



AC 114

CERTYFIKAT BADANIA TYPU UE (MODUŁ B) EU TYPE-EXAMINATION CERTIFICATE (MODULE B)

Nr
No. CW/PPER/47/05/2020**ZAŚWIADCZA SIĘ,**

że Polski Rejestr Statków S.A. (PRS) przeprowadził procedurę badania typu wymienionego niżej wyrobu i stwierdził jego zgodność z wymaganiami określonymi w załączniku V do Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2016/425 (PPE) w sprawie środków ochrony indywidualnej oraz uchylecia dyrektywy Rady 89/686/EEG, ze zmianami.

THIS IS TO CERTIFY

that Polski Rejestr Statków S.A. (PRS) did undertake the EU type-examination procedure for the product identified below which was found to be in compliance with the requirements of Annex V to the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, as amended.

Wnioskodawca
Applicant

Jiangxi Yifengyuan Biological Engineering Co., Ltd.
Yangsha Avenue, Jinxian County,
Nanchang City, Jiangxi Province, China.

Producent
Manufacturer

Jiangxi Yifengyuan Biological Engineering Co., Ltd.
Yangsha Avenue, Jinxian County,
Nanchang City, Jiangxi Province, China.

Typ wyrobu
Product type

Sprzęt ochrony dróg oddechowych. Sprzęt ochrony dróg oddechowych bez zasilania powietrzem. Półmaska filtrująca chroniąca przed COVID-19.
Respiratory protective equipment. Non-powered air-purifying particle respirator.
Filtering half mask to protect against COVID-19.

Opis wyrobu
Product description

Półmaska typ YFY-KN95 klasy FFP-2
Half mask type YFY-KN95 class FFP-2

Zastosowane normy
Specified standards

PN-EN 149 + A1:2010 oraz Rekomendacja RFU PPE-R/02.075 wersja 1.
EN-149:2001 + A1:2009 and Recommendation For Use PPE-R/02.075 version 1.

Niniejszy certyfikat pozostaje ważny do czasu nieważnienia przy zachowaniu warunków uznania (patrz str. 2).
This certificate remains valid unless cancelled or revoked, provided the approval conditions (see page 2) are complied with.

Data ważności
Expiry date

2021-05-26

Dyrektor Pionu Certyfikacji
Certification Division Director

Gdańsk, 2020-05-27

NOTIFIED BODY
NO.1463

Przemysław Gałka

Nr jednostki notyfikowanej
No. of notified body

1463

Polski Rejestr Statków S.A.
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2020-03-26

Wykaz dokumentacji
List of documents

1. Instrukcja użytkowania - zatwierdzona przez PRS S.A. dnia 2020-05-25.
2. Ocena ryzyka - zatwierdzona przez PRS S.A. dnia 2020-05-25.
3. Rysunek Półmaski typu YFY-KN95 - zatwierdzony przez PRS S.A. dnia 2020-05-25.
4. Raport z badań nr BT20051301623 wydany przez Befitlab Test Technology Co., Ltd w dniu 2020-05-22.
5. Sprawozdanie z przeglądu PRS S.A. nr CW/ZO/PPER/42/2020 z dnia 2020-05-26.

1. *Instructions for the use - approved by PRS S.A. on 2020-05-25.*
2. *Risk analysis - approved by PRS S.A. on 2020-05-25.*
3. *Assembly drawing Half Mask type YFY-KN95 - approved by PRS S.A. on 2020-05-25.*
4. *Test report No. BT20051301623 issued by Befitlab Test Technology Co., Ltd. dated 2020-05-22.*
5. *PRS S.A. Survey report No. CW/ZO/PPER/42/2020 dated 2020-05-26.*

Miejsca produkcji
(inne niż podane na stronie 1)
Places of production
(different than given on page 1)Ograniczenia uznania
Approval limitations

1. Półmaska nie jest przeznaczona do użytkowania medycznego i chirurgicznego.
2. Półmaska nie powinna być używana w środowisku o stężeniu tlenu poniżej 19.5 %.
3. Półmaska przeznaczona do użytku podczas jednej zmiany.
4. Półmaska oceniona zgodnie procedurą określoną w Zaleceniu Komisji 2020/403 (COVID-19).
5. Dane techniczne:
 - półmaska z regulowanym klipssem na nos,
 - półmaska wykonana z 4-warstwowej włókniny z filtrem z tkaniny,
 - wymiary: 162 x 110 mm,
 - kolor: biały,
 - docelowa grupa użytkowa: dorośli dla obu płci.

