编号 320582666202004070386

统一社会信用代码

91320582774679 58XE (1/1)

# 营业执照

(副本)

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

名　　称　张家港神港医疗用品有限公司

类　　型　有限责任公司

法定代表人　钱程

经营范围　一类医疗器械生产；二类6866医用高分子材料及制品、塑料制品制造、加工、销售；纸制品包装、塑料包装；包装装潢印刷品印刷、其他印刷品印刷；塑料、纸制品、金属制品、自动化设备、化工购销；自营和代理各类商品和技术的进出口业务。日用口罩（非医用）生产；第二类医疗器械销售；医护人员防护用品批发；医护人员防护用品零售；特种劳动防护用品销售；卫生用品和一次性使用医疗用品销售；（依法须经批准的项目，经相关部门批准后方可开展经营活动）

注册资本　1200万元整

成立日期　2005年05月17日

营业期限　2005年05月17日至******

住　　所　张家港市凤凰镇西参村

登记机关　张家港市行政审批局

2020 年 04 月 07 日

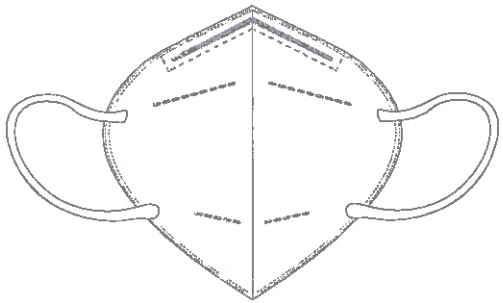
国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

SHENGANG
Together we care

SHENGANG
Together we care




Particulate Respirator

**10** PCS

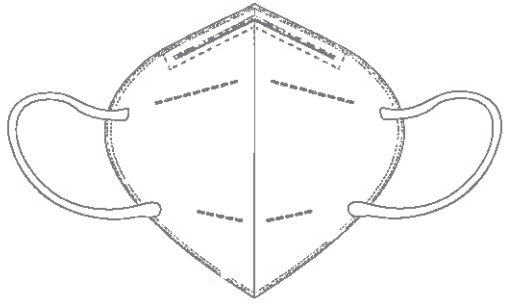
## Particulate Respirator CE 2163

**Product name:** Particulate Respirator
**Specifications:** M2004
**Materials:** PP nonwoven, Melt-blown fabric, Hot air cotton
**Executive Standard:** EN 149:2001+A1 2009 FFP2 NR
**Manufacturer:** Zhangjiagang Shengang Medical Products Co., Ltd
**Address:** Xican Village, Fenghuang Town, 215614 Zhangjiagang City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA
**Tel:** +86-0512-58423293

**Applicable range**

- Suitable for adults' daily travel protection, not suitable for toxic gas environment use. This product cannot be replaced with gas masks and medical masks.
- This protective mask cannot generate oxygen and should not be used in hypoxic environments.
- It's better not to use the product if the air is not flowing, breathing is not smooth, or during sleep.
- Please use it correctly to avoid serious consequences caused by improper use.
- Store in a dry and ventilated place (temperature: -30 ° C ~ 40 ° C, relative humidity <80%).
- Masks are disposable and cannot be washed

