# EU-KONFORMITÄTSERKLÄRUNG

## *EU DECLARATION OF CONFORMITY*

| | |
|---|---|
| **Name und Anschrift des Importeurs und Händlers in Europa**<br>*Name and address of importer and distributor responsible in Europe* | EUE BV<br>Derde Oosterparkstraat 73-1<br>1091 JV Amsterdam<br>Netherlands |

**DIESE KONFORMITÄTSERKLÄRUNG WIRD UNTER DER ALLEINIGEN VERANTWORTUNG ERSTELLT VON:**
*THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF:*

| | |
|---|---|
| **Name und Anschrift des Herstellers:**<br>*name and address of manufacturer:* | Changzhou Jinpeng Medical Equipment Co., Ltd<br>Adresse:Yanling Village, Zhenglu Town, Tianning District,<br>Changzhou, Jiangsu,China |
| **Produktidentifikation:**<br>*Product identification:* | **Markenname/** *brandname* **HUYOUCZ**<br>**Modell. Nr./** *model.no.* **KZ-JP-95-B** |

Die Konformitätsbewertung nach den wesentlichen Anforderungen wurde erstellt von Jinpeng gemäß
*The conformity assessment according to the essential requirements has been done by Jinpeng according to*

| | |
|---|---|
| **EU-Rechtsvorschriften der Gemeinschaft:**<br>*EU-Community Legislation:* | **Verordnung über persönliche Schutzausrüstung (PSA) (EU) 2016/425**<br>*Personal Protective Equipment (PPE) Regulation (EU) 2016/425*<br>**Anhang II Kategorie III** in Verbindung mit<br>*Annex II Category III in connection with*<br>**Anhang V (Modul B EU-Baumusterprüfungsbescheinigung)**<br>*Annex V (Module B EU Type Examination Certification)*<br>A18/000111 und<br>**Anhang VII (Modul D Qualitätssicherung Produktion)**<br>*Annex VII (Module D Quality assurance system of the production process)*<br>A18/000197 |
| **Harmonisierte Normen:**<br>*harmonized standards:* | **Persönliche Schutzausrüstung**<br>**EN 149:2001+A1:2009**<br>*Personal protective equipment*<br>*EN 149:2001+A1:2009*<br>Jiangsu Guojian Testing Technology Co., Ltd<br>3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu,China<br>Report No.:(2020) WSZ FHL NO.6737 |
| **WeitereSpezifikationen:**<br>*further specifications:* | **Partikelfiltermaske, Kategorie III, FFP2 NR**<br>*Particle filtering half mask, Category III, FFP2 NR* |
| **In Zusammenarbeit mit Benannter Stelle:**<br>*in corporation with:*<br>*Notified Body:* | **AENOR INTERNACIONAL S.A.U (CE 0099)**<br>Genova,6 28004 Madrid Espana |

Diese Erklärung ist gültig ab 19. 08. 2020 bis zum 19. 08. 2025
*This declaration is valid from 19.08.2020 until 19.08. 2025*

**UNTERZEICHNET FÜR UND IM NAMEN VON:**
*SIGNED FOR AND BEHALF OF:*

| | |
|---|---|
| **Ort und Datum der Ausstellung**<br>*Place and date of issue:* | **19.08.2020 Changzhou** |
| **Unterschrift** *Signature:* | |
| **Name, Funktion**<br>*Name and function:* | **Geschäftsführer**<br>**Jiannan Yao** |
| **Firmenname**/*Company name:* | **Changzhou Jinpeng Medical Equipment Co., Ltd** |

3204020951907

AENOR

# Certificado de Examen UE de Tipo
# EU Type-Examination Certificate

**A18/000111**

AENOR, como organismo notificado (nº 0099) para el Reglamento (UE) 2016/425, ha emitido este certificado a favor de
In compliance with Regulation (EU) 2016/425, the notified body AENOR (nº 0099) has issued this certificate to

