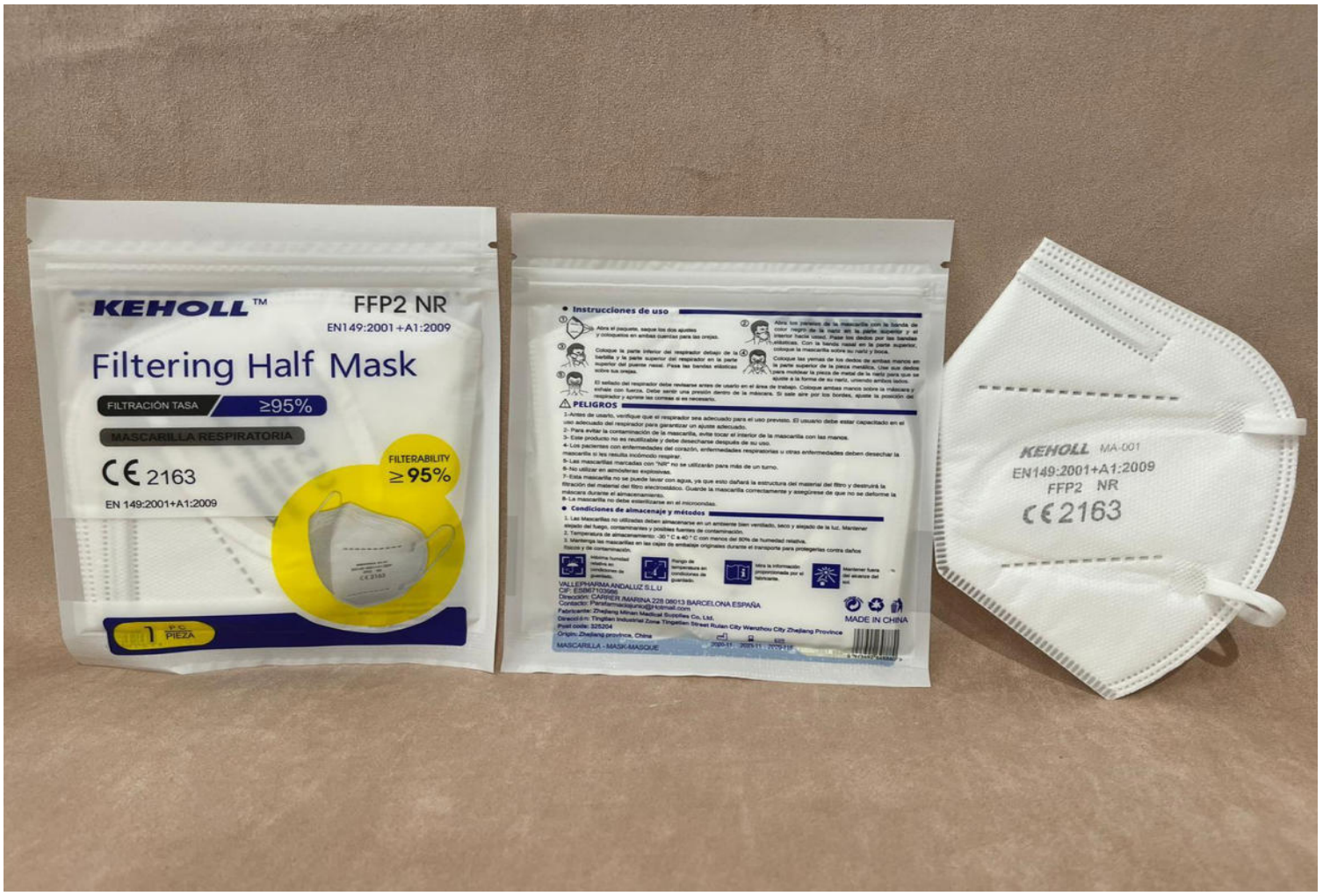

KEHOLL™
FFP2 NR
EN149:2001+A1:2009
Filtering Half Mask
FILTRACIÓN TASA ≥95%
MASCARILLA RESPIRATORIA
CE 2163
EN 149:2001+A1:2009
FILTERABILITY ≥95%
1 PIEZA
Instrucciones de uso
PELIGROS
Condiciones de almacenaje y métodos
MADE IN CHINA
KEHOLL MA-001
EN149:2001+A1:2009
FFP2 NR
CE 2163


