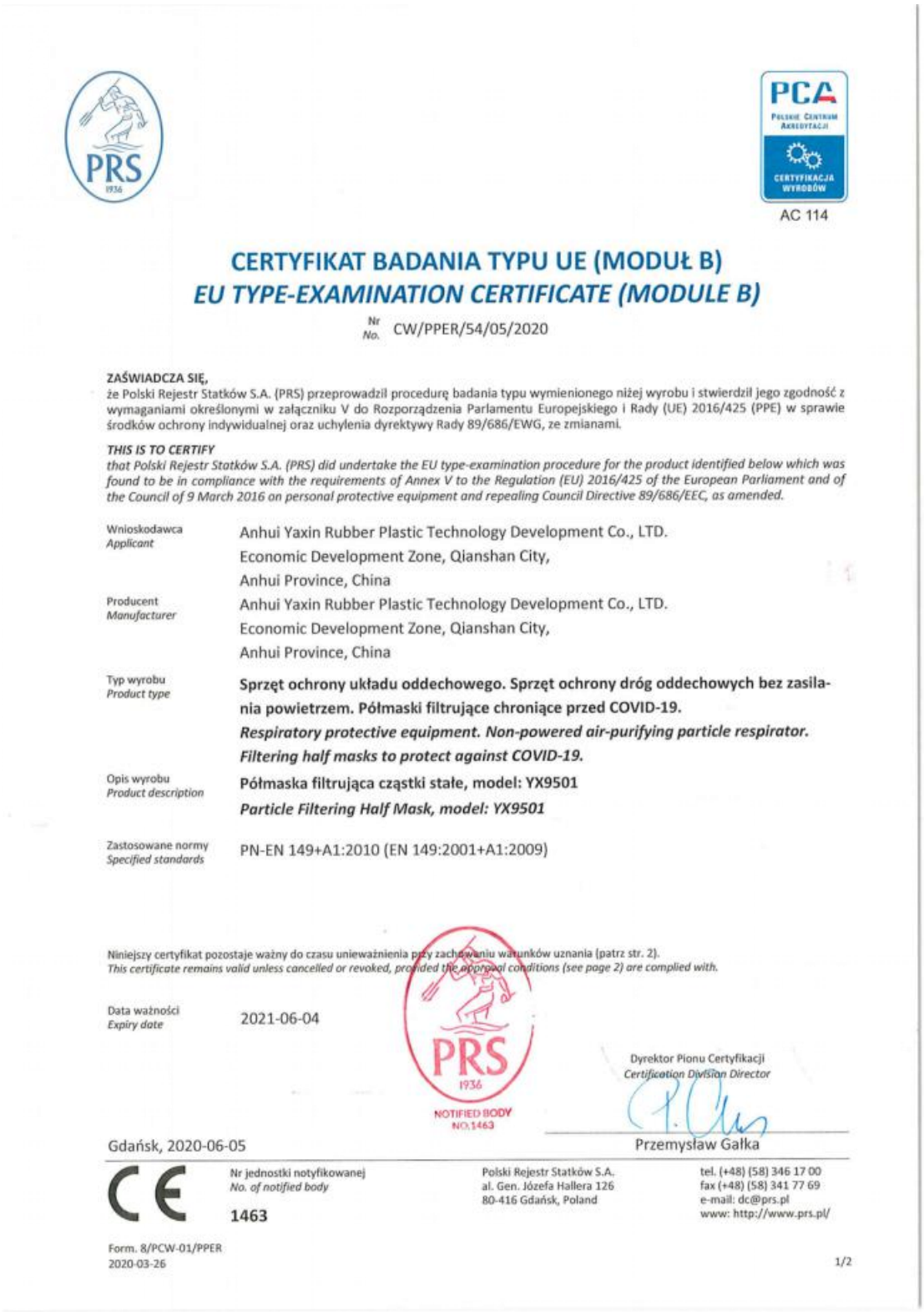
2、CE 认证



PRS 1936

PCA Polskie Centrum Akredytacji Certyfikacja Wyrobów AC 114

CERTYFIKAT BADANIA TYPU UE (MODUŁ B)

EU TYPE-EXAMINATION CERTIFICATE (MODULE B)

Nr / No. CW/PPER/54/05/2020

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 uchylenia dyrektywy Rady 89/686/EWG, 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*	Anhui Yaxin Rubber Plastic Technology Development Co., LTD. Economic Development Zone, Qianshan City, Anhui Province, China
Producent *Manufacturer*	Anhui Yaxin Rubber Plastic Technology Development Co., LTD. Economic Development Zone, Qianshan City, Anhui Province, China
Typ wyrobu *Product type*	**Sprzęt ochrony układu oddechowego. Sprzęt ochrony dróg oddechowych bez zasilania powietrzem. Półmaski filtrujące chroniące przed COVID-19.** ***Respiratory protective equipment. Non-powered air-purifying particle respirator. Filtering half masks to protect against COVID-19.***
Opis wyrobu *Product description*	**Półmaska filtrująca cząstki stałe, model: YX9501** ***Particle Filtering Half Mask, model: YX9501***
Zastosowane normy *Specified standards*	PN-EN 149+A1:2010 (EN 149:2001+A1:2009)

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* 2021-06-04

PRS 1936 NOTIFIED BODY NO.1463

Dyrektor Pionu Certyfikacji
Certification Division Director
Przemysław Gałka

Gdańsk, 2020-06-05

CE Nr jednostki notyfikowanej / *No. of notified body* 1463

Polski Rejestr Statków S.A.
al. Gen. Józefa Hallera 126
80-416 Gdańsk, Poland

tel. (+48) (58) 346 17 00
fax (+48) (58) 341 77 69
e-mail: dc@prs.pl
www: http://www.prs.pl/

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CW/PPER/54/05/2020

Wykaz dokumentacji
List of documents

1. Instrukcja użytkowania - zatwierdzona przez PRS dnia 2020-06-03.
2. Ocena ryzyka - zatwierdzona przez PRS dnia 2020-06-03.
3. Rysunek półmaski typ YX9501 - zatwierdzony przez PRS dnia 2020-06-03.
4. Raport z badań nr STFWT202010719 wydany przez Jiangsu Quality Supervision and Inspection Center for Special Safety Protection Products w dniu 2020-05-09.
5. Sprawozdanie z przeglądu PRS nr CW/MAP/PPER/04/2020 z dnia 2020-06-04.

1. Manual - approved by PRS on 2020-06-03.
2. Risk analysis - approved by PRS on 2020-06-03.
3. Assembly drawing No. model: YX9501 - approved by PRS on 2020-06-03.
4. Test report No. STFWT202010719 issued by Jiangsu Quality Supervision and Inspection Center for Special Safety Protection Products on 2020-05-09.
5. PRS Survey Report No. CW/MAP/PPER/04/2020 dated on 2020-06-04.

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

-

Ograniczenia uznania
Approval limitations

1. Półmaski filtrujące ocenione zgodnie z procedurą określoną w Zaleceniu Komisji (UE) 2020/403 z dnia 2020-03-13 oraz RfU PPE-R/02.075 wersja 1.
2. Oznakowanie półmasek filtrujących oraz opakowanie zgodne z RfU PPE-R/02.075 wersja 1, p. 4.1 i p.4.2.
3. Półmaskę przechowywać w temperaturze pokojowej bez bezpośredniego dostępu światła słonecznego.
4. Półmaskę przechowywać w pomieszczeniu o wilgotności względnej poniżej 80%.
5. Dane techniczne:
   - półmaska z regulowanym klipsem na nos,
   - półmaska wykonana z 5-warstwowej włókniny z filtrem z tkaniny,
   - wymiary: 157x 106 mm,
   - kolor: biały.
6. Półmaski filtrujące przeznaczone do jednorazowego użytku.
7. Dokumentacja techniczna zatwierdzona w języku angielskim.