## Changzhou Jinpeng Medical Equipment Co., Ltd

| | |
|---|---|
| Domicilio social / Registered office | No. 715 Heheng Road, Yanling Village, 213115 Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, (China) |
| para el producto / for the product | Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. / Respiratory protection devices. Half filter masks to protect against particles. |
| conforme con el Reglamento<br>in compliance with Regulation | Reglamento UE 2016/425 de Equipos de Protección Individual<br>(Regulation EU 2016/425 on Personal Protective Equipment) |
| Norma armonizada / Harmonized standard | EN 149:2001+A1:2009 |
| | Más información en el anexo / See annex for more information. |
| Centro de producción / Production site | No. 715 Heheng Road, Yanling Village, 213115 Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, (China) |
| Esquema de evaluación<br>Assessment scheme | Anexo V (Examen UE de Tipo – Módulo B) del Reglamento (UE) 2016/425.<br>Annex V (EU Type-examination – Module B) of Regulation (EU) 2016/425. |
| Fecha de emisión / First issued on<br>Fecha de expiración / Validity date | 2020-08-19<br>2025-08-19 |

Rafael GARCÍA MEIRO
Director General / CEO

Original Electronic Certificate

**AENOR INTERNACIONAL S.A.U.**
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

AENOR

# Certificado de Examen UE de Tipo
# EU Type-Examination Certificate

**A18/000111**

## Anexo al Certificado
## Annex to Certificate

Norma armonizada / Harmonized standard EN 149:2001+A1:2009

| Marca Comercial / Trade Mark | Referencia / Reference | Clasificación / Classification | Descripción / Description |
|---|---|---|---|
| HUYOUCZ | KZ-JP-95-B | FFP2 NR | MEDIA MASCARILLA, DE CINCO CAPAS DE FILTRADO, DOS LAZOS FIJOS DE SUJECIÓN A OREJAS, DE TIPO PLEGABLE. DISEÑADA PARA PROTEGER CONTRA PARTÍCULAS SÓLIDAS O LÍQUIDAS SUSPENDIDAS EN EL AIRE. NO REUTILIZABLE / FILTERING HALF MASK, FIVE FILTERING LAYERS, TWO EARLOOPS, FOLDING STYLE. DESIGNED TO PROTECT AGAINST AIRBORNE SOLID OR LIQUID PARTICLES. NON-REUSABLE |

Fecha de emisión / First issued on 2020-08-19
Fecha de expiración / Validity date 2025-08-19

Original Electronic Certificate

**AENOR INTERNACIONAL S.A.U.**
Génova, 6. 28004 Madrid. España
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Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

AENOR

# Certificado de Conformidad
# Certificate of Conformity

CE
0099

**A18/000197**

AENOR, como organismo notificado (nº 0099) para el Reglamento (UE) 2016/425, ha emitido este certificado a favor de
In compliance with Regulation (EU) 2016/425, the notified body AENOR (nº 0099) has issued this certificate to

## Changzhou Jinpeng Medical Equipment Co., Ltd

| | |
|---|---|
| Domicilio social / Registered office | No. 715 Heheng Road, Yanling Village, 213115 Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, (China) |
| para aprobar el<br>in order to approve the | Sistema de aseguramiento de la calidad del proceso de producción (módulo D)<br>Quality assurance system of the production process (module D) |
| conforme con el<br>in compliance with | Reglamento (UE) 2016/425, Anexo VIII<br>Regulation (EU) 2016/425, Annex VIII |
| Referencias / References | Detalladas en el Anexo al Certificado / Specified in Annex to the Certificate |
| Centro de producción / Production site | No. 715 Heheng Road, Yanling Village, 213115 Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, (China) |
| Esquema de evaluación<br>Assessment scheme | Este certificado se limita al sistema de aseguramiento de la calidad del proceso de producción para los equipos amparados por los certificados de examen UE de tipo detallados en el anexo a este Certificado y fabricados en el centro indicado más arriba.<br><br>This certificate is exclusively limited to the quality assurance of the production process for personal protective equipment covered by the EU type-examination certificates detailed in annex to the present certificate and to the above mentioned production site. |
| Fecha de emisión / First issued on | 2020-10-05 |
| Fecha de expiración / Validity date | 2023-10-05 |

Rafael GARCÍA MEIRO
Director General / CEO

Original Electronic Certificate

**AENOR INTERNACIONAL S.A.U.**
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

AENOR

# Certificado de Conformidad
# Certificate of Conformity

**A18/000197**

## Anexo al Certificado
## Annex to Certificate

| Protección / Protection | Certificados UE de tipo cubiertos / EU type examination certificates covered | Organismo notificado emisor / Issuing notified body | Fecha Validez / Validity date | Prenda / Garment |
|---|---|---|---|---|
| RESPIRATORIA / RESPIRATORY | A18/000111 | AENOR 0099 | 2025-08-19 | MASCARILLA / MASK |