1. *Half Mask can not be used for medical and surgical purposes.*
2. *Half Mask should not be used in an environment with oxygen contents less then 19.5%.*
3. *Half Mask designed for single shift use.*
4. *Half Mask according to Commission Recommendation 2020/403 (COVID-19.)*
5. *Specifications:*
 - *half mask with adjustable nose clip,*
 - *half mask made with 4ply non-woven fabric with melt-blown fabric filter,*
 - *size: 162 x 110 mm,*
 - *color: white,*
 - *target group: unisex.*

Warunki uznania
Approval conditions

- 1 Niniejszy certyfikat straci ważność po wprowadzeniu zmian lub modyfikacji w wyrobie bez uprzedniego uzgodnienia z PRS.
This certificate becomes invalid after changes or modifications to the product without prior agreement with PRS.
- 2 Znak zgodności może być umieszczony na uznanym wyrobie oraz może być wystawiona deklaracja zgodności tylko pod warunkiem, że łącznie z badaniem typu UE zostanie przeprowadzona ocena zgodności produkcji pod nadzorem jednostki notyfikowanej, według załącznika VII lub VIII wymienionego wyżej rozporządzenia.
The Mark of Conformity may only be affixed to the above type approved product and a manufacturer's Declaration of Conformity issued provided the production is assessed under surveillance of a notified body according to Annex VII or VIII of the a/m Regulation.

Test Report

TL-787

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Report No.: BT20051301623

Customer Information:

Customer..... : Jiang Xi Yifengyuan Biological Engineering Co.,Ltd
Address..... : Yangsha Avenue, Jinxian County, Nanchang City, Jiangxi Province (in the medical device industrial base)

Sample Information:

Sample Name..... : KN95 protective mask
Sample Specification.... : KN95
Sample Classification... : FFP2
Sample Description..... : Samples in good condition
Sampled Method..... : All parts were received from customer
Receipt Date..... : 2020-05-13

Testing Information:

Test Items..... : Leakage, Penetration of filter material , etc.
Test Reference..... : EN 149: 2001+A1: 2009
Test Result..... : Please refer to the following pages

Written by: Shyfeng Wu Inspected by: Yawei Li Approved by: Steven Zhu
Date: 2020-05-22 Date: 2020-05-22 Date: 2020-05-22



BEFITLAB TEST TECHNOLOGY SHANGHAI CO., LTD.

Member of International Standards Certification (ISC) Group

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Email: info@befitlab.com

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1、 Sample List

Manufacturer	Sample Name	Specification	Material	Lot
Jiang Xi Yifengyuan Biological Engineering Co.,Ltd	KN95 protective mask	KN95	40% Non-woven fabrics , 30% Melt-blown fabrics ,30% hot air cotton	20200510



2、 Sample Photos



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Appendix 1: Visual inspection

1.1. Visual inspection: The visual inspection shall include the marking and information supplied by the manufacturer.
1.2. Result: Not tested
1.3. Note: As requested by the client, marking and information supplied by the manufacturer was not inspected.

Appendix 2: Package

2.1. Package: 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.
2.2. Result: Pass
2.3. Note: In accordance with the requirement.

Appendix 3: Material

3.1. Material: 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. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. 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. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.
3.2. Result: Pass
3.3. Note: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

Appendix 4: Cleaning and disinfecting

4.1. Cleaning and disinfecting: 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.
4.2. Result: N/A
4.3. Note: Single shift use only.

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Appendix 5: Practical performance

5.1. Practical performance: The particle filtering half mask shall undergo practical performance tests under realistic conditions.
5.2. Result: Pass
5.3. Note: No imperfections.

Appendix 6: Finish of parts

6.1. Finish of parts: Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.
6.2. Result: Pass
6.3. Note: No sharp edges or burrs.

Appendix 7: Total inward leakage

7.1. Total inward leakage: 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								
7.2. Result: Pass								
7.3. Note:								
Subject	Sample No.	Condition	Walk (%)	Head Side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
Wu	1	A.R.	7.12	7.51	7.12	7.77	7.48	7.40
Li	2	A.R.	7.39	7.45	7.67	7.59	7.72	7.56
Zhang	3	A.R.	7.43	7.60	7.74	7.38	7.50	7.53
Xie	4	A.R.	7.15	7.50	7.03	7.31	7.08	7.21
Yang	5	A.R.	7.20	7.78	7.05	7.28	7.72	7.41
Lang	6	T.C.	7.02	7.68	7.50	7.49	7.72	7.48
Wang	7	T.C.	7.27	7.44	7.01	7.45	7.43	7.32
Yu	8	T.C.	7.77	7.76	7.56	7.08	7.73	7.58
Zhu	9	T.C.	7.01	7.07	7.13	7.34	7.26	7.16
Liu	10	T.C.	7.63	7.68	7.60	7.14	7.77	7.56
50 out of the 50 individual exercise results \leq 11 % 10 of the 10 individual arithmetic means \leq 8 %						Pass		

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Subject	Face length	Face Width	Face Depth	Mouth Width
Wu	123	150	115	53
Li	128	133	109	48
Zhang	115	146	113	55
Xie	119	141	118	58
Yang	109	126	109	51
Lang	113	132	116	54
Wang	116	129	123	52
Yu	120	125	115	58
Zhu	119	146	120	53
Liu	108	120	113	51