KEHOLL™
FFP2 NR
EN149:2001+A1:2009
FILTERING HALF MASK
CE 2163
FILTERABILITY ≥95%
Five Tier Structure
Attach Onto Face
Solid Cut
360 ° Fit To Skin
Inner Super Soft Non-woven Fabric
Effectively block dust, bacteria and other particles
20 PCS BOX
Scope of application
Storage conditions
Precaution
Product description
KEHOLL™
FILTERING HALF MASK
20 PCS BOX
Instructions
Open the package and take out the mask
Place the sharpcorners of the mask on the outside and wear on face
Cover the nose and mouth and hang the ear loop lightly on both ears
Adjust the mask and nose clip to fit the mask to the face

KEHOLL

CE认证CE certification

UNIVERSAL
CERTIFICATION
NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1127

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Zhejiang Minan Medical Supplies Co., Ltd.
Tingtian Industrial Zone, Tingtian Street Ruian City, Wezhou City, Zhejiang Province, China
are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: KEHOLL **Model:** MA-001
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

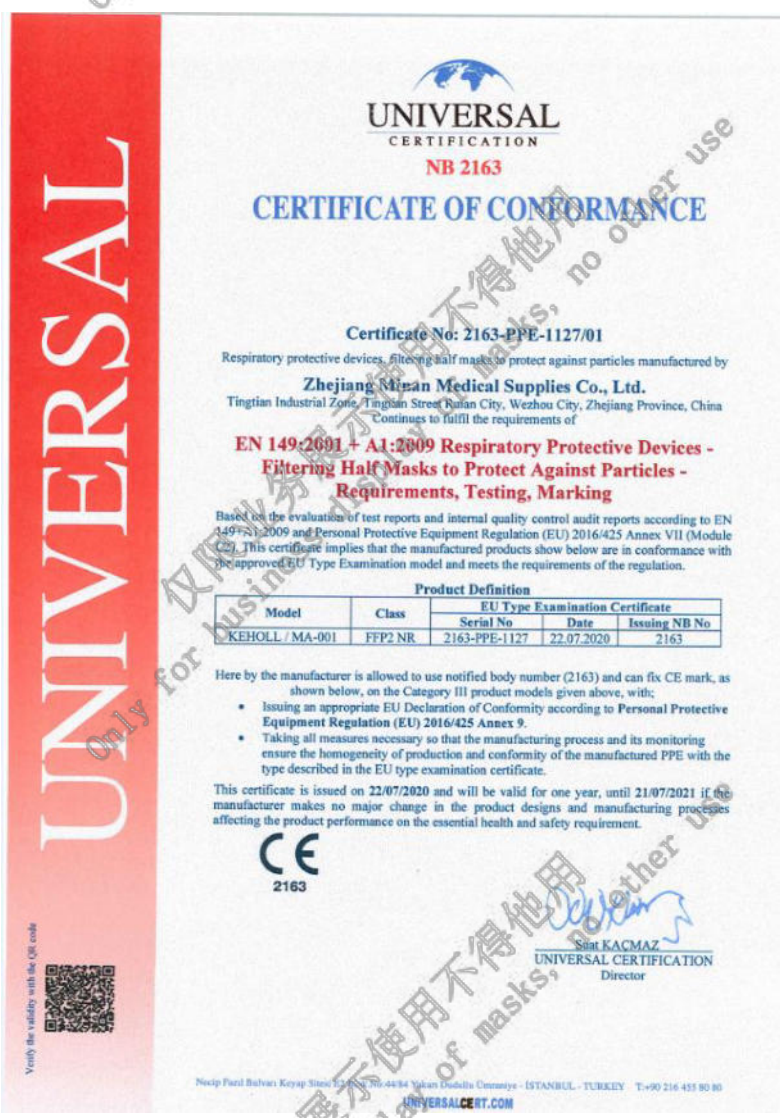
This certificate is initially issued on **22/07/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

UNIVERSAL
Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:40/44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM



UNIVERSAL
CERTIFICATION
NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1127/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Zhejiang Minan Medical Supplies Co., Ltd.
Tingtian Industrial Zone, Tingtian Street Ruian City, Wezhou City, Zhejiang Province, China
Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
KEHOLL / MA-001	FFP2 NR	2163-PPE-1127	22.07.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **22/07/2020** and will be valid for one year, until **21/07/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

UNIVERSAL
Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:40/44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM


LEIKANG
FFP2
EN 149:2001+A1:2009
FFP2 NR
LK-008
FILTERING HALF MASK
1 PC
NO MEDICAL DEVICE
WENZHOU LEIKANG MEDICAL TECHNOLOGY CO.,LTD
Made in China
Scan QR Code For Instruction


LEIKANG
FFP2
EN 149:2001+A1:2009
FFP2 NR
LK-008
FILTERING HALF MASK
20 PCS
NO MEDICAL DEVICE
WENZHOU LEIKANG MEDICAL TECHNOLOGY CO.,LTD
Made in China
Scan QR Code For Instruction

EU Declaration of Conformity

Annex IX PPE Regulation (EU)2016/425

This EU Declaration of Conformity refers to the following products

Product Name	Model	Classification/Fype	Batch No./Serial No./Identifier
Particle filtering half mask	LK-008	FFP2	

The Manufacturer's name and address is as follows:

Name	Wenzhou Leikang Medical Technology Co.,Ltd
Address	Room 401,4th floor, Building No.21, No.89 fengfang road, Economic Development zone, Ouhai District Wenzhou. Zhejiang Province, China

This Declaration of conformity is issued under the sole responsibility of the Manufacture.

Detailed description of the PPE to allow traceability/ identification of the PPE.

LK-008	White folder half mask without valve
	The mask photo
	

The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU)2016/425. References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared.

No.	EU Type Examination (Module-B)Certification Number
1	CE-2163-PPE-972

Product Category:

☐This product is CategoryII:

☐This product is CategoryIIi and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of CCQS Certification services limited. (NB2163)

☐This products is Category IIi and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of CCQS certification services limited. (NB2163)

Company: WENZHOU LEIKANG MEDICAL TECHNOLOGY CO., LTD

Address: Room 401,4th floor, Building No.21, No.89 fengfang road, Economic Development zone, Ouhai District Wenzhou. Zhejiang Province, China

_____ _____

Place, date ***Legally binding signature, Function***

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163- PPE-972

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Wenzhou Leikang Medical Technology Co., Ltd.
Room 401, 4th floor, Building No. 21, Wenzhou National University Science Park, No. 89 Fengfang Rd.
Economic Development Zone, Ouhai District, Wenzhou, Zhejiang Province, China

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: LEIKANG **Model:** LK-008
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **07/07/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
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UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE–972/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Wenzhou Leikang Medical Technology Co., Ltd.
Room 401, 4th floor, Building No. 21, Wenzhou National University Science Park, No. 89 Fengfang Rd.
Economic Development Zone, Ouhai District, Wenzhou, Zhejiang Province, China

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
LEIKANG / LK-008	FFP2 NR	2163-PPE–972	07.07.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **07/07/2020** and will be valid for one year, until **06/07/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

AC 114

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

Nr / *No.* CW/PPER/9/12/2020

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*
Guangdong YiDao Medical Technology Co., Ltd.
Room 302, Building 2, No. 1, Lane 1, Xiju RoadHengli, Dongguan City, Guangdong Province, China

Producent / *Manufacturer*
Guangdong YiDao Medical Technology Co., Ltd.
Room 302, Building 2, No. 1, Lane 1, Xiju RoadHengli, Dongguan City, Guangdong Province, China

Typ wyrobu / *Product type*
Sprzęt ochrony dróg oddechowych. Półmaski filtrujące do ochrony przed cząstkami.
Respiratory protective devices. Filtering half masks to protect against particles.

