

Report No.: BT20050901625

**Customer Information:**

Customer..... : Wenzhou Meiyi Medical Device Co.,Ltd  
Address..... : Hengjie Industrial,Xianjiang Street ,Ruian  
Wenzhou,Zhe jiang,China

**Sample Information:**

Sample Name..... : 3D FACIAL PROTECTIVE MASK(KN95 MASK)  
Sample Specification.... : MY-002  
Sample Classification... : FFP2  
Sample Description..... : Samples in good condition  
Sampled Method..... : All parts were received from customer  
Receipt Date..... : 2020-05-09

**Testing Information:**

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

Written by: Arzigul Inspected by: Yumei li Approved by: Steven Zou  
Date: 2020-05-18 Date: 2020-05-18 Date: 2020-05-18



**BEFITLAB TEST TECHNOLOGY SHANGHAI CO., LTD.**  
Member of International Standards Certification (ISC) Group

## 1、 Sample List

Manufacturer	Sample Name	Specification	Material	Lot
Wenzhou Meiyi Medical Device Co.,Ltd	3D FACIAL PROTECTIVE MASK(KN95 MASK)	MY-002	Spunbound polypropylene,melt blown polypropylene,	202004

## 2、 Sample Photos



**Appendix 1: Visual inspection**

**1.1. Visual inspection:** The visual inspection shall include the marking and information supplied by the manufacturer.

**1.2. Result:** Not tested

**1.3. Note:** As requested by the client, marking and information supplied by the manufacturer was not inspected.

**Appendix 2: Package**

**2.1. Package:** Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

**2.2. Result:** Pass

**2.3. Note:** In accordance with the requirement.

**Appendix 3: Material**

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

**3.2. Result:** Pass

**3.3. Note:** No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

**Appendix 4: Cleaning and disinfecting**

**4.1. Cleaning and disinfecting:** If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

**4.2. Result:** N/A

**4.3. Note:** Single shift use only.

## Appendix 5: Practical performance

**5.1. Practical performance:** The particle filtering half mask shall undergo practical performance tests under realistic conditions.

**5.2. Result:** Pass

**5.3. Note:** No imperfections.

## Appendix 6: Finish of parts

**6.1. Finish of parts:** Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

**6.2. Result:** Pass

**6.3. Note:** No sharp edges or burrs.

## Appendix 7: Total inward leakage

**7.1. Total inward leakage:** For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22% for FFP1, 8% for FFP2, 2% for FFP3

**7.2. Result:** Pass

**7.3. Note:**

Subject	Sample No.	Condition	Walk (%)	Head Side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
Wu	1	A.R.	7.12	7.51	7.12	7.77	7.48	7.40
Li	2	A.R.	7.39	7.45	7.67	7.59	7.72	7.56
Zhang	3	A.R.	7.43	7.60	7.74	7.38	7.50	7.53
Xie	4	A.R.	7.15	7.50	7.03	7.31	7.08	7.21
Yang	5	A.R.	7.20	7.78	7.05	7.28	7.72	7.41
Lang	6	T.C.	7.02	7.68	7.50	7.49	7.72	7.48
Wang	7	T.C.	7.27	7.44	7.01	7.45	7.43	7.32
Yu	8	T.C.	7.77	7.76	7.56	7.08	7.73	7.58
Zhu	9	T.C.	7.01	7.07	7.13	7.34	7.26	7.16
Liu	10	T.C.	7.63	7.68	7.60	7.14	7.77	7.56

50 out of the 50 individual exercise results  $\leq$  11 %

10 of the 10 individual arithmetic means  $\leq$  8 %

Pass

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

## Appendix 8: Penetration of filter material

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

Sodium chloride test 95 l/min

Paraffin oil test 95 l/min

FFP1	≤20%
FFP2	≤6%
FFP3	≤1%

≤20%
≤6%
≤1%

**8.2.Result:** Pass

### 8.3. Note:

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	2.45	
		12	2.53	
		13	2.52	
	Simulated wearing treatment	14	2.56	
		15	2.53	
		16	2.57	
	Mechanical strength+ Temperature conditioned	17	2.54	
		18	2.56	
		19	2.58	

