZIF MILL OFFICE OFFI
As received	02	0.39	Allege Allege Allege Allege
	03	0.47	THE TO THE TO STORY
BOCH THE COMPANIE STATE THE COMPANIE STATE OF THE COMPANIE STATE O	04	0.74	Pass
As received	05	0.56	AND CLY PROCESSION STATES
	06	0.88	ARAGRE AND CUSTO DESTRE
	As received	As received 02 03 04 As received 05	As received 01 0.42 02 0.39 03 0.47 04 0.74 As received 05 0.56

Table 7.16 Breathing resistance (mbar)
Test specification: EN 149:2001+A1:2009 Clause 8.9

015	Flow rate) (15) (15)	Distr	07	TECHNI	4 ECHIE		.50 US	08	THOU!	14°C		CHING	09	75,	35
			A	В	C	D	E	A	B	C	D	E	A	В	C	ó D	E
As received	Inhalation	30 L/min	0.68	0.60	0.62	0.72	0.63	0.65	0.59	0.55	0.63	0.62	0.61	0.65	0.59	0.68	0.67
13. 13. 13. 1		95 L/min	2.05	1.96	1.97	2.10	2.06	2.01	1.86	1.85	1.89	2.01	2.14	1.99	1.90	2.04	2.14
	Exhalation	160 L/min	2.87	2.70	2.86	2.90	2.96	2.55	2.65	2.61	2.84	2.93	2.67	2.84	2.93	2.87	2.90
J510 _ J5183	Assessment	MINGES EMINGS	J51 _	OF TREE	FCHROY	CH CHAN	MINGE	, C. HILL	20 CT2	Pass	A FICH	70°	N. MI	AGO C	AING C	551	15TRE

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

Test Report No.KZ2021841

Annex B: Photos of sample



End of Annex E