Fecha de emisión / First issued on 2020-10-05
Fecha de expiración / Validity date 2023-10-05

**AENOR INTERNACIONAL S.A.U.**
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

Original Electronic Certificate

SIRIM
INTERNATIONAL CERTIFICATION

# CERTIFICATE OF APPRECIATION

This is to certify that the Quality Management System of

**[Changzhou Jinpeng Medical Equipment Co., Ltd]**
Unified Social Credit Code: 91320402745551034J
Operation Address : No.715, Heheng Road, Yanling village, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China
Registered Address : No.715, Heheng Road, Yanling village, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China

applicable to

**[Production and sales of daily masks (non-medical)]**

has been assessed and registered by SIRIM against the provisions of

**ISO 9001:2015**

This registration is subject to the company maintaining a Quality Management System to the above standard, which will be monitored by SIRIM.
The validity of this certificate may be verified on both CNCA's website (www.cnca.gov.cn) & SIRIM's website: www.sirim-global.com

Certificate No: 8120Q10181R0S
Initial Certification: 2020.09.01
Issue/Relssue Date: 2020.09.01

Registration Valid Until: 2023.08.31
Certificate Expiry: 2021.08.31

Certification Check

Signed by

Registered Office: Building 98, 507-06 Ru Shan Road, Pu Dong, Shanghai

161019130764

# Test Report

Report No.: [2020] WSZ FHL NO.6737

Product Name Particle filtering half mask

Applicant Changzhou Jinpeng Medical Equipment Co.,Ltd.

Manufacturer Changzhou Jinpeng Medical Equipment 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

检验专用章

# Test Report

| | | | |
|---|---|---|---|
| Product name | Particle filtering half mask | Model name | KZ-JP-95-B |
| | | Brand | HUYOUCZ |
| Laboratory/ Add. | Jiangsu Guojian Testing Technology Co., Ltd./ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China | | |
| Applicant/ Add/Tel | Changzhou Jinpeng Medical Equipment Co.,Ltd./715 Heheng Road, Yanling Village, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China./13861225085 | | |
| Manufacturer/ Add/Tel | Changzhou Jinpeng Medical Equipment Co.,Ltd./715 Heheng Road, Yanling Village, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China./13861225085 | | |
| Sample classification | FFP2 | Sample number | GW6737-2020 |
| Sample quantity | 110 pcs | Date of receipt of sample | 17/06/2020 |
| Test type | Entrusted inspection | Article/Batch/Style number | — |
| Date (s) of performance of tests | 17/06/2020~26/06/2020 | Testing location | Same as the Laboratory |
| Sample state | Meeting the requirements of testing | 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 | | |
| 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.<br>Date of issue: 26/06/2020 | | |
| Note | The test results presented in this report relate only to the submitted sample as received. | | |

Lu Bing
Approver (name, signature)

Wan Heng
Reviewer (name, signature)

Yang Ying
Chief Tester (name, signature)

| | |
|---|---|
| **Sample description:** | — |
| **Test item particulars:** | |
| Type of use ..... | ☐ re-useable particle filtering half mask<br>☒ 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 be 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.<br>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.<br>Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods.<br>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;<br>2) T.C. Temperature conditioned:<br>a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C;<br>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 requirements | 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 |
| | | | — | 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 | |
| | | | — | 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 | |
| | | | — | 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. | ☐ Fulfil the requirements after testing, or ☒ 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. | ☐ Tests results refer to S. No. 7(7.9.2), or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer | |

| S.No. (Cl.No.) | Test item | | Unit | Technical requirements | 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 | Sample 1: Having a wider visual field | | | | |
| | | | | | Sample 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] | 0.1% | 0.1% | 0.1% | Pass |
| | | | | | S.W.[1] | 0.1% | 0.1% | 0.1% | |
| | | | | | M.S+ T.C.[2] | 0.2% | 0.2% | 0.2% | |
| | | Paraffin oil | — | ≤6% | A.R.[1] | 0.3% | 0.4% | 0.4% | Pass |
| | | | | | S.W.[1] | 0.4% | 0.4% | 0.3% | |
| | | | | | M.S+ T.C.[2] | 1.0% | 1.2% | 1.1% | |
| | | [1] average penetration over a time of 30s, beginning 3 min after the start of the test reported<br>[2] max. penetration during exposure test reported;<br>Note:<br>The penetration of the filter of the particle filtering half mask shall meet the requirements below:<br>Maximum penetration of sodium chloride aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%<br>Maximum penetration of paraffin oil aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1% | | | | | | | |