Paraffin oil test	As received	20	4.15
		21	4.21
		22	4.19
	Simulated wearing treatment	23	4.25
		24	4.23
		25	4.26
	Mechanical strength+ Temperature conditioned	26	4.31
		27	4.29
		28	4.28
	Flow conditioning: Single filter: 95.0 L/min		

## Appendix 9: Compatibility with skin

**9.1. Compatibility with skin:** Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

**9.2. Result:** Pass

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

## Appendix 10: Flammability

**10.1. Flammability:** When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

**10.2. Result:** Pass

**10.3. Note:**

Condition	Sample No.	Result	Assessment
As received	29	Burn for 2s	Pass
	30	Burn for 1s	
Temperature conditioned	31	Burn for 1s	
	32	Burn for 1s	

## Appendix 11: Carbon dioxide content of the inhalation air

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

**11.2. Result:** Pass**11.3. Note:**

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

**Appendix 12: Head harness**

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

**12.2. Result:** Pass

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

**Appendix 13: Field of vision**

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

**13.2. Result:** Pass

**13.3. Note:** Pass the practical performance tests.

**Appendix 14: Exhalation valve**

**14.1. Exhalation valve:** A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9. Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s. When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

**14.2. Result:** N/A

**14.3. Note:** No exhalation valve.

**Appendix 15: Breathing resistance**

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

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

**15.2. Result:** Pass

**15.3. Note:**

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

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

**Appendix 16: Clogging**

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

**16.1.1 Breathing resistance:** Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

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

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

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

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

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

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

**16.2. Result:** N/A

**16.3. Note:** Single shift use only.

**Appendix 17: Demountable parts**

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

**17.2. Result:** N/A

**17.3. Note:** No demountable parts.

\*\*\*\*\* End \*\*\*\*\*

**Notice Items:**

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



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

Nr  
No. CW/PPER/48/05/2020

### 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/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

Wenzhou Meiyi Medical Device Co., Ltd.  
Hengjie Industrial, Xianjiang Street,  
Ruian Wenzhou, Zhejiang, China.

Producent  
Manufacturer

Wenzhou Meiyi Medical Device Co., Ltd.  
Hengjie Industrial, Xianjiang Street,  
Ruian Wenzhou, Zhejiang, 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

**Maska ochronna na twarz typ (KN95) MY-002 klasy FFP-2**

*3D facial protective mask type (KN95) MY-002 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

Przemysław Gałka

Gdańsk, 2020-05-27



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 S.A. dnia 2020-05-25.
2. Ocena ryzyka - zatwierdzona przez PRS S.A. dnia 2020-05-25.
3. Rysunek Maski typu MY-002 - zatwierdzony przez PRS S.A. dnia 2020-05-25.
4. Raport z badań nr BT20050901625 wydany przez Befitlab Test Technology Co., Ltd w dniu 2020-05-18.
5. Sprawozdanie z przeglądu PRS S.A. nr CW/ZO/PPER/43/2020 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 Mask type MY-002 - approved by PRS S.A. on 2020-05-25.*
4. *Test report No. BT20050901625 issued by Befitlab Test Technology Co., Ltd. dated 2020-05-18.*
5. *PRS S.A. Survey report No. CW/ZO/PPER/43/2020 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. Maska nie jest przeznaczona do użytkowania medycznego i chirurgicznego.
2. Maska nie powinna być używana w środowisku o stężeniu tlenu poniżej 19.5 %.
3. Maska przeznaczona do użytku podczas jednej zmiany.
4. Maska oceniona zgodnie procedurą określoną w Zaleceniu Komisji 2020/403 (COVID-19).
5. Dane techniczne:
  - maska z regulowanym klipsem na nos,
  - maska wykonana z 4-warstwowej włókniny z filtrem z tkaniny,
  - wymiary: 155 x 115 mm,
  - kolor: biały,
  - docelowa grupa użytkowa: dorośli dla obu płci.

