



EU DECLARATION OF CONFORMITY



We,

Manufacturer: Jiangxi Yifengyuan Biological Engineering Co., Ltd.

Address: Yangsha Avenue, Jinxian County, Nanchang City, Jiangxi Province (in the medical device industrial base)

Declare on our own responsibility, that the:

Product name: Halfmasktype YFY-KN95 class FFP-2

Model name: YFY-FFP2 Kids

are in compliance with following Regulation/directives :

R 2016/425 Personal Protective Equipment

and are in compliance with following harmonized standard:

EN 149:2001+A1:2009

Identical products were certified by Notified Body for PPE Module B+C2:

Notified Body No: 1463

Polski Rejestr Statków S.A.

al. gen. Józefa Hallera 126, 80-416 Gdańsk

Nanchang, Jiangxi May.24. 2020

Place, date





AC 114

**CERTYFIKAT ZGODNOŚCI Z TYPEM W OPARCIU O WEWNĘTRZNĄ KONTROLĘ
PRODUKCJI ORAZ NADZOROWANE KONTROLE PRODUKTU
W LOSOWYCH ODSTĘPACH CZASU (Moduł C2)**

**CONFORMITY TO TYPE CERTIFICATE BASED ON INTERNAL PRODUCTION CONTROL
PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (Module C2)**

Nr CW/PPER/68/09/2020 Okres objęty certyfikatem 2020-09-24 – 2021-09-23
No. Period covered by the certificate

Dokumenty odniesienia: Rozporządzenie UE 2016/425 dotyczące środków ochrony indywidualnej (PPE), załącznik VII
General reference documents: Regulation (EU) 2016/425 on personal protective equipment (PPE), Annex VII

Posiadacz certyfikatu **Jiangxi Yifengyuan Biological Engineering Co., Ltd.**
Certificate holder Yangsha Avenue, Jinxian County,
Nanchang City, Jiangxi Province, China.

Wyrób Product	Certyfikat badania typu UE EU Type-examination certificate	Normy zharmonizowane/Specyfikacje Harmonised standards/Specifications
Półmaska typ YFY-KN95 klasy FFP-2 Half mask type YFY-KN95 class FFP-2	CW/PPER/47/05/2020	PN-EN 149+A1:2010 EN 149:2001+A1:2009

A Roczna ocena zgodności wyrobów z normą/specyfikacją i badanym typem
Annual assessment of products compliance with standard/specification and type-examined

1 Miejsca i daty wizyt
Visit locations and dates Jiangxi Yifengyuan Biological Engineering Co., Ltd.

2a Wyboru dokonał (imię, nazwisko)
Selection carried out by (Name) Zbigniew Orłowski
Związek z jednostką notyfikowaną
Relationship to notified body Ekspert Biura Certyfikacji Wyrobów i Osób
Products and Persons Certification Bureau Expert

2b Przedstawiciel firmy (imię, nazwisko)
Company representative (Name) Eric Yan
Stanowisko
Position Quality Manager

3 Związek pomiędzy wizytowaną firmą a posiadaczem certyfikatu badania typu UE
Relationship of company visited to EU type-examination certificate holder

- ☐ Posiadacz certyfikatu
Certificate holder ☒ Miejsce produkcji
Production site ☐ Inne miejsce produkcji
Secondary production site ☐ Importer
Importer ☐ Dystrybutor
Distributor
☐ Sprzedaż detaliczna
Retail outlet ☐ Europejskie biuro firmy
European office of the company ☐ Inny:
Other:

Wykaz środków ochrony indywidualnej
List of personal protection equipment

☒ Dostępny
Available ☐ Niedostępny
Not available

Wybór próbek
Sample selection ☒ Wybrano – Nr egz./partii:
Selected – lot/batch No. NO1/105/2020

☐ Nie wybrano
Not selected

4 Wybór próbek
Sample selection ☒ Prawidłowy
Correct ☐ Nieprawidłowy
Incorrect Wyniki badań
Result of tests ☒ Pozytywne
Positive ☐ Negatywne
Negative

5 Wybór próbek i badania wykazały zgodność z przywołanymi normami/specyfikacjami i badanym typem
Sample selection and testing demonstrated compliance with the reference standards/specifications and type-examined

