- 1. Table of Contents (Page 1)
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- 3. Packaging & Pictures (Page 3-8)
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- 5. European Test & Technical Documentation Review Report(Page 12-21)
- 6. CE Declaration of Conformity (Page 22)
- 7. ISO Production Standards Report (Page 23)

Civil Protective Mask ExxiInherent YX152 Without Valve

**Brand: ExxiInherent** 

Type No.: YX152

EU Standard: EN149 2001 + A1:2009, Regulation (EU) 2016/425,

tested by SGS (0598) Finland

Classifications: FFP2, Protects against Bacterial, particulates and

virus, Filtration efficiency≥95%

Inspection: The Netherlands Ministry of Labor and the Tax

Investigation Bureau provide the passed proof

Features: Against COVID-19, purchased by British and German

**Federal Ministry of Health** 

Material: Total 4 layers, PP nonwoven(outer layer), Melt-blown

fabric(2 layers), PP nonwoven(Inner layer)

Mask Specifications: Universal 15.50x10.50cm, Color box and

instructions in eight European languages

Earloop Design: Breathable and comfortable for prolonged

wearing

Date of manufacture: From October 2020

**Expiration date: 3 years** 

Packing specifications: 1 pc./PE bag, 20 pcs./box, 60

boxes/carton, 16 cartons/block pallet

**P2** 





























Certificate FI20/966321, continued

## **Hunan EEXI Technology &** Service Co., Ltd.

# Regulation (EU) 2016/425 Module B, EU type-examination

PPE Product

Eexilnherent (logo) YX152 particle filtering half mask, consisting of a white five layer (polypropylene) disposable face mask, with nose clip, and polyester ear loops with polypropylene hook;

Eexilnherent (logo) YX153 particle filtering half mask, consisting of a white five layer (polypropylene) disposable face mask, with polypropylene valve, nose clip, and polyester ear loops with polypropylene hook.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference:

YX152/YX153, Rev 1, dated: 2020-08-07.

SGS Reference Number UK/CRS 241545.

S003 (EN ISO/IEC 17065)

Certificate CN20/42194



The management system of

# Hunan EEXI Technology & Service Co., Ltd.

No.6, North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, 410300, P.R. China

has been assessed and certified as meeting the requirements of

## **Regulation (EU) 2016/425**

Module C2

For the following activities

Manufacture of Eexilnherent (logo) YX152/YX153 Particle Filtering Half Mask.

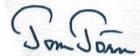
(Note: All products marked CE0598 must have a valid EU typeexamination certificate issued under Module B or a valid EC typeexamination certificate issued under Article 10 of Directive 89/686/EEC.)

This certificate is valid from 14 August 2020 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 14 August 2020



Authorised by



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HUNAN EEXI TECHNOLOGY&SERVICE CO.,LTD

NO.6, NORTH OF PINGTOU ROAD, LIUYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE, HUNAN, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

(A)Particle filtering half mask Sample Description

Claimed FFP2

Style No. YX152

Composition (A)non-woven fabric, melt-blown fabric, bridge of nose, ear band

(A)WHITE Sample Color

HUNAN EEXI TECHNOLOGY&SERVICE CO.,LTD Manufacturer

Test Performed Selected test(s) as requested by applicant

Sample Receiving Date Jul 10, 2020

**Testing Period** Jul 13, 2020 - Jul 22, 2020

Test Result(s) Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

### Conclusion:

Sample No.	Recommendation Level	
(A)	FFP2 NR	

Signed for and on behalf of

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)



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Test Result

### Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking

EN 149:2001+A1:2009

<u>Clause 7.4 Packaging</u> (EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Comply	Pass

Clause 7.5 Material (EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Comply	
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Comply	Pass
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting (EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.  With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable (Not designed to be re-usable)	N.A.

## Clause 7.7 Practical Performance (EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass



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## Test Report SL52035 Clause 7.8 Finish of Parts (EN 149:2001+A1:2009, Clause 8.2) SL52035272857501TX

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Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

## Clause 7.9.1 Total Inward Leakage (EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3  and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3	Detail refer to Appendix 1	Pass