1. The filtering half masks evaluted in accordance with the Comission Recommendation (EU) 2020/403 dated 2020-03-13 and RfU PPE-R/02.075 version 1.
2. Marking of filtering half masks and package according to RfU PPE-R/02.075 version 1, p. 4.1 and p.4.2.
3. Store at room temperature without direct sunlight.
4. Store in a room with a relative humidity below 80%.
5. Specifications:
   - half mask with adjustable nose clip,
   - half mask made with 5-ply non-woven fabric with melt-blowen fabric filter,
   - size: 157 x 106 mm,
   - color: white.
6. Filtering half -mask shall not be used for more than one shift.
7. Technical documentation approved in English.

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.

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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 / *No.* CW/PPER/49/08/2020

Okres objęty certyfikatem / *Period covered by the certificate* 2020-08-21 – 2021-08-20

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

Posiadacz certyfikatu / *Certificate holder*
Anhui Yaxin Rubber Plastic Technology Development Co., LTD.
Economic Development Zone, Qianshan City,
Anhui Province, China

Wyrób / *Product*	Certyfikat badania typu UE / *EU Type-examination certificate*	Normy zharmonizowane/Specyfikacje / *Harmonised standards/Specifications*
Półmaska filtrująca cząstki stałe, model: YX9501 *Particle Filtering Half Mask, model: YX9501*	*CW/PPER/54/05/2020*	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* — Anhui Yaxin Rubber Plastic Technology Development Co., LTD.

2a Wyboru dokonał (imię, nazwisko) / *Selection carried out by (Name)* — Mateusz Płomiński
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)* — Michael Chen
Stanowisko / *Position* — General 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 próbki / *Sample selection* ☒ Wybrano – Nr egz./partii: / *Selected – lot/batch No.* 761/LIX/2020 ÷ 772/LIX/2020 ☐ Nie wybrano / *Not selected*

4 Wybór próbki / *Sample selection* ☒ Prawidłowy / *Correct* ☐ Nieprawidłowy / *Incorrect* — Wyniki badań / *Result of tests* ☒ Pozytywne / *Positive* ☐ Negatywne / *Negative*

5 Wybór próbki 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*

CE

Nr jednostki notyfikowanej / *No. of notified body*
1463

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al. Gen. Józefa Hallera 126
80-416 Gdańsk, Poland

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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 ☐ Tak *Yes* ☐ Nie *No*
On the basis of the assessment, it has been concluded the production is homogeneous

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. Maska ochronna 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. Maska ochronna nie jest przeznaczona do użytkowania medycznego i chirurgicznego.

1. Protective 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. Protective mask can not be used for medical and surgical purposes.

D **Załączniki**
Attachments

Sprawozdania z wizyty Nr
Visit reports No.
CW/PPER/MAP/25/2020 z dnia 2020-08-20

Sprawozdania z badań Nr
Test reports No.
Raport z badań nr S/84/2020 wydany przez Wojskowy Instytut Chemii i Radiometrii z dnia 2020-08-13. Numer akredytacji PCA AB 380.
Test report no. S/84/2020 issued by Military Institute of Chemistry and Radiometry dated on 2020-08-13. PCA accreditation number AB 380.

Ogólna ocena z rocznego nadzoru ☒ Pozytywna *Positive* ☐ Negatywna *Negative*
Overall assessment of the annual surveillance

PRS 1936 NOTIFIED BODY NO.1463

Dyrektor Pionu Certyfikacji
Certification Division Director

Gdańsk, 2020-08-21

Michał Chudziński

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2020-03-26

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附: CE 自我符合性声明

CE

DECLARATION OF CONFORMITY

Manufacturer:
Name: Anhui Yaxin Rubber Plastic Technology Development Co.,Ltd
Address: Economy zone,Qianshan, Anhui,China.
E-mail:hzhcmichael@163.com

Whose Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the product(s)

Product Name	Single-use medical face mask(non-sterile)	**Model**	Flat Ear-Loop Type
BASIC UDI-DI	/	**UMDNS Code**	12447
Intended Use	It is used for patients in order to reduce the risk of the spread of infections,and it is not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.		
Classification	I, (MDR, Annex VIII Rule 1)		

meet(s) the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable Standards:

ISO 13485:2016
ISO 10993-5：2009
EN 1041:2008
EN ISO 14971:2012
ISO 10993-10:2010
EN 15223-1:2016
ISO 10993-1：2018
EN 14683:2019

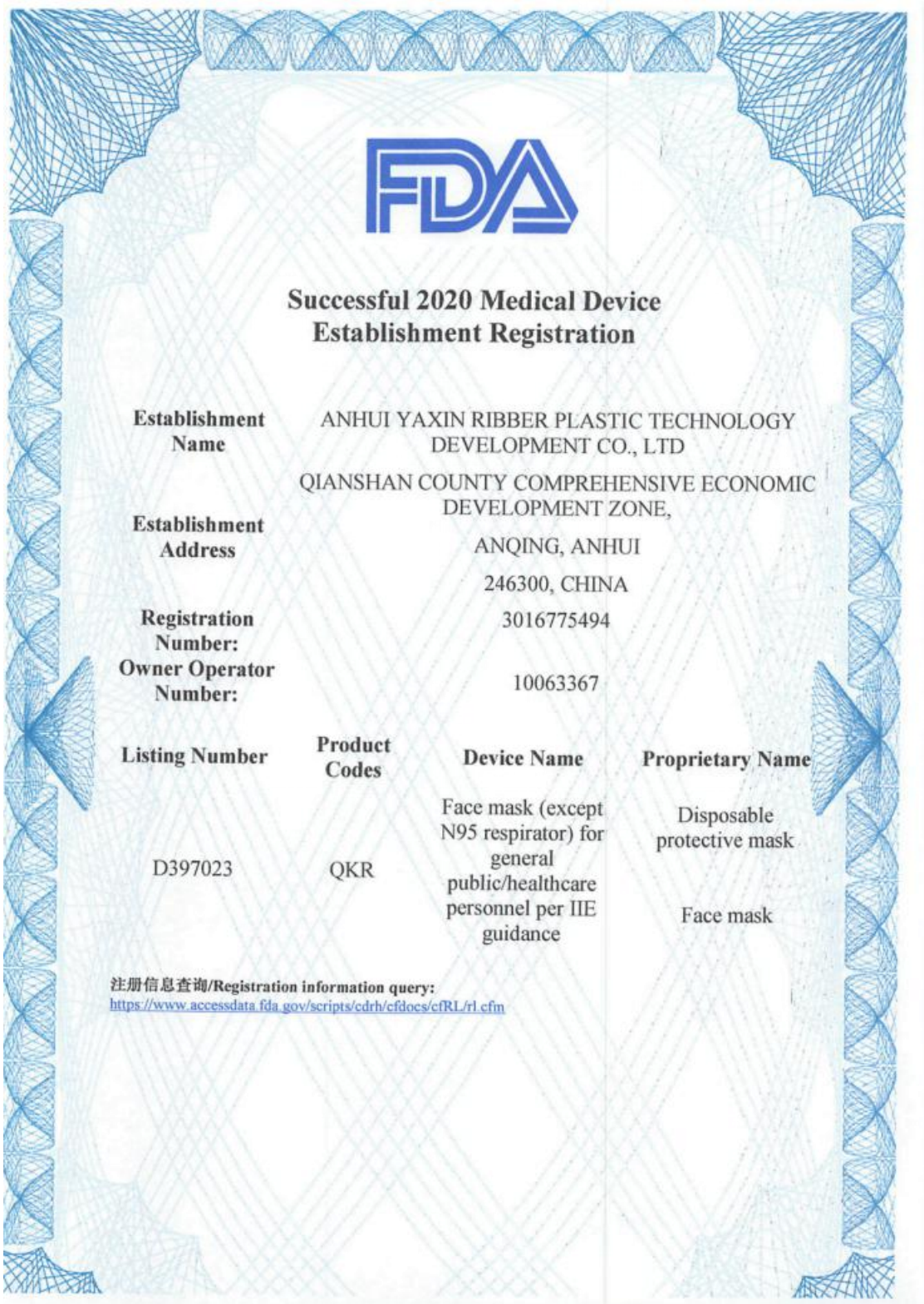
We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745.We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Xianfeng Chu
Position held in the company: General Manager
Place: Anhui,China.