☒ Tak
Yes ☐ Nie
No



Nr jednostki notyfikowanej
No. of notified body

1463

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www: http://www.prs.pl/

B Roczna ocena niejednorodności produkcji
Annual assessment of production non-homogeneity

1 Zastosowana metoda przy dokonaniu oceny
Method employed to perform assessment

- ☐ Inspekcja procesu produkcyjnego i zapisów z prób
On-site review of production and test records
- ☐ Audit kontroli procesu produkcyjnego
On-site audit of production control
- ☐ Ocena niejednorodności produkcji poprzez ocenę jednej dużej próbki
Production non-homogeneity assessed by selection of a single, large sample
- ☐ Ocena niejednorodności produkcji poprzez ocenę próbek w ciągu roku
Production non-homogeneity assessed by assessment of samples throughout the year

2a Ocenę przeprowadził (imię, nazwisko) -----
Assessment carried out by (Name)

Związek z jednostką notyfikowaną -----
Relationship to notified body

2b Przedstawiciel firmy (imię, nazwisko) -----
Company representative (Name)

Stanowisko -----
Position

3 Na podstawie przeprowadzonej oceny stwierdzono, że proces produkcyjny jest jednorodny
On the basis of the assessment, it has been concluded the production is homogeneous

☐ Tak
Yes

☐ Nie
No

C Podsumowanie
Conclusion

Uzasadnienie niezgodności
Justification of non-conformities

Nie było żadnych niezgodności / There were no non-conformities.

Wnioski jednostki notyfikowanej
Conclusions of notified body

Środek ochrony osobistej jest kompatybilny z typem określonym w certyfikacie badania typu UE.

Personal protective equipment is compatible with the type defined in the EC type-examination certificate.

Uwagi
Remarks

1. Półmaska filtrująca przeznaczone do jednorazowego użytku.
 2. Dokumentacja techniczna zatwierdzona w języku angielskim.
 3. Produkt ten nie może być stosowany jako maska przeciwgazowa w środowisku toksycznym.
 4. Półmaska filtrująca nie jest przeznaczona do użytkowania medycznego i chirurgicznego.
1. *Filtering Half Mask shall not be used for more than one shift.*
 2. *Technical documentation approved in English.*
 3. *This product can not be used as a gas mask in a toxic environment.*
 4. *Filtering Half Mask can not be used for medical and surgical purposes.*

D Załączniki
Attachments

Sprawozdania z wizyty Nr CW/ZO/PPER/128/2020 z dnia/ dated 2020-09-24.
Visit reports No.

Sprawozdania z badań Nr Raport z badań nr 804/PB-COV/2020/NO wydany przez CIOP-PIB w dniu 2020-08-28. Numer
Test reports No. akredytacji PCA AB038.
Test report no. 804/PB-COV/2020/NO issued by CIOP-PIB on 2020-08-28. PCA accreditation number AB038.

Ogólna ocena z rocznego nadzoru
Overall assessment of the annual surveillance

☒ Pozytywna
Positive

☐ Negatywna
Negative

Dyrektor Pionu Certyfikacji
Certification Division Director

Przemysław Gałka

Gdańsk, 2020-09-24





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 unieważnienia 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



NOTIFIED BODY
NO.1463

Dyrektor Pionu Certyfikacji
Certification Division Director

Gdańsk, 2020-05-27

Przemysław Gałka



Nr jednostki notyfikowanej
No. of notified body

1463

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e-mail: dc@prs.pl
www: <http://www.prs.pl/>

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 klipsem 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.



中国认可
国际互认
检测
TESTING
CNAS L5772

Test Report

EN 149:2001+A1:2009 protective devices. Filtering half masks to protect against particles. Requirements, testing, marking

Product: Children's Folding Protective Mask

Report No.: PTC20110605702C-EN01

Client: Jiangxi Yifengyuan Biological Engineering Co., Ltd.

Client Address: Yangsha Avenue, Jinxian County, Nanchang City, Jiangxi Province (in the medical device industrial base)

Manufacturer: Jiangxi Yifengyuan Biological Engineering Co., Ltd.