### **Appendix 1: Summarization of Test Data**

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	5.45	6.43	6.86	7.07	4.58	6.08
Luo	2	A.R.	7.48	5.62	8.18	6.84	7.04	7.03
Lu	3	A.R.	6.29	6.73	5.95	5.00	6.46	6.09
Wang	4	A.R.	4.50	5.09	5.51	5.31	5.85	5.25
Bao	5	A.R.	7.94	5.47	7.84	6.22	7.66	7.03
Ding	6	T.C.	7.68	5.17	4.14	6.08	5.02	5.62
Li	7	T.C.	7.17	8.81	7.98	6.63	7.70	7.66
Chen	8	T.C.	5.49	5.95	4.87	6.39	5.03	5.55
Song	9	T.C.	6.56	5.94	6.38	6.59	6.18	6.33
Ye	10	T.C.	8.62	8.04	6.87	7.31	7.30	7.63

### Facial Dimension(mm)

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50
Ding	134	150	110	52



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Test Report	SL520	35272857501TX	Date:July 22,2020	Page 4 of 10
Liu	120	135	117	50
Ye	126	137	105	52

<u>Clause 7.9.2 Penetration of Filter Material</u> (EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

	Test Requirement	Results	Comment	
	of the filter of the particle filter the following table.	ering half mask shall meet the		
Classifica	Maximum penetrati	on of test aerosol		
tion	Sodium chloride test 95 I/min %	Paraffin oil test 95 l/min %	Detail refer to Appendix 2	Pass
	max.	max.		
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

### Appendix 2: Summarization of Test Data

### Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
		1	0.396
	As received	2	0.425
		3	0.385
		4	0.402
Sodium chloride test	Simulated wearing treatment	5	0.367
		6	0.387
	Mechanical strength +Temperature conditioned	7	0.572
		8	0.602
	conditioned	9	0.596
		10	0.456
	As received	11	0.571
		12	0.508
		13	0.623
Paraffin oil test	Simulated wearing treatment	14	0.548
AL REPRODUCES CONTRACTOR		15	0.492
		16	0.565
	Mechanical strength +Temperature	17	0.773
	conditioned	18	0.687



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Test Report SL520352728 <u>Clause 7.10 Compatibility with Skin</u> (EN 149:2001+A1:2009, Clause 8.4 & 8.5) SL52035272857501TX Date:July 22,2020

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Test Requirement	st Requirement Results		
Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	No irritation or any other adverse effect to health	Pass	

### Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature	Detail refer to	Dana
When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	Appendix 3	Pass

### Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result
A	1	NIL
As received	2	NIL
T	3	NIL
Temperature conditioned	4	NIL

## Clause 7.12 Carbon Dioxide Content of The Inhalation Air (EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

### Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Re	sult(%)
	1	0.4824	
s received	2	0.4817	Mean value:0.48
	3	0.4805	



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## Test Report SL5203527288 <u>Clause 7.13 Head Harness</u> (EN 149:2001+A1:2009, Clause 8.4 & 8.5) SL52035272857501TX

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Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	Comply	Pass

<u>Clause 7.14 Field of Vision</u> (EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

<u>Clause 7.15 Exhalation Valve(s)</u> (EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to No exhalation valve	
(b) If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	Not applicable due to No exhalation valve	N.A.
(c) Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	Not applicable due to No exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve	



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## Clause 7.16 Breathing Resistance (EN 149:2001+A1:2009, Clause 8.9)

	Test	Requirement	Results	Comment		
The penetration of the equirements of the Classification	ne following tab	of the particle filtering half mask shall meet th g table. imum permitted resistance (mbar)				
Classification				Detail refer to	Pass	
	Inna	alation	Exhalation	Appendix E		
	30 I/min	95 l/min	160 l/min	Appendix 5		
FFP1	0.6	2.1	3.0			
FFP2	0.7	2.4	3.0			
FFP3	1.0	3.0	3.0			

### Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

		FI						2 3									
	Flow rate(	l/min)	Α	В	С	D	E	Α	В	C	D	E	Α	В	С	D	E
As received	Inhalation	30	0.4	0.5	0.4	0.5	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.4	0.4	0.5	0.5
	IIIIaiation	95	1.9	1.9	1.9	1.8	1.9	2.0	1.9	1.8	2.0	1.8	1.9	2.0	2.0	1.8	1.9
	Exhalation	160	2.8	2.7	2.7	2.8	2.8	2.7	2.7	2.8	2.7	2.7	2.8	2.8	2.7	2.8	2.7
	Et		4 5								6						
Simulated	Flow rate(	l/min)	Α	В	С	D	E	Α	В	С	D	E	Α	В	C	D	E
wearing	Inhalation	30	0.5	0.4	0.5	0.5	0.4	0.4	0.5	0.5	0.4	0.5	0.4	0.4	0.5	0.5	0.4
treatment	minalation	95	1.9	2.0	1.9	1.9	1.9	2.0	2.0	1.9	1.9	2.0	2.0	1.9	1.9	2.0	1.9
	Exhalation	160	2.7	2.8	2.7	2.7	2.8	2.8	2.7	2.7	2.8	2.8	2.7	2.7	2.7	2.8	2.7
					7					8					9		
	Flow rate(	l/min)	Α	В	C	D	E	Α	В	C	D	E	Α	В	C	D	E
Temperature	I be to be to be to be	30	0.3	0.4	0.3	0.4	0.3	0.3	0.4	0.3	0.3	0.4	0.3	0.4	0.3	0.3	0.4
conditioned	Inhalation	95	1.9	2.0	1.9	1.9	2.0	2.0	1.9	1.9	2.0	2.0	1.9	1.9	2.0	2.0	1.9
	Exhalation	160	2.8	2.7	2.7	2.8	2.7	2.7	2.8	2.7	2.8	2.7	2.8	2.7	2.7	2.8	2.7