| S.No. (Cl.No.) | Test item | Unit | Technical requirements | 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:0.1s | Pass |
| | | | | | The Sample is burning. Burning time:0.1s | |
| | | | | T.C. | The Sample is burning. Burning time:0.1s | |
| | | | | | The Sample is burning. Burning time:0.1s | |
| 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 | 0.7224% | Pass |
| | | | | Sample 2 | 0.7218% | |
| | | | | Sample 3 | 0.7230% | |
| | | | | average | 0.72% | |
| 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 |

| S.No. (Cl.No.) | Test item | | Unit | Technical requirements | 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. | No exhalation valve(s) | N/A |
| | | | — | 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. | 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. | 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. | 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 results refer to Table C&D, or ☒ 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. | No demountable parts | N/A |

**Table A- Leakage—Total Inward Leakage**

| S.No. (Cl.No.) | Test item | Unit | Technical requirements[1)] | 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. | 4.5 | 5.0 | 5.8 | 6.0 | 4.5 | 5.2 | Pass |
| | | | | | 5.2 | 6.6 | 7.2 | 7.3 | 5.7 | 6.4 | |
| | | | | | 4.8 | 5.7 | 5.8 | 6.2 | 4.7 | 5.4 | |
| | | | | | 5.4 | 6.2 | 6.7 | 6.9 | 4.9 | 6.0 | |
| | | | | | 4.8 | 5.7 | 6.0 | 6.2 | 4.3 | 5.4 | |
| | | | | T.C. | 5.2 | 6.3 | 7.0 | 7.2 | 5.7 | 6.3 | |
| | | | | | 4.2 | 5.5 | 5.6 | 5.8 | 4.6 | 5.1 | |
| | | | | | 4.7 | 5.4 | 5.6 | 6.2 | 4.2 | 5.2 | |
| | | | | | 4.8 | 5.7 | 5.9 | 6.1 | 4.6 | 5.4 | |
| | | | | | 5.2 | 5.8 | 6.4 | 6.6 | 4.7 | 5.7 | |

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**

| Test Subject No. | Length of face (mm) | Width of face (mm) | Depth of face (mm) | Width of mouth (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 | 120 | 135 | 125 | 50 |

**Table B- Breathing Resistance**

| S.No. (Cl.No.) | Test item | | Unit | Technical requirements[1)] | 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. | 0.6 | 0.5 | 0.6 | 0.5 | 0.6 | Pass |
| | | | | | | 0.5 | 0.6 | 0.6 | 0.6 | 0.6 | |
| | | | | | | 0.6 | 0.6 | 0.5 | 0.6 | 0.5 | |
| | | | | | S.W. | 0.6 | 0.6 | 0.5 | 0.6 | 0.6 | |
| | | | | | | 0.6 | 0.5 | 0.6 | 0.6 | 0.5 | |
| | | | | | | 0.5 | 0.6 | 0.6 | 0.5 | 0.6 | |
| | | | | | T.C. | 0.6 | 0.6 | 0.5 | 0.6 | 0.6 | |
| | | | | | | 0.6 | 0.5 | 0.6 | 0.6 | 0.5 | |
| | | | | | | 0.5 | 0.6 | 0.6 | 0.5 | 0.6 | |
| | | Inhalation 95 L/min | | ≤2.4 | A.R. | 1.8 | 1.7 | 1.8 | 1.8 | 1.7 | Pass |
| | | | | | | 1.8 | 1.8 | 1.7 | 1.8 | 1.8 | |
| | | | | | | 1.7 | 1.8 | 1.8 | 1.7 | 1.8 | |
| | | | | | S.W. | 1.8 | 1.7 | 1.8 | 1.8 | 1.7 | |
| | | | | | | 1.7 | 1.8 | 1.8 | 1.7 | 1.8 | |
| | | | | | | 1.8 | 1.8 | 1.7 | 1.8 | 1.8 | |
| | | | | | T.C. | 1.7 | 1.8 | 1.8 | 1.7 | 1.7 | |
| | | | | | | 1.8 | 1.8 | 1.7 | 1.8 | 1.8 | |
| | | | | | | 1.8 | 1.7 | 1.8 | 1.8 | 1.8 | |
| | | Exhalation 160 L/min | | ≤3.0 | A.R. | 2.6 | 2.7 | 2.6 | 2.6 | 2.6 | Pass |
| | | | | | | 2.6 | 2.6 | 2.6 | 2.6 | 2.7 | |
| | | | | | | 2.7 | 2.6 | 2.7 | 2.5 | 2.6 | |
| | | | | | S.W. | 2.6 | 2.7 | 2.6 | 2.6 | 2.6 | |
| | | | | | | 2.7 | 2.6 | 2.6 | 2.7 | 2.6 | |
| | | | | | | 2.6 | 2.6 | 2.7 | 2.6 | 2.5 | |
| | | | | | T.C. | 2.6 | 2.7 | 2.6 | 2.6 | 2.7 | |
| | | | | | | 2.7 | 2.6 | 2.6 | 2.5 | 2.6 | |
| | | | | | | 2.6 | 2.6 | 2.7 | 2.6 | 2.6 | |