Signature:
Date: 2020年6月28日
Seal/Stamp:

Anhui Yaxin Rubber Plastic Technology Development Co.,Ltd

3、FDA 证书



Successful 2020 Medical Device Establishment Registration

Establishment Name	ANHUI YAXIN RIBBER PLASTIC TECHNOLOGY DEVELOPMENT CO., LTD
Establishment Address	QIANSHAN COUNTY COMPREHENSIVE ECONOMIC DEVELOPMENT ZONE, ANQING, ANHUI 246300, CHINA
Registration Number:	3016775494
Owner Operator Number:	10063367

Listing Number	Product Codes	Device Name	Proprietary Name
D397023	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Disposable protective mask Face mask

注册信息查询/Registration information query:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

4、俄罗斯通关豁免函

Общество с ограниченной ответственностью "Центр Экспертиз "Атрибут"

Место нахождения: Российская Федерация, 109316, г. Москва, Остаповский проезд, дом 3 строение 8 офис 412,
телефон: +79296743005, электронная почта: osp.atribut@yandex.ru.
Аттестат аккредитации № RA.RU.10KA01, выдан 08.08.2017 года

Исх. № 1158 от 17.04.2020 года

Anhui Yaxin Rubber plastic Technology
Development Co.,Ltd
Адрес: Economic Development Zone,
Qianshan City, Anhui Province, China

ИНФОРМАЦИОННОЕ ПИСЬМО

В ответ на Ваш запрос о принадлежности к объектам обязательного подтверждения соответствия заявленной продукции сообщаем следующее:

В соответствии с Техническими регламентами Таможенного союза «О безопасности продукции легкой промышленности» (ТР ТС 017/2011) продукция::

Наименование продукции	Код ОКПД2	Код ТНВЭД
Маски нетканые гигиенические, одноразовые/многоразовые	13.92.29	6307

не включена в «Единый перечень продукции, подлежащей обязательной сертификации» и «Единый перечень продукции, подтверждение соответствия которой осуществляется в форме принятия декларации о соответствии», утвержденные постановлением Правительства Российской Федерации от 01 декабря 2009 года № 982 (с изменениями, утвержденными Постановлениями Правительства РФ).

Одновременно сообщаем, что вышеуказанная продукция не подпадает под действие Технических Регламентов Таможенного Союза с выдачей единых документов, утвержденный Решением Комиссии Таможенного союза от 07апреля 2011 года № 620 (взамен утратившего силу «Единого перечня, подлежащего обязательной оценке (подтверждения) соответствия в рамках Таможенного союза с выдачей единых документов», утвержденного Решением Комиссии Таможенного союза от 18 июня 2010 года № 319).

Настоящее разъяснение действительно до внесения изменений в документы Правительства Российской Федерации и Евразийской экономической комиссии, устанавливающие необходимость проведения обязательного подтверждения соответствия данных товаров.

Ответственность за правильность предоставленной информации по идентификации продукции и ее кодам несет организация, направившая запрос.

Руководитель (уполномоченное лицо) органа по сертификации Общество с ограниченной ответственностью "Центр Экспертиз "Атрибут"

подпись

Николай Александрович Минаев

(Ф.И.О.)

Общество с ограниченной ответственностью "Центр Экспертиз "Атрибут"

Место нахождения: Российская Федерация, 109316, г. Москва, Остаповский проезд, дом 3 строение 8 офис 412,
телефон: +79296743005, электронная почта: osp.atribut@yandex.ru.
Аттестат аккредитации № RA.RU.10KA01, выдан 08.08.2017 года

Исх. № 1159 от 17.04.2020 года

Anhui Yaxin Rubber plastic Technology
Development Co.,Ltd
Адрес: Economic Development Zone,
Qianshan City, Anhui Province, China

ИНФОРМАЦИОННОЕ ПИСЬМО

В ответ на Ваш запрос о принадлежности к объектам обязательного подтверждения соответствия заявленной продукции сообщаем следующее:

В соответствии с Техническими регламентами Таможенного союза «О безопасности средств индивидуальной защиты» (ТР ТС 019/2011) продукция:

Наименование продукции	Код ОКПД2	Код ТНВЭД
Маски нетканые гигиенические, одноразовые/многоразовые	13.92.29	6307

не включена в «Единый перечень продукции, подлежащей обязательной сертификации» и «Единый перечень продукции, подтверждение соответствия которой осуществляется в форме принятия декларации о соответствии», утвержденные постановлением Правительства Российской Федерации от 01 декабря 2009 года № 982 (с изменениями, утвержденными Постановлениями Правительства РФ).

Одновременно сообщаем, что вышеуказанная продукция не подпадает под действие Технических Регламентов Таможенного Союза с выдачей единых документов, утвержденный Решением Комиссии Таможенного союза от 07апреля 2011 года № 620 (взамен утратившего силу «Единого перечня, подлежащего обязательной оценке (подтверждения) соответствия в рамках Таможенного союза с выдачей единых документов», утвержденного Решением Комиссии Таможенного союза от 18 июня 2010 года № 319).

Настоящее разъяснение действительно до внесения изменений в документы Правительства Российской Федерации и Евразийской экономической комиссии, устанавливающие необходимость проведения обязательного подтверждения соответствия данных товаров.

Ответственность за правильность предоставленной информации по идентификации продукции и ее кодам несет организация, направившая запрос.

Руководитель (уполномоченное лицо) органа по сертификации Общество с ограниченной ответственностью "Центр Экспертиз "Атрибут"

подпись

Николай Александрович Минаев

(Ф.И.О.)

5、澳大利亚出口资质

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	332806	Ultra Business Solutions - Airway protection face mask
ARTG entry for	Medical Device Included Class 1	
Sponsor	Ultra Business Solutions	
Postal Address	1-5 / 1 Admiralty Drive, Breakfast Point, NSW, 2137 Australia	
ARTG Start Date	30/03/2020	
Product category	Medical Device Class 1	
Status	Active	
Approval area	Medical Devices	

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Anhui Yaxin Rubber Plastic Technology Development Co Ltd	Economic Development Zone Qianshan City, Anhui Province, China

Products

1. Airway protection face mask

Product Type	Single Device Product	Effective date	30/03/2020
GMDN	18094 Airway protection face mask		
Intended purpose	A face mask placed over the nose and mouth to provide respiratory protection.		

