

TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 30.06.2020 / 2163- KKD-893



This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Quality Supervision and Inspection Center for Special Safety Protection Products accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-7901 for the product identified below, dated 10.06.2020 with Serial Id STFWT202012331G based on EN 149: 2001 + A1 2009 standard and the technical file dated 24 June 2020 Version 01 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the client.

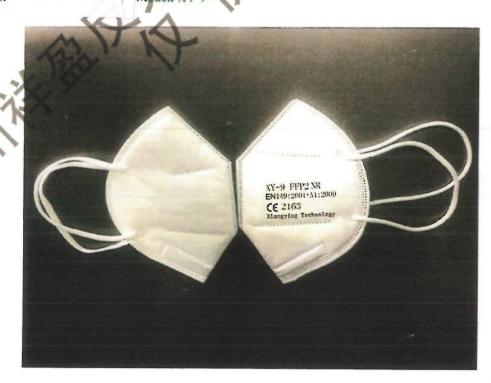
The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

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 rested model. The redinical report consists of a total of 6 pages.

Product Description: Particle Filtering

Classification: FFP2 NR

Trademark:





UFR-383 12.12.2018 Rev.01



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. The test resuts with human subjects did not report any problem with the ergonomics of the product.

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. The manufacturer declares in his technical file that according to the results of risk analysis and the material properties they use in the manufacturing, the product has no hazardous content for health.

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. The material selection is processed in the technical manufacturing process and documented.

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 is evaluated and reported in the test report.

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 with sanding 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;
- 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;
- 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





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

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 to st provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into count 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 agoing 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. The product is for single use and tested with simulated wearing conditioning.

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 no ture to ignite.

2.8. PPE for intervention in very dangerous situations

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

The instructions must also describe the procedure to be adopted in order to verify that IPE 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 forecare by the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foresecable 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 man's 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 memoracturer's notes.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10.1. Resolutiony 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 tmosphere and/or an atmosphere having an inadequate oxygen concentration.

The authable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the poliuted 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 Regulation, Essential Health and Safety Requirements given above.

			N 149:2001 + A1:2009 Stan	dard Requirements							
41100 W	Classification: Partic	ele Filtering Half M	fask								
Article	The mask subject to	evaluation based or	the test results and technical file pr	ovided by the manufacturer is classific	ed as:						
	Filtering Efficiency a	nd maximum Total	Inward Leakage: Classified as FFP	2							
	Mask is classified for	single shift use. N	R								
irnele	Packing: Particle fil	ltering half masks	are packaged to protect them fro	om contamination before use and w	on cardboard boxes to prev						
.4	medianicai damage,	me masks are in p	lastic sealed bags in the card box.	The packaging design and the produc	tote considered to withstand						
5.70	foreseeable condition	s of use based on the	ne visual inspection results given in	the test report.	/ >)						
	Material: Materials	ised in particle filti	ering half masks, according to the si	imulated wearing treatment and tempo	crature conditioning results:						
Arricle	understood it withstar	Material: Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mecha									
	tanure of the facepie	ce of straps, any r	naterial from the filter media relea	sed by the air flow through the file	The not constitute a boson						
.5	nuisance for the wear	er. The manufactur	er declares that the materials used in	manufacturing of the mask does not l	have an adverse affect the he						
	and sarety of users.			.4/>- 4							
	Based on the test res	ults, the masks did	not collapse when subject to simu	lated wearing and tenarance conditi	oning. No nuisance situation						
	reported during the pr	actical performance	e tests by human subjects.	1 1 1 1							
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.6	manufacturer.			XXX	enon proceedire provided by						
	Practical Performan	ce :		180							
			~	14							
	The test report indica	tes that the human	subjects did not face any difficulty	in performing the excercises while the	toy were weared by the can						
	masks, in walking ter	The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sam masks, in walking test or work simulation tests. The wearers did not separate the property of the property of the excercises while they were weared by the sam masks, in walking test or work simulation tests. The wearers did not separate the property of the excercises while they were weared by the sam									
	security of fastenings	and field of vision.	Also no imperfactions reported dur	ring total inward tests about the comfe	ort, field of vision and factor						
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7			- N-N	MA.							
	Ass	essed Elements	Positive Neg	Requirements in account 149:2001 + A1:20							
	2.Head h	arness comfort	-	Positive results are obt.							
		of fastenings	1 1	0 subjec							
	5.Field o	Vision	1-X-4-17/	0 No imperfe							
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(T.C.) Temperature Conditioning (A.R.) As Received, original (S.W.) Simulated wearing treatment



Penetration of filter material: Paraffin Oil Testino	Penetration of	filter materials .	Paraffin Oil Test	in a
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Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009				
(A.R.)	28#	5.01					
(A.R.)	29#	5.21					
(A.R.)	30#	5.13	FFP1 ≤ 20 %	1075 J. 1. 10 J. 1. 10 J. 11			
(S.W.)	(S.W.) 31# 5.		PPF1 5 20 %	Filtering half masks fulfill th			
(S.W.)	32#	5.51	FFP2 ≤ 6 %	requirements of the standard EN EN 149:2001 + A1:2009			
(S.W.)	33#	5.32		given in 19.2 in range of the			
(M.S. T.C.)	34#	5.57	FFP3 ≤ 1 %	FFP1. FFP2 classes.			
(M.S. T.C.)	35#	5.61	an agent and the state of				
(M.S. T.C.)	36#	5.58		1//1			