Manufacturer Address: Yangsha Avenue, Jinxian County, Nanchang City, Jiangxi Province (in the medical device industrial base)

Contact: Tangyan

Model(s): YFY-FFP2 Kids

Classification: FFP2 NR

Date of Tests: 2020.11.12~2020.11.18

Signed for and on Behalf of PTC

Prepare by:

Checked by:

Approved by:

Arme

Jue

Tim Mo



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Test Result:

Requirement	Test Result	Conclusion
7.5 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.	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.	Pass
7.9.1 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.	FFP2, Test results are shown in Annex A Table 7.9.1-A&B	Pass
7.10 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.	No irritation or any other adverse effect to health.	Pass

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Annex A: Summarization of Test Data

Table 7.9.1-A: Inward Leakage Test Data

Test specification: EN 149:2001+A1:2009 Clause 8.5

Subject	Sample No.	Condition	Walk (%)	Head Side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
Lv	1	A.R	4.7	4.8	4.4	5.6	6.3	5.2
Li	2	A.R	3.4	2.8	3.0	3.1	2.5	3.0
Zhong	3	A.R	3.9	5.7	5.9	6.7	3.0	5.0
Xu	4	A.R	3.6	4.4	3.7	3.1	3.7	3.7
Ma	5	A.R	3.2	4.2	4.1	5.1	4.1	4.1

Table 7.9.1-B: Facial dimension

Subject	Face Length	Face Width	Face Depth	Mouth Width
Lv	113	139	104	53
Li	120	135	112	55
Zhong	108	135	106	56
Xu	120	150	120	70
Ma	130	170	130	80

Test	Uncertainty
Total inward leakage	3.8%

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Photo(s) of Sample:



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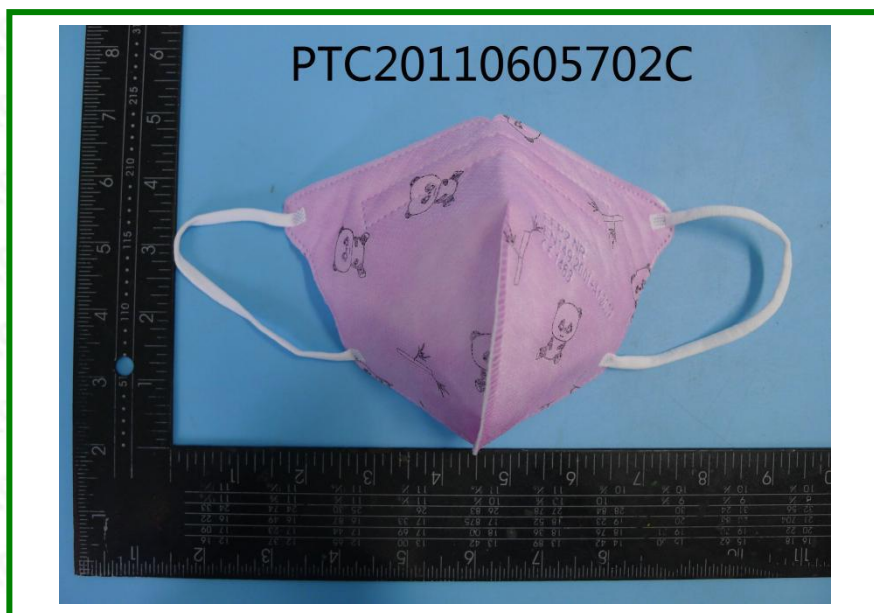


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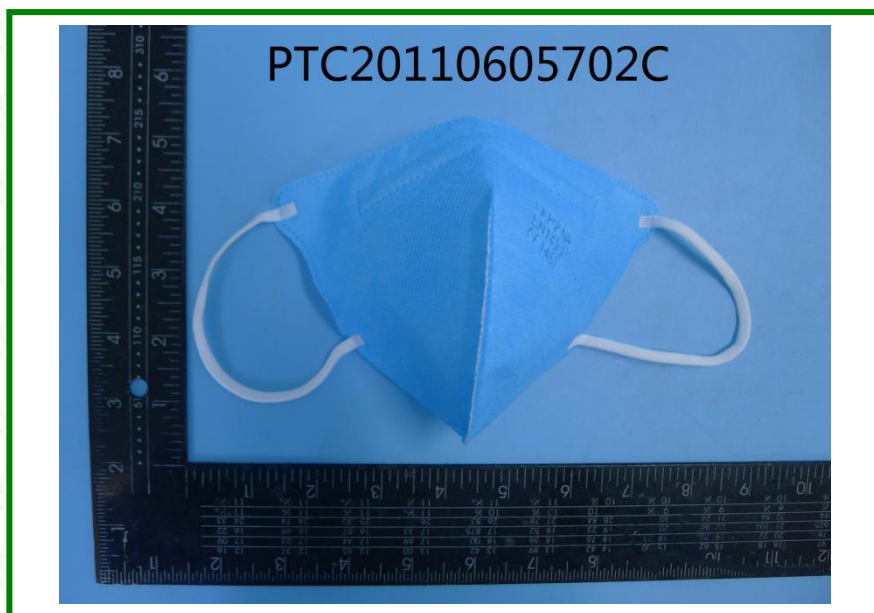