Specific Conditions

Public Summary

6、欧洲代理注册回执

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M. Schmitz - Konte

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20203152

Bijlagen
-

Uw aanvraag
24 juni 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 26 juni 2020
Betreft: notificatie medisch hulpmiddel klasse I

Geachte heer Wei,

Hierbij bevestig ik de ontvangst op 24 juni 2020 van de notificatie van het medische hulpmiddel klasse I, dat bedrijf Anhui Yaxin Rubber Plastic Technology Development Co.,Ltd, met Europees gemachtigde Lotus NL B.V. , als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen.
Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over dit product het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Single-use medical face mask(non-sterile)
(geen merknaam) (NL-CA002-2020-52276)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw product overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaand hulpmiddel te registreren in Eudamed.[3]

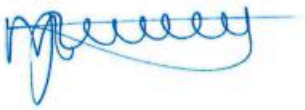
[1] O.g.v. art. 29 MDR.
[2] O.g.v. art. 31 MDR.
[3] www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. Zie vraag en antwoord nummer 20.

Pagina 1 van 2

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

7、中国商品条码系统成员证书

六、产品检测报告

1、一次性民用 KN95 口罩检测报告

171021110579

检验检测报告

TEST REPORT

STFWT202010719

产品名称 Product Name	折叠式防护口罩
委托单位 Trust Unit	安徽亚鑫橡塑科技发展有限公司
生产单位 Manufacturer	安徽亚鑫橡塑科技发展有限公司
检验检测类别 Test Category	委托送样检验

江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

检 验 检 测 报 告

Test Report

STFWT202010719

产品名称 Product Name	折叠式防护口罩	规格型号 Specification Type	YX9501
		商 标 Trademark	——
委托单位 Trust Unit	安徽亚鑫橡塑科技发展有限公司	电 话 Tel	18158530916
生产单位 Manufacturer	安徽亚鑫橡塑科技发展有限公司	样品等级 Sample Grade	KN95
样品数量 Sample Quantity	40 只	送样日期 Sample Receiving Date	2020-04-22
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	——
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 GB 2626-2006 标准规定的 KN95 级要求。 签发日期： 2020-05-09 SignatuimDate		
备 注 Remarks	本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。 本报告仅对来样负责。		

批 准： 陈敏 Approver　　审 核： 吴高高 Examiner　　主 检： 蔡燕文 Majortester

检 验 检 测 结 果
Testing Results

STFWT202010719

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	一般要求	——	材料： a)直接与面部接触的材料应无害； b)滤材应对人体无害； c)所用材料应具有足够的强度，在正常使用寿命中不应出现破损或变形。 结构： a)应不易产生结构性破损，部件的设计、组成和安装不应对使用者构成任何危险； b)头带的设计应可调，便于佩戴和摘除，应能将面罩牢固地固定在脸上，且佩戴时不应出现明显的压迫或压痛现象； c)应尽可能具有较小的死腔和较大的视野； d)随弃式面罩的结构应能保证与面部的密合，且应在使用寿命期内不出现变形。	结构： a)不易产生结构性破损，部件的设计、组成和安装未对使用者构成任何危险； b)头带的设计可调，便于佩戴和摘除，能将面罩牢固地固定在脸上，且佩戴时未出现明显的压迫或压痛现象； c)具有较小的死腔和较大的视野； d)随弃式面罩的结构能保证与面部的密合，且在使用寿命期内不出现变形。	——
2	外观检查	——	样品表面不应破损、变形和有明显的其它缺陷，部件材料和结构应能够耐受正常使用条件及可能遇到的温度、湿度和机械冲击，头带应可调。	符合要求	合 格
3	呼吸阻力	Pa	每个样品的总吸气阻力应不大于350，总呼气阻力应不大于250	试样编号 / 实测值： 总吸气阻力 未预处理 1# 138.5 总吸气阻力 未预处理 2# 137.8 总吸气阻力 预处理 5# 141.2 总吸气阻力 预处理 6# 140.7 总呼气阻力 未预处理 3# 117.3 总呼气阻力 未预处理 4# 116.7 总呼气阻力 预处理 7# 119.5 总呼气阻力 预处理 8# 116.9	合 格
4	视野	——	下方视野≥60°	63°	合 格
5	死腔	——	二氧化碳体积分数应不大于1%	二氧化碳体积分数为0.5%	合 格

检 验 检 测 结 果
Testing Results

STFWT202010719

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results				单项评价 Individual Judgment
				试样编号		实测值		
6	过滤效率/%（NaCl 颗粒物）	——	KN90：≥90.0 KN95：≥95.0 KN100：≥99.97	未预处理	9#	初始	99.6	合 格
						加载	99.1	
					10#	初始	99.4	
						加载	99.0	
					11#	初始	99.6	
						加载	99.2	
					12#	初始	99.7	
						加载	99.2	
					13#	初始	99.7	
						加载	99.2	
					14#	初始	99.7	
						加载	99.1	
					15#	初始	99.6	
						加载	99.2	
					16#	初始	99.4	
						加载	98.7	
					17#	初始	99.4	
						加载	98.8	
					18#	初始	99.5	
						加载	98.9	
				温度湿度处理	19#	初始	99.0	
						加载	98.3	
					20#	初始	99.1	
						加载	98.4	
					21#	初始	99.0	
						加载	98.3	
					22#	初始	98.9	
						加载	98.2	
					23#	初始	99.1	
						加载	98.7	
7	头带	——	面罩的每条头带、带扣及其他调节部件在承受 10N 拉力且持续 10s 时，不应出现滑脱或断裂。	未预处理： 1#面罩的每条头带、带扣及其他调节部件在承受10N拉力且持续10s后，未出现滑脱或断裂。 预处理后： 5#面罩的每条头带、带扣及其他调节部件在承受10N拉力且持续10s后，未出现滑脱或断裂。				合 格

检 验 检 测 结 果
Testing Results

STFWT202010719

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement		检验检测结果 Results			单项评价 Individual Judgment
8	呼气阀盖	——	面罩的呼气阀盖在承受 10N 拉力且持续 10s 时，不应出现滑脱或断裂。		无呼气阀，不测此项。			——
9	呼气阀气密性	——	各样品均不得出现下述情况之一： a）抽气流速已经达到 500mL/min 时，系统负压达不到 1180Pa； b）呼气阀恢复至常压时间小于 20s。		无呼气阀，不测此项。			——
10	泄漏性/%（随弃式面罩的 TIL）	——	滤料级别	以每个动作的 TIL 为评价基础时（即 10 人×5 个动作），50 个动作中至少有 46 个动作的 TIL	未预处理	31#	有 47 个动作的 TIL 小于 11	合 格
						32#	有 47 个动作的 TIL 小于 11	
						33#	有 47 个动作的 TIL 小于 11	
						34#	有 47 个动作的 TIL 小于 11	
						35#	有 47 个动作的 TIL 小于 11	
			KN90 KN95 KN100	<13 <11 <5	温度湿度处理	36#	有 47 个动作的 TIL 小于 11	
						37#	有 47 个动作的 TIL 小于 11	
						38#	有 47 个动作的 TIL 小于 11	
						39#	有 47 个动作的 TIL 小于 11	
						40#	有 47 个动作的 TIL 小于 11	
			滤料级别	以人的总体 TIL 为评价基础时，10 个受试者中至少有 8 个人的总体 TIL	未预处理	31#	有 9 个人的 TIL 小于 8	
						32#	有 9 个人的 TIL 小于 8	
						33#	有 9 个人的 TIL 小于 8	
						34#	有 9 个人的 TIL 小于 8	
						35#	有 9 个人的 TIL 小于 8	
			KN90 KN95 KN100	<10 <8 <2	温度湿度处理	36#	有 9 个人的 TIL 小于 8	
						37#	有 9 个人的 TIL 小于 8	
						38#	有 9 个人的 TIL 小于 8	
						39#	有 9 个人的 TIL 小于 8	
						40#	有 9 个人的 TIL 小于 8	