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



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Clause 7.17 Clogging (EN 149:2001+A1:2009, Clause 8.9 & 8.10)

	Test Requirement		Results	Comment
alved particle fil fter clogging the FP1: 4 mbar, FI he exhalation re ow. alveless particle fter clogging the	eathing resistance tering half masks: inhalation resistances shall not FP2: 5 mbar, FFP3: 7 mbar at 95 esistance shall not exceed 3 mb editering half masks: inhalation and exhalation resis FP2: 4 mbar, FFP3: 5 mbar at 95	5L/min continuous flow har at 160 L/min continuous tances shall not exceed:	Optional for single shift device only	N.A.
II types (valved neet the cloggin	enetration of filter material I and valveless) of particle filter g requirement shall also meet th	e requirements.		
Classificatio	Maximum penetration Sodium chloride test 95 l/min		Optional for single	
n	Sodium chionde test 95 i/min	%	shift device only	N.A.
1				
EED1	max.	max.		
FFP1 FFP2				

<u>Clause 7.18 Demountable Parts</u> (EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	Comply	Pass

Test	Uncertainty	
Total inward leakage	3.4%	
Penetration of filter material	4.8%	
Carbon dioxide content of the inhalation air	3.9%	
Breathing resistance (30L/min)	5.9%	
Breathing resistance (95L/min)	4.9%	
Breathing resistance (160L/min)	4.3%	



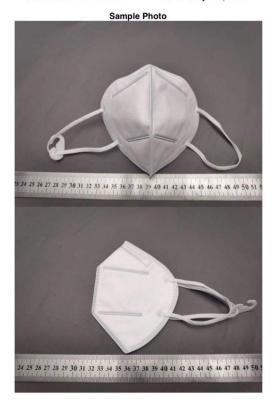
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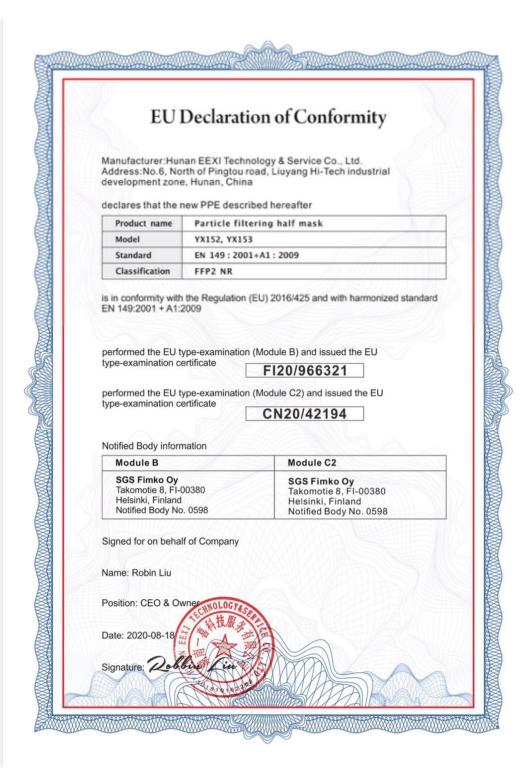
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\*\*\*End of Report\*\*\*





The management system of

# Hunan EEXI Technology & Service Co., Ltd.

No. 6, North of Pingtou Road, Liuyang Hi-tech Industrial Development Zone, Hunan Province, 410300, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design and manufacture of non-sterile surgical face mask, non-sterile single use medical face mask and non-sterile medical protective face mask

This certificate is valid from 16 June 2020 until 15 June 2023 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 5 June 2023

Issue 1. Certified since 16 June 2020

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