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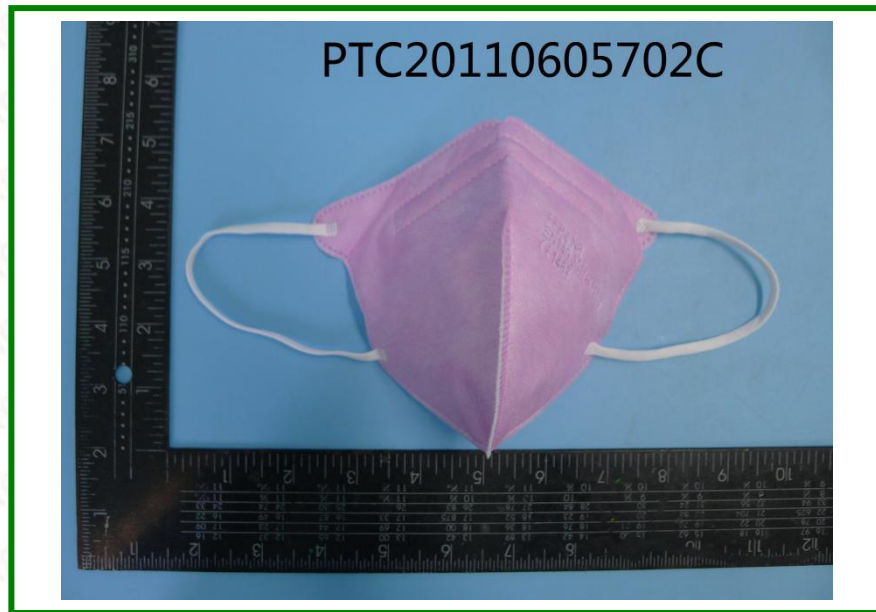


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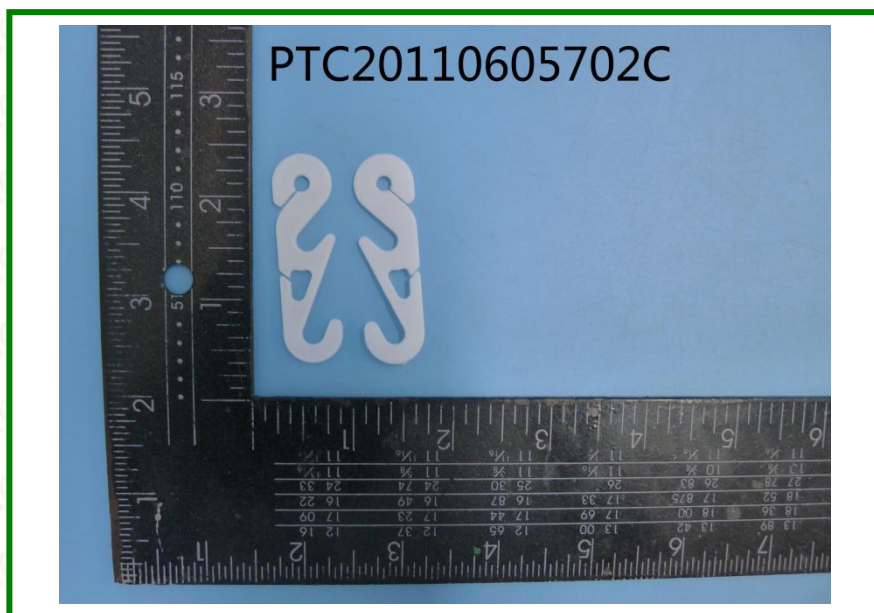


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