Conditioning: (M.S.) Mechanical Strength

(T.C.) Temperature Conditioning

(A.R.) As Received, original

(S.W.) Simulated wearing treatment

Arnele 7.10

Article 7.9.2

Compatibility with skin: In Practical Performance report, the likelihood of mask materials is control with the skin causing irritation or other adverse effect on health was not reported. (No negative reporting on practical performance more library results)

Flammability:

Arnele 7.11

Condition	No. of Sample	Visual inspection	Regimements a accordance with EN	Result
(A.R.)	37#	Didn't burn	Filtering half mask	Passed
(A.R.)	385	Didn't burn	shall not burn or not	Laboratory claims that the
(T.C.)	39#	Didn't burn	continue to burn for	tested items did not burn for
(T.C.)	40#	Dida't burn	more than 5 s after	5 seconds and fulfils the requirement of the standard

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

Carbon dioxide content of the inhalation air:

d	enel	
7	12	
1.	140	

Condition	No. of Sample	CO: conte	mor the inhalation a	An average COs content of the inhalation	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	415	4.0	0,53		20 41 11 1	Passed
(A.R.)	425	7	0.94	0/52 (9/3	CO: content of the inhalation air	Filtering half masks
(A.R.)	13=	1	0,52	953 [%]	shall not exceed an average of 1,0% by volume	fulfil requirements of the standard

Article 7.13

Head harness: In stactical Performance and TIL real reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the head harness are capable of holding the mask firmly enough.

Article 7,14

Field of vision: in Pragrical Performance report, no adverse effects were reported for the field of vision availability when the mask is weared

Arnele 7.15

Exhabition Valve(s): The model under inspection have no valves

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.

Passec





Aruele 7.17	Clogging: This test is not applied to Particle Filtering Half Mask which is not reusable.
	(For single shift use devices, the clonging 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+A12-009 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 XY-9. The mask template (drawing) indicates that the mask will carry information about the manufacturer / trademark (Xiangying a colonology) of the manufacturer. Type of mask, the reference to EN 149-A1:2009 standard and classification including the re-usability of the usak. The manufacturer also printed CE mark will 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 approaches for serial production. Model drawing XY-9 exists in the technical file of the manufacturer. Annex 6 of technical file.
trucle 10	Information to be supplied by the manufacturer: In each of the analtest 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. The manufacturer shall include this documented user information text in every smallest commercially available package. Annex 8 of Technical file.

PREPARED BY

Neslihan EKE BİRTÜRK PPE Expert APPROVED BY

Suat KAÇMAZ General Manager WXW FCE

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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

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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.

KZ2021741

Client

Universal Certification and Surveillance Service Trade Ltd.Co.

Model(s)

XY-9

Number of samples

Received date

: 2020.07.20

Date(s) of tests

: 2020.07.20-2020.07.2

DESCRIPTION OF SAMPLES

General information

Classification FFP2

Main components

Manufacturer

Manufacturer address

White folding mask

Authorized Signatory, Lab Director

Reviewer:

Fu Danhua

Feng Yun

Issued:

2020.07.24

Page 1 of 5

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Test Report No.KZ2021741

Conditions:

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

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

Conclusion

Test Items

Clause 7.9.2 Penetration of filter material		YZL .	Pass		
Clause 7.16	Breathing resistance	1-13'xk	Pass		

Remarks:

Pass = Meet EN 149:2001+A1:2009 FFP2 Requirement

Fail = Below EN 149:2001+A1:2009 FFP2 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

Pass 1

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

FFP1	≤20%	≤20%
FFP2	≤6%	€6%
FFP3	≤1%	€1%

Note 1: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.16 Breathing resistance

Pass2

Classification	and the second second	Maximum permitted resistance (mb	ar)
		Exhalation	
, et	30 L/min	95 L/min	160 L/min
FFP1	0.6	2.11	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note 2: FFP2 respirator. Test results are shown in Annex A Table 7.16.

End of Test Results

Test Report No.KZ2021741

Annex A: Summarization of Test Data

Table 7.9.2 Penetration of filter material

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

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
ELECTE BURE BURE AND STREET	of por por	01	3.80	(4)
Sodium chloride test	As received	02	4.28	A STATE OF S
A STATE OF THE PARTY OF THE PAR	THE REAL PROPERTY OF	03	4.38	F WE SET
Sept and Market Court of	THE REAL PROPERTY.	04	4.73	Pass
Paraffin oil test	As received	05	4,52	1 10 10
Server Alexander Server of		06	4.44	Company of the second

Table 7.16 Breathing resistance (mbar)

Test specification: EN 149:2001+A1:2009 Clause 8.9

	Flow rate		07					08			09						
	Tiow	rate	A	В	C	D	Е	A	В	С	D	Е	A	В	С	D	Е
As received	Inhalation	30 L/min	0.55	0.60	0.54	0.54	0.60	0.53	0.47	0.53	0.49	0.46	0.49	0,48	0.51	0.52	0.55
		95 L/min	2,02	2.01	2.04	1.93	2.05	2.11	1.79	1.85	1.75	1.84	2.00	1.84	1.95	1.96	2.07
	Exhalation	160 L/min	2.58	2.39	2.49	1.95	2.43	2,80	1.98	2.16	2,13	2.21	2.54	1.99	2.51	1.99	2.07
0.17	Assessment	(1)	1	-	M	C	90	100	19	Pass	,15			7			

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

End of Annex A

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Annex B: Photos of sample



End of Annex B