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.

**Table C- Clogging Test—Breathing resistance**

| S.No. (Cl.No.) | Test item[1) 2)] | | Unit | Technical requirements[1) 2)] (mbar) | 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 | mbar | — | 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. (Cl.No.) | Test item | | Unit | Technical requirements | Test result | | Single item decision |
|---|---|---|---|---|---|---|---|
| 19 (7.17) | Clogging test- Penetration of filter material | Paraffin oil | — | — | A.R. | | N/A |
| | | | | | T.C. | | |
| | | | | | T.C. | | |

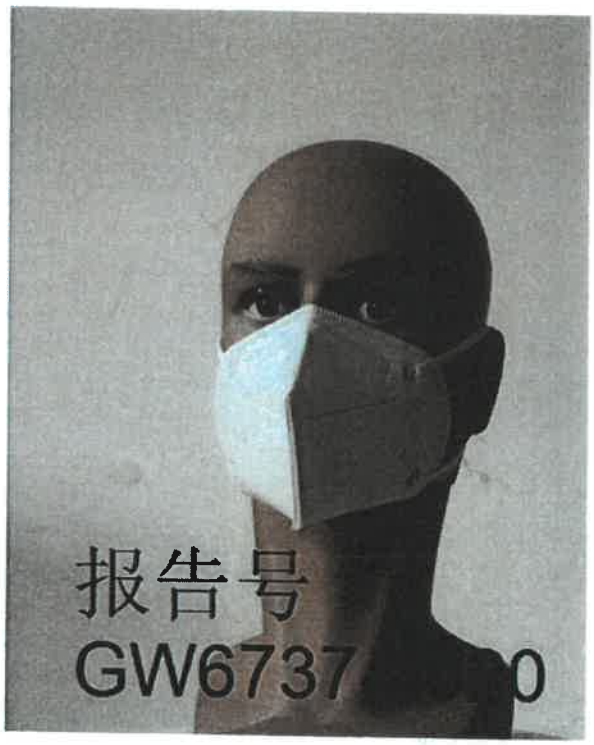
Note: Maximum penetration of test aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%

| 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

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国际互认
检测
TESTING
CNAS L7901

# 检验检测报告

# TEST REPORT

STFWT20204824

| | |
|---|---|
| Product Name | Particle Filtering Half Mask |
| Trust Unit | Changzhou Jinpeng Medical Equipment Co., Ltd |
| Manufacturer | Changzhou Jinpeng Medical Equipment Co., Ltd |
| Test Category | Trust Test |

SPC 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

# Test Report

STFWT20204824 

| | | | |
|---|---|---|---|
| Product Name | Particle Filtering Half Mask | Specification Type | Adult |
| | | Trademark | --- |
| Trust Unit | Changzhou Jinpeng Medical Equipment Co., Ltd | Tel | 13861225085 |
| Manufacturer | Changzhou Jinpeng Medical Equipment Co., Ltd | Sample Grade | KN95 |
| Sample Quantity | 60 只 | Sample Receiving Date | 2020-03-13 |
| Test Category | Trust Test | Serial Number | 20200308 |
| Samples Conditions | Accord with detecting request | | |
| Document and Decide Accordance | GB 2626-2006《Respiratory Protective Apparatus Self-suction filtered anti-particulate respirator》 | | |
| Test Conclusion | The samples were tested, and the items tested meet the requirements of GB 2626-2006 standard KN95 level.<br>SignatuimDate:2020-03-24 | | |
| Remarks | This report is responsible for samples only. | | |