Opis wyrobu / *Product description*
Półmaska filtrująca dla dzieci, FFP2 NR. Model: YD-006
Filtering Half Mask for Children, FFP2 NR. Model: YD-006

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* 2025-12-02

PRS 1936 NOTIFIED BODY NO. 1463

Dyrektor Pionu Certyfikacji
Certification Division Director

Michał Chudziński

Gdańsk, 2020-12-03

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/

Wykaz dokumentacji
List of documents

1. Instrukcja użytkowania - zatwierdzona przez PRS dnia 2020-12-02.
2. Ocena ryzyka - zatwierdzona przez PRS dnia 2020-12-02.
3. Rysunek półmaski - model SGN9502 - zatwierdzony przez PRS dnia 2020-12-02.
4. Raport z badań nr PTC20102904301C-EN01V01 wydany przez Precise Testing & Certification (Guangdong) Co., Ltd. (PTC) w dniu 2020-11-16.
5. Sprawozdanie z przeglądu PRS nr CW/KKr/PPER/62/2020 z dnia 2020-12-03.

1. Instruction for use - approved by PRS on 2020-12-02.
2. Risk analysis - approved by PRS on 2020-12-02.
3. Assembly drawing for model: SGN9502 - approved by PRS on 2020-12-02.
4. Test report no. PTC20102904301C-EN01V01 issued by Precise Testing & Certification (Guangdong) Co., Ltd. (PTC) on 2020-11-16.
5. PRS Survey Report No. CW/KKr/PPER/62/2020 dated on 2020-12-03.

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

-

Ograniczenia uznania
Approval limitations

1. Dane techniczne:
- półmaska filtrująca z regulowanym klipsem na nos,
- półmaska filtrująca wykonana z 4-warstwowej włókniny z filtrem z tkaniny,
- wymiary: 130 x 86 mm,
- kolor: biały.
2. Półmaski filtrujące przeznaczone do jednorazowego użytku.
3. Dokumentacja techniczna zatwierdzona w języku angielskim.

1. Specifications:
- filtering half mask with adjustable nose clip,
- filtering half mask made with 4-layers non-woven fabric with melt-blown fabric filter,
- size: 130 x 86 mm,
- color: white.
2. Filtering half mask shall not be used for more than one shift.
3. 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.

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/29/01/2021

Okres objęty certyfikatem / *Period covered by the certificate* 2021-01-13 – 2022-01-12

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

Posiadacz certyfikatu / *Certificate holder*

Guangdong YiDao Medical Technology Co., Ltd.
Room 302, Building 2, No. 1, Lane 1, Xiju RoadHengli, Dongguan City
Guangdong Province, China.

Wyrób / *Product*	Certyfikat badania typu UE / *EU Type-examination certificate*	Normy zharmonizowane/Specyfikacje / *Harmonised standards/Specifications*
Półmaska filtrująca dla dzieci, FFP2 NR. Model: YD-006 *Filtering Half Mask for Children, FFP2 NR.* *Model: YD-006*	*CW/PPER/9/12/2020*	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*: Guangdong YiDao Medical Technology Co., Ltd.

2a Wyboru dokonał (imię, nazwisko) / *Selection carried out by (Name)*: Krzysztof Kirysiuk
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)*: Xiushi Zhang
Stanowisko / *Position*: CEO

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.* 20210113 ☐ 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**

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

tel. (+48) (58) 346 17 00
fax (+48) (58) 346 03 92
e-mail: mailbox@prs.pl
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 ☐ 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. Półmaska filtrująca przeznaczona 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 in English approved.
3. This product can not be used as a gas mask in a toxic enviroment.
4. Filtering Half Mask can not be used for medical or surgical purposes.

D **Załączniki**
Attachments

Sprawozdania z wizyty Nr
Visit reports No. CW/KKr/PPER/10/2021

Sprawozdania z badań Nr
Test reports No. Raport z badań nr CL/PCLB8/19/1/2021 wydany przez Laboratorium Badawcze PRS S.A. z dnia 2021-01-13.
Test report no. CL/PCLB8/19/1/2021 issued by PRS S.A. Testing Laboratory dated on 2021-01-13.

Ogólna ocena z rocznego nadzoru
Overall assessment of the annual surveillance

☒ Pozytywna *Positive* ☐ Negatywna *Negative*

PRS 1936 NOTIFIED BODY NO.1463

Dyrektor Pionu Certyfikacji
Certification Division Director

Gdańsk, 2021-01-13

Michał Chudziński