检 验 检 测 结 果
Testing Results

STFWT202010719

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
11	可燃性	——	暴露于火焰的各部件在从火焰移开后，不应燃烧；如果燃烧，续燃时间不应超过 5s。	未预处理： 1#、2#试样暴露于火焰的各部件在从火焰移开后，未燃烧。 预处理后： 3#、4#试样暴露于火焰的各部件在从火焰移开后，未燃烧。	合 格
12	连接和连接部件	——	可更换式过滤元件与面罩之间，呼吸导管与过滤元件及面罩之间的所有连接和连接部件，在承受 10N 轴向拉力且持续 10s 时，不应出现滑脱、断裂或变形。	随弃式面罩，不测此项。	——

样 品 图 片

以下空白

注 意 事 项

1、检验检测报告无“检验检测报告专用章”或检验检测单位公章无效。

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特防检测
中心官方微信公众号

2、KN95 口罩 FFP2 检测报告

Test Report

Report No.:[2020] WSZ FHL NO.7629

Product Name	Filtering half mask
Applicant	Anhui Yaxin Rubber Plastic Technology Development Co.,Ltd
Manufacturer	Anhui Yaxin Rubber Plastic Technology Development Co.,Ltd
Test Type	Entrusted inspection

Jiangsu Guojian Testing Technology Co.,Ltd

3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China

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[2020] WSZ FHL NO.7629

Test Report

Product name	Filtering half mask	Model name	YX9512
		Brand	—
Laboratory/Add	Jiangsu Guojian Testing Technology Co., Ltd/ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China		
Applicant/Add/Tel	Anhui Yaxin Rubber Plastic Technology Development Co.,Ltd/ Economic Development Zone, Qianshan City, Anhui Province, China /18158530916		
Manufacturer/Add/Tel	Anhui Yaxin Rubber Plastic Technology Development Co.,Ltd/Economic Development Zone, Qianshan City, Anhui Province, China/18158530916		
Sample classification	FFP2	Sample number	GW7629-2020
Sample quantity	105 pcs	Date of receipt of sample	13/08/2020
Test type	Entrusted inspection	Article/Batch/Style number	—
Date(s) of performance of tests	18/08/2020~26/08/2020	Testing location	Same as the Laboratory
Sample state	Meeting the requirements of testings	Sample description	Refer to page 3
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking		
Test items	Packaging, material, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage, demountable parts		
Test conclusion	The samples upon testing comply with FFP2 classification requirements according to the standard EN 149:2001+A1:2009. The details of test results see on Pages 3-11. Issue date:28/08/2020		
Note	The test results presented in this report relate only to the submitted sample as received.		

Su Hequn 苏和群 — Approver(name,signature)

Wan Heng 万恒 — Reviewer(name,signature)

Yang Ying 杨莹 — Chief Tester(name,signature)

Sample description:	white
Test item particulars:	
Type of useuse ..... :	☐ re-useable particle filtering half mask ☒ single shift only particle filtering half mask
Classes of devices ..... :	☐ FFP1 ☒ FFP2 ☐ FFP3
Exhalation valve(s) ..... :	☐ Yes ☒ No
Inhalation valve(s) ..... :	☐ Yes ☒ No
Designed to protect against both solid &liquid aerosols. :	☒ Yes ☐ No
Possible test case verdicts:	
- Test case does not required to the test object ..... :	NRq(Not required)
- Test case does not apply to the test object..... :	N/A (Not Applicable)
- Test object does meet the requirement ..... :	P (Pass)
- Test object does not meet the requirement..... :	F (Fail)
General remarks:	
The test results presented in this report relate only to the submitted sample as received. This report shall not be reproduced, except in full, without the written approval of the issuing Laboratory can provide assurance that parts of a report are not taken out of context. Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods. Throughout this report a ☐ comma / ☒ point is used as the decimal separator.	
Environmental condition of the testing in this report:	
1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C; 2) T.C. Temperature conditioned: a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C; and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.	

S.No. (Cl.No.)	Test item		Unit	Technical requirement	Test result	Single item decision
1 (7.3)	Visual inspection	Marking/ information	—	Marking and the information supplied by the manufacturer, requirements refer to Cl.9 and Cl.10	The clause were not required	NRq
2 (7.4)	Packaging	Visual inspection	—	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.	Particle filtering half masks packaged and protected against mechanical damage and contamination.	Pass
3 (7.5)	Material	Visual inspection	—	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.	Materials were suitable withstand handling and wear.	Pass
		Visual inspection	—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1:neither facepiece nor straps have mechanical failure	
					Sample 2:neither facepiece nor straps have mechanical failure	
					Sample 3:neither facepiece nor straps have mechanical failure	
		Visual inspection	—	After undergoing S.W. and T.C., none of the particle filtering half masks shall not collapse.	Sample 4:no collapse	
					Sample 5:no collapse	
					Sample 6:no collapse	
		Visual inspection	—	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Not constitute a hazard or nuisance for the wearer	
4 (7.6)	Cleaning and disinfecting		—	Particle filtering half mask designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5.	The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	N/A
			—	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. Testing shall be done in accordance with 8.11.	The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	

[2020] WSZ FHL NO.7629

S.No. (Cl.No.)	Test item		Unit	Technical requirement	Test result				Single item decision
5 (7.7)	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1 has the feeling of comfortable wearing				Pass
					Sample 2 has the feeling of comfortable wearing				
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm				
					Sample 2: All fastenings are firm				
		Field of vision	—	Field of vision is acceptable	Samples 1: Having a wider visual field				
					Samples 2: Having a wider visual field				
6 (7.8)	Finish of parts	Visual inspection	—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs				Pass
7 (7.9.2)	Leakage— Penetration of filter material	Sodium chloride	—	≤6%	A.R.[1]	0.5%	0.4%	0.6%	Pass
					S.W.[1]	0.4%	0.4%	0.6%	
					M.S+ T.C.[2]	0.5%	0.7%	0.6%	
		Paraffin oil		≤6%	A.R.[1]	0.3%	0.5%	0.2%	Pass
					S.W.[1]	0.4%	0.5%	0.3%	
					M.S+ T.C.[2]	0.6%	0.7%	0.4%	
		[1] average penetration over a time of 30s, beginning 3 min after the start of the test reported [2] max. penetration during exposure test reported; Note: The penetration of the filter of the particle filtering half mask shall meet the requirements below: Maximum penetration of sodium chloride aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1% Maximum penetration of paraffin oil aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%							

[2020] WSZ FHL NO.7629

S.No. (Cl.No.)	Test item	Unit	Technical requirement	Test result		Single item decision
8 (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.	A.R.	5 pcs all don't cause irritation	Pass
		—		T.C.	5 pcs all don't cause irritation	
9 (7.11)	Flammability	—	When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.4s	Pass
					The Sample is burning. Burning time:0.5s	
		—		T.C.	The Sample is burning. Burning time:0.4	
					The Sample is burning. Burning time:0.4s	
10 (7.12)	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). Remark: 3 half masks (S1, S2 and S3) A.R. tested.	Sample 1	0.7015%	Pass
				Sample 2	0.7026%	
				Sample 3	0.7010%	
				Average	0.70%	
11 (7.13)	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.	A.R.	All of 5 pieces particle filtering half mask meet the requirements	Pass
				T.C.	All of 5 pieces particle filtering half mask meet the requirements	
12 (7.14)	Field of vision	—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field		Pass