Approver 陈敏 Examiner 杨森 Majortester 熊水萍

# Testing Results



| Serial | Test Items | Unit | Requirement | Results | Individual Judgment |
|---|---|---|---|---|---|
| 1 | General requirements | —— | Materials:<br>a) Materials in direct contact with the face should be harmless to the skin.<br>(b) The filter media shall be harmless to humans.<br>(c) The material used shall have sufficient strength to withstand breakage or deformation during its normal service life.<br>Structure:<br>(a) should not be susceptible to structural damage and the design, composition and installation of the components should not pose any hazard to the user.<br>(b) The headband should be designed to be adjustable and easy to wear and remove, should securely fasten the mask to the face and should be worn without visible compression or pain, and the headband design of the replaceable half mask and full mask should be replaceable.<br>(c) Should have as small a dead space and a large field of view as possible.<br>(d) The disposable mask shall be constructed to ensure a close fit to the face and shall be free from deformation during its service life. | Structure:<br>a) That is not susceptible to structural damage and the design, composition and installation of the components do not pose any hazard to the user.<br>b) The headband is designed to be adjustable for easy wearing and removal, to hold the mask securely to the face, and to be worn without significant compression or pressure pain.<br>c) Has a smaller dead space and a larger field of view. | —— |
| 2 | External Inspection | —— | The surface shall be free from breakage, deformation and other obvious defects, the material and construction of the components shall be able to withstand normal conditions of use and the temperature, humidity and mechanical shocks that may be encountered, the headband shall be adjustable and the headband design of the replaceable mask shall be replaceable. Parts should not be dislodged, damaged or deformed after pre-treatment with temperature and humidity. | Meet the requirements. | Qualified |
| 3 | Respiratory resistance | Pa | Total inhalation resistance should not exceed 350 and total exhalation resistance should not exceed 250 for each sample. | Sample No. / MV<br>Total inspiratory resistance – Unprocessed: 21# 122.4; 22# 119.2<br>Total inspiratory resistance – Pretreatment: 25# 119.4; 26# 117.6<br>Total exhalation resistance – Unprocessed: 23# 107.4; 24# 99.5<br>Total exhalation resistance – Pretreatment: 27# 92.4; 28# 91.9 | Qualified |
| 4 | Vision | —— | Lower field of view≥60° | 64° | Qualified |
| 5 | Dead Space | | Volume percentage of carbon dioxide shall be ≤ 1% | Volume percentage of carbon dioxide is 0.6%. | Qualified |

# Testing Results



| Serial | Test Items | Unit | Requirement | Results | | | | Individual Judgment |
|---|---|---|---|---|---|---|---|---|
| | | | | Sample No. | | MV | | |
| 6 | Filtration efficiency/% (NaCl particulate matter) | —— | KN95：≥95.0 | Unprocessed | 1# | Initial | 97.7 | Qualified |
| | | | | | | Loaded | 97.5 | |
| | | | | | 2# | Initial | 97.9 | |
| | | | | | | Loaded | 97.7 | |
| | | | | | 3# | Initial | 98.0 | |
| | | | | | | Loaded | 97.7 | |
| | | | | | 4# | Initial | 98.2 | |
| | | | | | | Loaded | 98.0 | |
| | | | | | 5# | Initial | 97.9 | |
| | | | | | | Loaded | 97.7 | |
| | | | | | 6# | Initial | 98.4 | |
| | | | | | | Loaded | 98.2 | |
| | | | | | 7# | Initial | 98.2 | |
| | | | | | | Loaded | 98.0 | |
| | | | | | 8# | Initial | 98.4 | |
| | | | | | | Loaded | 98.1 | |
| | | | | | 9# | Initial | 98.6 | |
| | | | | | | Loaded | 98.4 | |
| | | | | | 10# | Initial | 98.4 | |
| | | | | | | Loaded | 98.1 | |
| | | | | Pretreatment | 11# | Initial | 97.6 | |
| | | | | | | Loaded | 97.4 | |
| | | | | | 12# | Initial | 97.8 | |
| | | | | | | Loaded | 97.6 | |
| | | | | | 13# | Initial | 97.6 | |
| | | | | | | Loaded | 97.4 | |
| | | | | | 14# | Initial | 97.9 | |
| | | | | | | Loaded | 97.7 | |
| | | | | | 15# | Initial | 98.0 | |
| | | | | | | Loaded | 97.8 | |
| 7 | Headband | —— | Each headband, buckle and other adjusting parts of the mask should not slip or break when subjected to a 10N tension for 10s. | Not processed: 31#Each headband, buckle and other adjusting parts of the 1# mask did not slip or break after being subjected to 10N of tension for 10s. After pretreatment: Each headband, buckle and other adjusting parts of the 5# mask did not slip or break after being subjected to 10N tension for 10s. | | | | Qualified |