1. *Mask can not be used for medical and surgical purposes.*
2. *Mask should not be used in an environment with oxygen contents less than 19.5%.*
3. *Mask designed for single shift use.*
4. *Mask according to Commission Recommendation 2020/403 (COVID-19.)*
5. *Specifications:*
  - *mask with adjustable nose clip,*
  - *mask made with 4ply non-woven fabric with melt-blown fabric filter,*
  - *size: 155 x 115 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.*



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**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/52/06/2020Okres objęty certyfikatem  
Period covered by the certificate

2020-06-16 – 2021-06-15

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 VIIPosiadacz certyfikatu  
Certificate holder **Wenzhou Meiyi Medical Device Co., Ltd.**  
Hengjie Industrial, Xianjiang Street,  
Ruian Wenzhou, Zhejiang, China.

Wyrób Product	Certyfikat badania typu UE EU Type-examination certificate	Normy zharmonizowane/Specyfikacje Harmonised standards/Specifications
<b>Maska ochronna na twarz typ (KN95) MY-002 klasy FFP-2</b> 3D facial protective mask type (KN95) MY-002 class FFP-2	CW/PPER/48/05/2020	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 ----
- 2a Wyboru dokonano (imię, nazwisko)  
Selection carried out by (Name) ----  
Związek z jednostką notyfikowaną  
Relationship to notified body ----
- 2b Przedstawiciel firmy (imię, nazwisko)  
Company representative (Name) ----  
Stanowisko  
Position ----
- 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.  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

Polski Rejestr Statków S.A.  
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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*

Zbigniew Orłowski (zdalnie/remote)  
 Ekspert Biura Certyfikacji Wyrobów i Osób  
*Products and Persons Certification Bureau Expert*

**2b Przedstawiciel firmy (imię, nazwisko)**  
**Company representative (Name)**  
 Stanowisko  
*Position*

Eason Fang  
 Quality Manager

**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*

**D Załączniki**  
**Attachments**

Sprawozdania z wizyty Nr  
*Visit reports No.* CW/ZO/PPER/69/2020 (zdalnie/remote)

Sprawozdania z badań Nr  
*Test reports No.* Raport z badań nr 2020(D)-0587 wydany przez National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing) w dniu 2020-06-03.  
*Test report no.2020(D)-0587 issued by National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing) on 2020-06-03.*

Ogólna ocena z rocznego nadzoru  
**Overall assessment of the annual surveillance**

Pozytywna  
 Positive

Negatywna  
 Negative



NOTIFIED BODY  
 NO.1463

Dyrektor Pionu Certyfikacji  
*Certification Division Director*

Przemysław Gałka

Gdańsk, 2020-06-16



60mm

70mm

**温州美意医疗器械有限公司**  
**WENZHOU MEIYI MEDICAL DEVICE CO.,LTD.**  
**合格证 CERTIFICATION**

产品名称: KN95口罩 (非医用)  
 Product Name: 3D Facial Protective Mask (KN95 MASK Non medical)  
 品牌: RYK  
 Brand: RYK  
 型号: MY-002  
 Model: MY-002  
 规格: 15.5x11.5cm  
 Specification: 15.5x11.5cm  
 产品数量: 2个  
 Product Quantity: 2Pcs  
 执行标准: EN 149:2001+A1-2009  
 Executive standard: EN 149:2001+A1-2009  
 GB2626-2006  
 材料: 50%无纺布, 20%PTFE纳米熔喷, 30%热风棉  
 Material Science: 50%Non-woven, 20%PTFE nano melt blown, 30%Hot air cotton  
 生产批号: 202007  
 Production batch: 202007  
 生产日期: 2020/07/03  
 Production Date: 2020/07/03  
 有效期: 3年  
 Shelf Life: 3 years  
 生产地址: 浙江省温州瑞安市仙降街道横街村  
 Production address: Hengjie Industrial Zone, Xianjiang Street, Rui'an Wenzhou Zhejiang, China  
 MADE IN CHINA