Appendix 8: Penetration of filter material

8.1. Penetration of filter material: The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

Sodium chloride test 95 l/min

Paraffin oil test 95 l/min

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

8.2. Result: Pass

8.3. Note:

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	4.60	
		12	4.49	
		13	4.51	
	Simulated wearing treatment	14	4.63	
		15	4.58	
		16	4.66	
	Mechanical strength+ Temperature conditioned	17	4.75	
		18	4.71	
		19	4.80	

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Paraffin oil test	As received	20	2.86
		21	2.95
		22	2.94
	Simulated wearing treatment	23	2.95
		24	2.93
		25	2.94
	Mechanical strength+ Temperature conditioned	26	2.97
		27	3.12
		28	3.09
Flow conditioning: Single filter: 95.0 L/min			

Appendix 9: Compatibility with skin

9.1. Compatibility with skin: 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.

9.2. Result: Pass

9.3. Note: No irritation or any other adverse effect to health.

Appendix 10: Flammability

10.1. Flammability: 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.

10.2. Result: Pass

10.3. Note:

Condition	Sample No.	Result	Assessment
As received	29	No Burn	Pass
	30	No Burn	
Temperature conditioned	31	No Burn	
	32	No Burn	

Appendix 11: Carbon dioxide content of the inhalation air

11.1. Carbon dioxide content of the inhalation air: The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

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11.2. Result: Pass

11.3. Note:

Condition	Sample No.	Result	Assessment
As received	33	0.2%	Mean value 0.2% Pass
	34	0.3%	
	35	0.2%	

Appendix 12: Head harness

12.1. Head harness: The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. 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.

12.2. Result: Pass

12.3. Note: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.

Appendix 13: Field of vision

13.1. Field of vision: The field of vision is acceptable if determined so in practical performance tests.

13.2. Result: Pass

13.3. Note: Pass the practical performance tests.

Appendix 14: Exhalation valve

14.1. Exhalation valve: A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. 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. 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. When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

14.2. Result: N/A

14.3. Note: No exhalation valve.

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Appendix 15: Breathing resistance

15.1. Breathing resistance: The breathing resistance apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

15.2. Result: Pass

15.3. Note:

As received	Flow rate	36					37					38					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
	Inhalation	30 l/min	0.3	0.3	0.4	0.3	0.4	0.4	0.4	0.4	0.3	0.3	0.3	0.3	0.3	0.4	0.3
		95 l/min	1.4	1.4	1.4	1.4	1.5	1.4	1.3	1.4	1.4	1.5	1.4	1.5	1.4	1.5	1.4
Exhalation	160 l/min	1.8	2.0	1.8	1.9	1.9	1.9	1.8	1.9	2.0	2.0	1.9	1.9	1.8	2.0	1.9	
Simulated wearing treatment	Flow rate	39					40					41					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
	Inhalation	30 l/min	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.3	0.4	0.3	0.3	0.3	0.3
		95 l/min	1.4	1.3	1.3	1.5	1.4	1.4	1.3	1.3	1.5	1.4	1.5	1.4	1.5	1.4	1.5
Exhalation	160 l/min	2.0	1.9	2.0	1.8	1.8	1.8	1.9	1.9	1.9	1.9	2.0	1.9	1.9	1.9	2.0	
Temperature conditioned	Flow rate	42					43					44					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
	Inhalation	30 l/min	0.3	0.3	0.3	0.4	0.4	0.3	0.3	0.4	0.4	0.3	0.3	0.3	0.3	0.3	0.4
		95 l/min	1.4	1.4	1.3	1.3	1.5	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.4	1.3	1.5
Exhalation	160 l/min	2.0	1.8	1.9	1.9	1.8	2.0	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.8	2.0	
Flow conditioned	Flow rate	45					46					47					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
	Inhalation	30 l/min	0.4	0.3	0.3	0.4	0.4	0.3	0.3	0.3	0.4	0.3	0.4	0.3	0.4	0.4	0.4
		95 l/min	1.4	1.5	1.3	1.3	1.5	1.4	1.4	1.5	1.5	1.4	1.4	1.5	1.4	1.5	1.5
Exhalation	160 l/min	1.8	1.8	1.8	1.9	1.8	1.8	1.8	2.0	2.0	1.9	1.9	1.9	1.9	2.0	1.8	
Assessment	Pass																

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

Appendix 16: Clogging

16.1. Clogging: For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory.

16.1.1 Breathing resistance: Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

16.1.2 Penetration of filter material: The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

16.2. Result: N/A

16.3. Note: Single shift use only.



Appendix 17: Demountable parts

17.1. Demountable parts: All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

17.2. Result: N/A

17.3. Note: No demountable parts.

***** End *****

Notice Items:

1. It is not valid if the report without our stamp.
2. This report must not be altered, increased or deleted.
3. The report is just responsible for the tested sample.
4. The sample(s) information was/were submitted and identified on behalf of the client.
5. Any questions on the report should be put forward within fifteen days since the date on which you receive the report, and overdue is inadmissible.
6. The report must not be partially duplicated except in full, without prior written approval of the company.
7. If any problem, please Call: 021-59100859 or Email: info@befitlab.com
8. Company website: www.accreditservice.com