# Testing Results



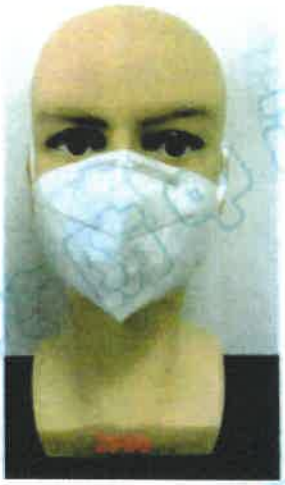
| Serial | Test Items | Unit | Requirement | | Results | | | Individual Judgment |
|---|---|---|---|---|---|---|---|---|
| 8 | Breath valve cover | —— | The exhalation valve cover is subjected to 10N axial tension for 10s, there should be no slippage, fracture and deformation. | | Without this component, this item will not be evaluated | | | —— |
| 9 | Breathing valve air tightness | —— | Each sample shall be free from one of the following conditions.(a) When the pumping flow rate has reached 500 mL/min, the system negative pressure is less than 1180 Pa.(b) The time for the expiratory valve to return to atmospheric pressure is less than 20s. | | Without this component, this item will not be evaluated | | | —— |
| 10 | Leakage/% (Total Inward Leakage of Disposable Mask) | —— | Filter media level | Based on Til of each action (i. e. 10 persons and 5 actions) , TIL of at least 46 actions in 50 actions | Unprocessed | 16# | There are 47 actionss with a TIL less than 11. | Qualified |
| | | | | | | 17# | There are 47actionss with a TIL less than 11. | |
| | | | | | | 18# | There are 47actionss with a TIL less than 11. | |
| | | | | | | 19# | There are 47actionss with a TIL less than 11. | |
| | | | | | | 20# | There are 47actionss with a TIL less than 11. | |
| | | | KN95 | <11 | Pretreatment | 21# | There are 47 actionss with a TIL less than 11. | |
| | | | | | | 22# | There are 47 actionss with a TIL less than 11. | |
| | | | | | | 23# | There are 47actionss with a TIL less than 11. | |
| | | | | | | 24# | There are 47 actionss with a TIL less than 11. | |
| | | | | | | 25# | There are 47 actionss with a TIL less than 11. | |
| | | | Filter media level | Total Inward Leakage for at least 8 out of 10 subjects when evaluated on a total person basis | Unprocessed | 16# | There were 9 people with a TIL less than 8. | |
| | | | | | | 17# | There were 9 people with a TIL less than 8. | |
| | | | | | | 18# | There were 9 people with a TIL less than 8. | |
| | | | | | | 19# | There were 9 people with a TIL less than 8. | |
| | | | | | | 20# | There were 9 people with a TIL less than 8. | |
| | | | KN95 | <8 | Pretreatment | 21# | There were 9 people with a TIL less than 8. | |
| | | | | | | 22# | There were 9 people with a TIL less than 8. | |
| | | | | | | 23# | There were 9 people with a TIL less than 8. | |
| | | | | | | 24# | There were 9 people with a TIL less than 8. | |
| | | | | | | 25# | There were 9 people with a TIL less than 8. | |

# Testing Results



| Serial | Test Items | Unit | Requirement | Results | Individual Judgment |
|---|---|---|---|---|---|
| 11 | Flammability | —— | The parts exposed to the flame should not burn after being removed from the flame; if they do, the renewal time should not exceed 5s. | Not processed:<br>1#, 2#The parts of the specimen exposed to the flame did not burn after being removed from the flame.<br>After pretreatment:<br>3#, 4#The parts of the specimen exposed to the flame did not burn after being removed from the flame. | Qualified |
| 12 | Connect and connect parts | —— | Replaceable type filter element and masks, breathing tube and filter element and mask all connections and links between parts, in 10 n under axial tension and lasts 10 s, should not appear slippage, fracture or deformation. | With the abandoned mask, do not check this | —— |

# Test sample picture



The following blank