[2020] WSZ FHL NO.7629

S.No. (Cl.No.)	Test item		Unit	Technical requirement	Test result		Single item decision
13 (7.15)	Exhalation valve(s)	Visual inspection	—	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	A.R.	No exhalation valve(s)	N/A
					T.C.	No exhalation valve(s)	
		Visual inspection	—	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.	A.R.	No exhalation valve(s)	
					T.C.	No exhalation valve(s)	
		Flow conditioning	—	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.	A.R.	No exhalation valve(s)	
					T.C.	No exhalation valve(s)	
		Strength of attachment of exhalation valve housing	—	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.	A.R.	No exhalation valve(s)	
					T.C.	No exhalation valve(s)	
14 (7.17)	Clogging-Breathing resistance & Penetration of filter material		—	Optional for single shift use devices, mandatory for re-usable devices. Tested by Cl. 7.17.1/2/3.	Tests not requested for single shift use face mask		N/A
15 (7.18)	Demountable parts		—	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	All demountable parts are readily connected and secured.		Pass

[2020] WSZ FHL NO.7629

Table A- Leakage—Total Inward Leakage

S.No. (Cl.No.)	Test item	Unit	Technical requirement	Test result							Single item decision
				Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	
16 (7.9.1)	Leakage—Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than **11%**; And in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than **8%.**	A.R.	0.5	0.7	1.3	1.5	0.8	1.0	Pass
					0.7	1.3	1.5	1.5	0.7	1.2	
					0.4	0.9	1.0	1.0	0.4	0.7	
					0.4	1.3	1.6	1.5	0.9	1.1	
					1.2	1.8	1.9	1.9	1.3	1.6	
				T.C.	0.7	1.0	1.3	1.2	0.7	1.0	
					0.6	1.0	1.2	1.4	0.6	1.0	
					0.8	1.3	1.6	1.7	0.9	1.2	
					1.0	1.5	1.8	1.8	1.1	1.4	
					0.4	0.8	1.0	1.2	0.6	0.8	

Note 1:
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
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.

Table A-1- Test subjects—Facial dimension

Subject	Face Length(mm)	Face Width(mm)	Face Depth(mm)	Mouth Width(mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	115	129	120	50

[2020] WSZ FHL NO.7629

Table B- Breathing Resistance

S.No. (Cl. No.)	Test item		Unit	Technical requirement	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
17 (7.16)	Breathing resistance	Inhalation 30 L/min	mbar	≤0.7	A.R.	0.4	0.4	0.3	0.4	0.4	Pass
						0.4	0.3	0.4	0.4	0.3	
						0.3	0.4	0.4	0.3	0.4	
					S.W.	0.4	0.3	0.4	0.4	0.3	
						0.3	0.4	0.4	0.3	0.4	
						0.4	0.4	0.3	0.4	0.4	
					T.C.	0.3	0.4	0.4	0.3	0.4	
						0.4	0.4	0.3	0.4	0.4	
						0.4	0.3	0.4	0.4	0.3	
		Inhalation 95 L/min		≤2.4	A.R.	1.1	1.0	1.1	1.0	1.1	Pass
						1.1	1.1	1.0	1.1	1.1	
						1.0	1.1	1.1	1.1	1.0	
					S.W.	1.1	1.0	1.1	1.1	1.0	
						1.0	1.1	1.1	1.0	1.1	
						1.1	1.1	1.0	1.1	1.1	
					T.C.	1.1	1.1	1.0	1.1	1.1	
						1.1	1.0	1.1	1.1	1.0	
						1.0	1.1	1.1	1.0	1.1	
		Exhalation 160 L/min		≤3.0	A.R.	1.7	1.7	1.6	1.7	1.7	Pass
						1.7	1.6	1.7	1.7	1.6	
						1.6	1.7	1.7	1.6	1.7	
					S.W.	1.7	1.6	1.6	1.7	1.7	
						1.6	1.7	1.7	1.6	1.7	
						1.7	1.7	1.7	1.7	1.6	
					T.C.	1.6	1.7	1.7	1.6	1.7	
						1.7	1.7	1.6	1.7	1.7	
						1.7	1.6	1.7	1.7	1.6	

Note 1: Limitation may need be changed according to classification, refer to Table 2 — Breathing resistance of EN 149:2001 +A1:2009 for the Technical requirements.

[2020] WSZ FHL NO.7629

Table C- Clogging Test—Breathing resistance

S.No.	Test item		Unit	Technical requirement	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
18 (7.17)	Clogging test— Breathing resistance	Inhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						
		Exhalation 95 L/min		—	A.R.						N/A
					T.C.						

Note 1: Valved particle filtering half masks
After clogging the inhalation resistances shall not exceed FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar at 95 l/min continuous flow;
The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Note 2: 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 95 l/min continuous flow.

Table D- Clogging Test—Penetration of filter material

S.No.	Test item		Unit	Technical requirement	Test result		Single item decision
19 (7.17)	Clogging Test— Penetration of filter material	Paraffin oil	—	—	A.R.		N/A
					T.C.		
					T.C.		

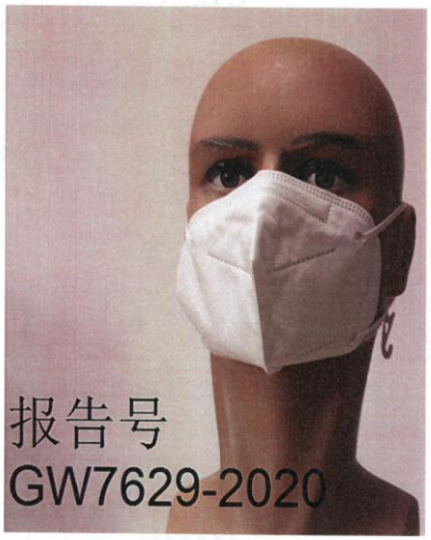
Note: Maximum penetration of test aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%

Abbreviations :		
A.R. As received	M.S. Mechanical strength	S.W. Simulated wearing treatment
T.C. Temperature conditioned	F.C. Flow conditioned	C.D. Cleaning and Disinfecting

Annex A- Estimates of the uncertainty of measurement

Test item	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%

Annex B- Sample Photo



The end

3、一次性平面口罩检测报告

检 验 报 告

TEST REPORT

报 告 编 号 REPORT NO.	国纺委字第 W202020824 号
产 品 名 称 NAME OF SAMPLE	一次性平面口罩
委 托 单 位 CUSTOMER	安徽亚鑫橡塑科技发展有限公司
检 验 类 别 TEST CATEGORY	委托检验

浙江省轻工业品质量检验研究院

（浙江省纺织测试研究院）

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心（浙江）

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

检验报告

国纺委字第 W202020824 号　　第 1 页 共 3 页

委托单位名称 Name of Customer	安徽亚鑫橡塑科技发展有限公司	地 址 Address	安徽省安庆市潜山县综合经济开发区
生产单位 Manufacturer	安徽亚鑫橡塑科技发展有限公司	地 址 Address	安徽省安庆市潜山县综合经济开发区
样品信息 Sample information	样品名称 Name of sample：一次性平面口罩 样品特性 Characteristics：蓝色 商标 Trademark：--- 规格/号型 Specification/model：17.5cm*9.5cm 等 级 Level：--- 安全技术类别 Category of safety specification：--- 样品款号/货号 Art. No.：20200505 ----------		
以上为客供信息（Above-mentioned information by Customer-supplied）			
来样方式 The sent way of sample	快递	样品数量 Sample quantity	40 只
送检日期 Receiving Date of Sample	2020-05-22	检测类别 Test Category	委托检验
判定依据 RatingRequirements	GB/T 32610-2016		

检测结论/Test Summary：

实测结果详见附页。

（检验报告专用章/Test Seal）

批准日期/ Date of Approval：2020-05-31

备 注 Remarks	1、样品标识未标注防护效果级别，按最低标准要求 D 级判定。 2、生产日期：2020-05-07。

签 发：
Approved by

检验报告

国纺委字第 W202020824 号　　第 2 页 共 3 页

序号	检测项目		检测方法	单位	标准要求（D 级）	实测值	单项评价	结果备注
1	防护效果		GB/T 32610-2016 附录 B	%	≥65	65.1	符合	——
2	呼吸阻力	吸气阻力	GB/T 32610-2016	Pa	≤175	129	符合	——
		呼气阻力		Pa	≤145	117		
3	过滤效率（盐性介质）		GB/T 32610-2016 附录 A	%	≥90	94.7	符合	——
4	外观质量		GB/T 32610-2016 6.1	——	符合 GB/T32610-2016 标准要求	10 个口罩的外观质量符合标准	符合	——
5	口罩带及口罩带与口罩体的连接处断裂强力		GB/T 32610-2016	N	≥20	23	符合	——
6	口罩下方视野		GB 2890-2009 6.8	°	≥60	74	符合	——

检验报告

国纺委字第 W202020824 号　　第 3 页 共 3 页

样品图片

—以下空白—

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DECLARATION

1. Our organization guarantees impartiality, independence and honesty of inspection, and is responsible for the results of inspection, keeping the samples supplied by the entrusting party confidential and at the same time protecting the ownership of the samples supplied.
2. The test report will be deemed invalid without signatures of the inspector/reviewer and authorized personnel, and the red special inspection stamp of our organization.
3. The test report will be invalid if it is altered. Copies of the report are invalid without the red special inspection stamp of our organization.
4. The test results shown in this report are applicable only to the samples provided by customers.
5. All the pages of the report are integral parts of the report. Our organization will not be responsible for any misunderstanding or other results caused by using separate page(s) of the report.
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The Affiliated Inspection Centers

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浙江省体育用品质量检验中心
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浙江省锁具产品质量检验中心
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Telephone：0571-85027738
E-Mail：Locktest@126.com

网上业务受理/报告查询：http://www.zjttj.cn
Online Business-Reception/Report Inquires: http:// www.zjttj.cn
投诉电话：0571-85023552
Complaint Tel：0571-85023552

4、SGS 检测报告

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0599

Test Report **SL52035272093301TX** **Date:July 22,2020** **Page 1 of 5**

ANHUI YAXIN RUBBER PLASTIC TECHNOLOGY DEVELOPMENT CO., LTD
WANSHUI ROAD.QIANSHAN ECONOMY DEVELOPMENT ANQING CITY, ANHUI PROVINCE

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

Sample Description	:	(A)Face mask
Style No.	:	YX-001
Composition	:	(A)25gsm non-woven fabric + 25gsm meltblown fabric
Sample Color	:	(A)Blue
Manufacturer	:	ANHUI YAXIN RUBBER PLASTIC TECHNOLOGY DEVELOPMENT CO., LTD
Supplier	:	ANHUI YAXIN RUBBER PLASTIC TECHNOLOGY DEVELOPMENT CO., LTD
Batch Number	:	YXM01
Sample Receiving Date	:	Jul 02, 2020
Testing Period	:	Jul 02, 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).
Test Performed	:	Selected test(s) as requested by applicant

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~175mm x 150mm
Positive Control Average	:	1775 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:
1) Performance Requirement: Type I⩾95%, Type II⩾98%, Type IIR ⩾98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A
Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area : 4.9 cm^2
Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	58.5	56
	1-2	55.6	
	1-3	54.3	
	1-4	59.3	
	1-5	54.1	
2	2-1	50.4	55
	2-2	59.6	
	2-3	49.6	
	2-4	59.2	
	2-5	56.2	
3	3-1	57.7	57
	3-2	56.0	
	3-3	55.1	
	3-4	54.7	
	3-5	59.1	
4	4-1	55.5	57
	4-2	57.8	
	4-3	57.7	
	4-4	59.3	
	4-5	56.8	
5	5-1	58.3	58
	5-2	56.4	
	5-3	58.1	
	5-4	57.6	
	5-5	58.7	

Remark:
1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	Seen	Fail	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		31			
Overall result:		Acceptable			

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

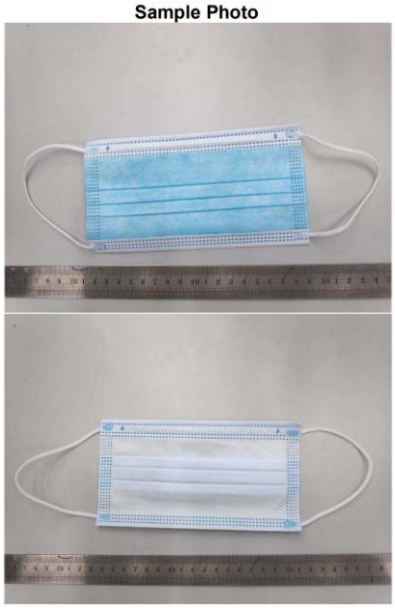
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.45	6	1.74
2#	3.43	<3	<0.87
3#	3.42	57	16.67
4#	3.41	66	19.35
5#	3.45	<3	<0.87

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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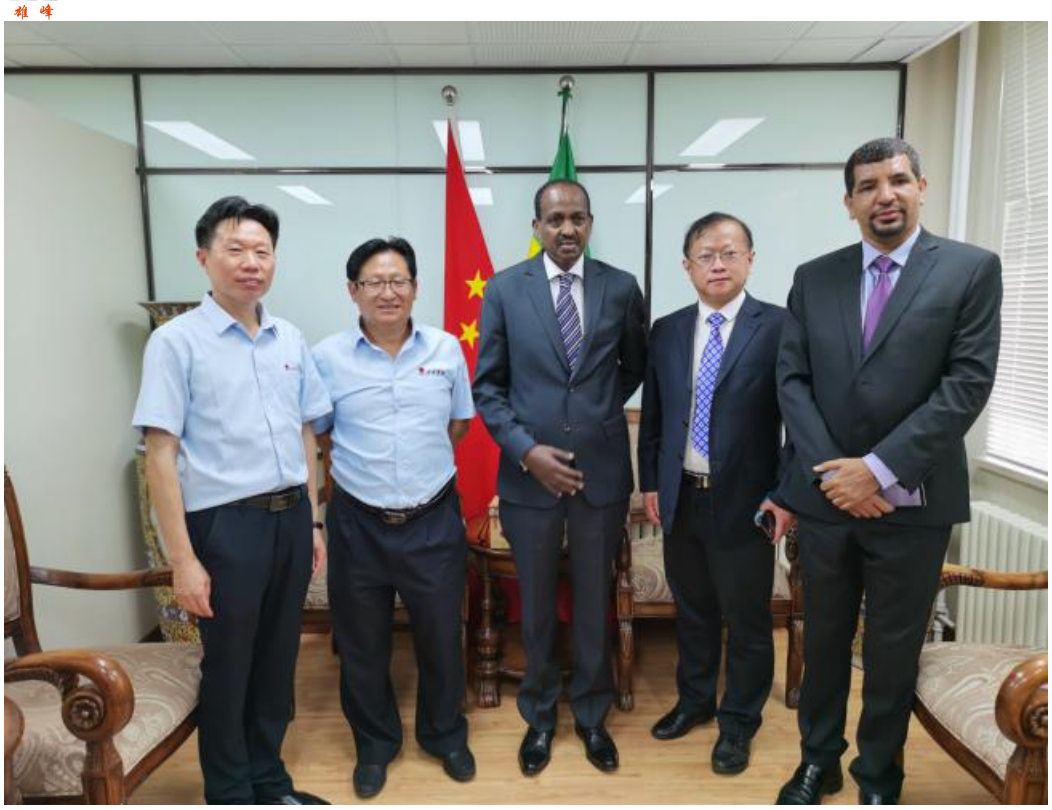
七、领导关怀

2008 年 10 月 27 日，中共中央政治局常委、国务院总理李克强，中共中央政治局委员，中央书记处书记，政协副主席刘奇葆等领导在公司董事长储险峰的陪同下视察雄峰展厅。

2020 年 8 月 8 日，埃塞俄比亚联邦民主共和国大使特肖梅 • 托加代表团一行莅临雄峰集团亚鑫公司考察，集团董事长储险峰以及中高层管理人员陪同参加。



2020 年 6 月 11 日，安徽雄峰集团向埃塞俄比亚联邦民主共和国捐赠防疫物资一批，特肖梅•托加大使代表埃塞俄比亚接受捐赠，集团董事长储险峰,集团高级顾问、中非友好协会会长武岷参与捐赠仪式。

2020 年 6 月 11 日，安徽雄峰集团向尼日利亚联邦共和国捐赠防疫物资一批，萨劳•阿米努公使代表尼日利亚接受捐赠，集团董事长储险峰,集团高级顾问、中非友好协会会长武岷参与捐赠仪式。

ATT GERMANY GMBH

EU-Konformitätserklärung für eine PSA der Kategorie III

Der in der EU niedergelassene Inverkehrbringer

ATT Germany GmbH
Ludwig-Erhard-Str. 1A
65760 Eschborn

trägt die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung und erklärt hiermit, dass die nachstehend beschriebene Persönliche Schutzausrüstung (PSA)

Atemschutzmasken, weiß, PP-Vlies

Yaxin

Atemschutzmaske FFP2 NR ohne Ventil, Model: YX9501

gemäß den uns vorliegenden relevanten Prüfberichten und/oder Bescheinigungen den Bestimmungen der Verordnung (EU) 2016/425 entspricht:
Dabei wurden die folgenden harmonisierten Normen erfüllt:

EN 149:2001+A1:2009

Die notifizierte Stelle:

Polski Rejestr Statków S.A.
al. Gen. Józefa Hallera 126
80-416 Gdańsk
Poland

Kennnummer: 1463

hat die EU-Baumusterprüfung (Modul C2) durchgeführt und die EU-Baumusterprüfbescheinigung

Zertifikats-Nr.: CW/PPER/54/05/2020

ausgestellt. Die PSA unterliegt folgendem Konformitätsbewertungsverfahren:
Konformität mit dem Baumuster auf der Grundlage einer Qualitätssicherung bezogen auf den Produktionsprozess (Modul D) gemäß Anhang VIII – durchgeführt durch:

Polski Rejestr Statków S.A., Kennnummer: 1463

Unterzeichnet für und im Namen von der ATT Germany GmbH:

Eschborn, den 28.12.2020

Like Ge
Geschäftsführer

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Steuer-Nr.:
040 288 80070

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Commerzbank
IBAN:
DE89 5004 0000 0382 9884 00
BIC: COBADEFF

YX9501 FFP2 NR - Atemschutzmaske

Zertifikat + EU-Konformitätserklärung einsehbar unter:
https://psa.attgermany.com/wp-content/uploads/2020/12/Yaxin_15044_Zertificat.pdf

Anwendungen:

Filtrierende Halbmasken der Kategorie FFP2, das normalerweise in der allgemeinen Arbeitsumgebung verwendet wird, sollen einen zuverlässigen Atemschutz bieten und vor bestimmten luftgetragenen Partikeln und Staub schützen, Körperflüssigkeiten blockieren usw.

Vorsichtmaßnahmen:

1. Diese Maske, die mit „NR“ gekennzeichnet ist, darf nicht für mehr als eine Schicht verwendet werden.
2. Niemals Teile in der vom Hersteller angegebenen Konfiguration ersetzen, ändern hinzufügen oder weglassen.
3. Diese Maske trägt zum Schutz gegen bestimmte partikelförmige Verunreinigungen bei, schließt jedoch das Risiko einer Erkrankung oder Infektion nicht vollständig aus.
4. Verwenden Sie die Maske nicht mit Gesichtsbehaarung oder anderen Bedingungen, die eine gute Gesichtsabdichtung verhindern können, die Anforderungen an eine Leckage werden nicht erfüllt.
5. Tragen Sie die Atemschutzmaske ununterbrochen, solange Sie Verschmutzungen ausgesetzt sind.
6. Verlassen Sie den verschmutzten Bereich sofort, wenn Schwindel, Übelkeit oder andere Beschwerden auftreten.
7. Wenn Sie KEINEN richtigen Dichtsitz erreichen können, betreten Sie NICHT den Gefahrenbereich.
8. Verwerfen und ersetzen Sie die Maske, wenn:

a. Die Maske wurde entfernt, während Sie sich in den kontaminierten Bereichen befinden.
b. Das Verstopfen der Maske verursacht Atembeschwerden.
c. Die Maske ist oder wurde beschädigt.

Anleitung

1. Entfalten Sie die Maske und ziehen Sie die Bänder an beiden Enden um die Ohren herum und positionieren Sie die Maske auf ihrem Gesicht mit dem verstellbaren Nasenbügel nach oben zeigend.
2. Passen Sie den Nasenbügel an ihre Nasen an, um zu gewährleisten, dass die Maske sicher versiegelt und der Nasenform angepasst ist.
3. Drücken Sie die Maske leicht auf ihr Gesicht auf, um sie der Gesichtsform anzupassen.
4. Führe Sie ein Dichtungstest mit die Maske durch.

Dichtungstest:

1. Bedecken Sie die Maske vorsichtig mit beiden Händen ohne den Dichtsitz zu verändern. 2. stark Ausatmen; 3. Bei einer Leckage im Nasenbereich, den Nasenbügel neu anpassen. Dichtsitzprüfung wiederholen. 4. Bei einer Leckage am Maskenrand, den Sitz der Bänder überprüfen und anpassen. Dichtsitzprüfung wiederholen.

Lagerung/ Aufbewahrung /Transport:

Halten Sie die Masken in der Verpackung bis zur Verwendung von direktem Sonnenlicht oder Verunreinigungen fern. Lagerung Bedingungen: Temperatur zwischen -30°C bis +70°C, Luftfeuchtigkeit <80%, kein korrosives Gas, gute Belüftung. Während des Transports von Feuchtigkeit, Licht und Wärme fernhalten und es darf nur in Originalverpackung transportiert werden.

Die Atemschutzmaske ist nur für den einmaligen Gebrauch bestimmt und nicht wiederverwendbar.

Nicht steril.

EU-Type Examination Notified Body

Notified Body: Polski Rejestr Statków S.A.

Adresse: al. Gen. Józefa Hallera 126, 80-416 Gdańsk, Poland

Notified Body No: 1463

Model: YX9501 EN149:2001+A1:2009 CE 1463

Inhalt: FFP2 NR Atemschutzmasken

Herstellungsdatum: auf der Verpackung **Ablaufdatum:** auf der Verpackung

Hersteller: Anhui Yaxin Rubber Plastic Technology Development Ltd.
Economic Development Zone, Qianshani Clty, Anhui Province, China

Inverkehrbringer: ATT Germany GmbH, Ludwig-Erhard-Str. 1, 65760 Eschborn, Germany