2023.05.05

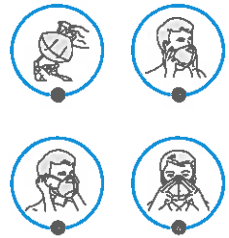



Particulate Respirator

**10** PCS

## Particulate Respirator CE 2163

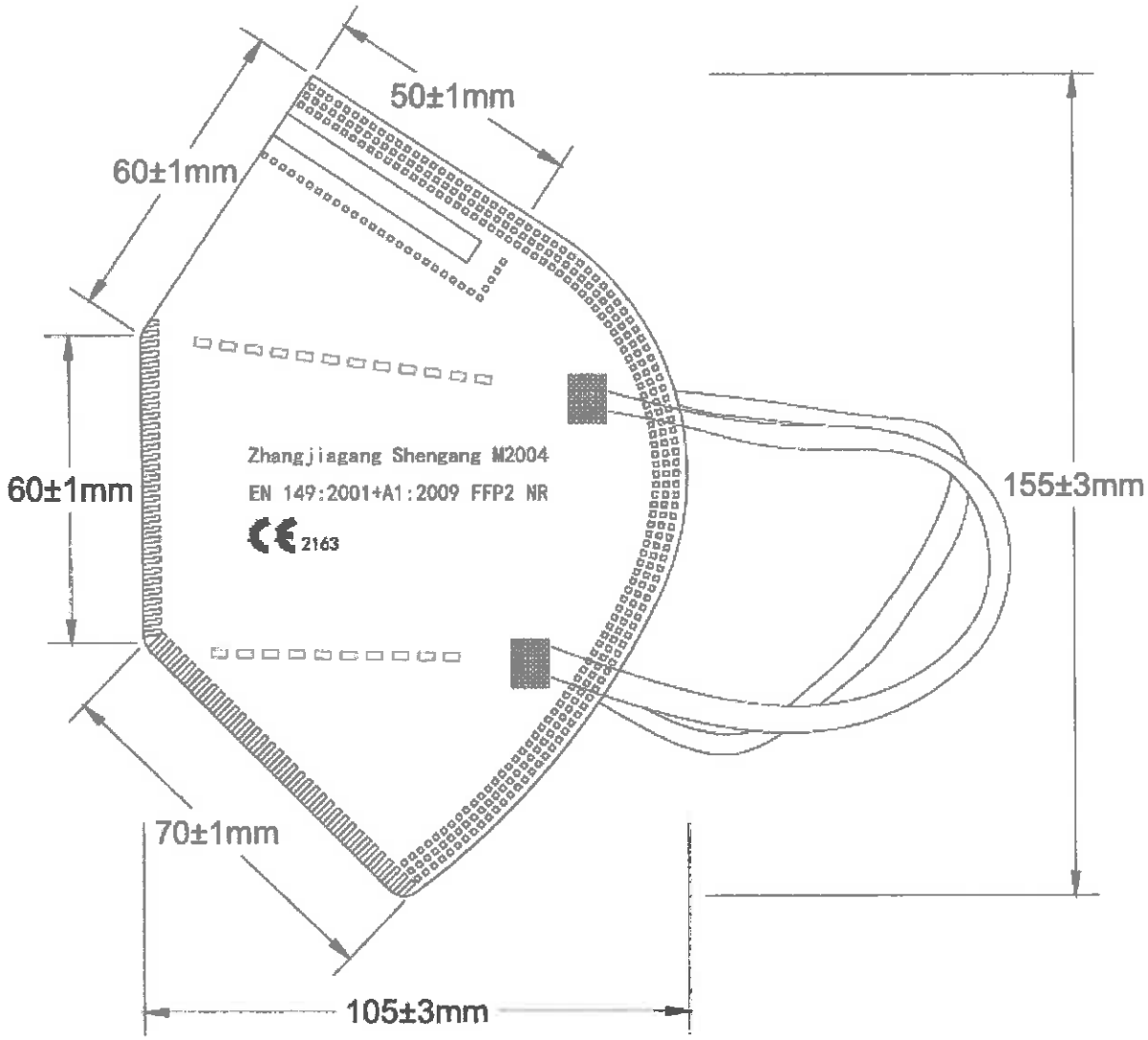
**Way of wearing:**



**Warning tips**

- When feeling breathing resistance is significantly increased, or when the mask is dirty or damaged, it should be replaced in time.
- This product should not be shared with others.

**Please pay attention to the air tightness check after wearing the mask.**


50±1mm
60±1mm
60±1mm
155±3mm
Zhangjiagang Shengang M2004
EN 149:2001+A1:2009 FFP2 NR
CE 2163
70±1mm
105±3mm

## The User information of Particulate Respirator

**【Product Name & Model No.】** Filtering half mask M2004 15.5x10.5cm

**【Primary Structure】** Main mask,nose clip and ear loop.The main mask is made of 5layer filters,non-sterile and disposable.

**【Use Range】** Mechanically generated dusts, non-oil mists from processing minerals including coal, iron ore, wood, cotton, flour, and certain other substances in concentrations up to ten times the Occupational Exposure Limits or according to local regulations.

**【Warnings】**

Paint spraying and sandblasting applications or for protection against gases and vapors. Do not use in atmospheres containing less than 19.5% oxygen, as this respirator does not supply oxygen. Not for use in oil mist atmospheres

**【Using Instructions】**

1:Stretch a mask,and check the integrity of its front surface.

2:Position the mask under your chin with the nose-piece up.

3:Extend the mask to cover your mouth and nose,loop the straps over your ears and adjust them to a comfortable state.

4:Use forefingers and middle fingers of both hands to mold the nosepiece to the shape of your nose by pushing downward and inward.

5:Place both hands completely over the mask,and perform positive and negative pressure tests to keep your mask from leaking.

**【Storage Condition and Methods】**

The mask should be stored in dry, ventilated, and non-corrosive gas environment, relative humidity < 80%, temperature from -30℃to 40℃. Keep away from fire and flammable materials. Heavy load, direct sunlight, rain or snow should be avoided during transportation.

**【The Manufactured date】**

See the box

**【The Expiry time】**

3 years

**【Manufacturer & Address】** Zhangjiagang Shengang Medical Products Co.,Ltd

Xican Village,Fenghuang Town,215614 Zhangjiagang City,Jiangsu Province,PEOPLE'S REPUBLIC OF CHINA

**【Telephone】** 0512-58423293

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

# EU TYPE EXAMINATION CERTIFICATE

## Certificate No: 2163-PPE-840

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

**Zhangjiagang Shengang Medical Products Co., Ltd.**
Xican Village, Fenghuang Town, 215614 Zhangjiagang City, Jiangsu 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:** SHENGANG **Model:** M2004
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 **25/06/2020** 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
UNIVERSALCERT.COM

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

# CERTIFICATE OF CONFORMANCE

## Certificate No: 2163-PPE–840/01

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

**Zhangjiagang Shengang Medical Products Co., Ltd.**
Xican Village, Fenghuang Town, 215614 Zhangjiagang City, Jiangsu 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. |
| SHENGANG / M2004 | FFP2 | 2163-PPE–840 | 25.06.2020 | 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 **25/06/2020** and will be valid for one year, until **25/06/2021** 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

UNIVERSAL
CERTIFICATION

## TECHNICAL ASSESSMENT REPORT

**REPORT DATE / NO:** 25.06.2020 / 2163- KKD-840

**Manufacturer:** Zhangjiagang Shengang Medical Products Co., Ltd.
**Address:** Xican Village, Fenghuang Town, 215614 Zhangjiagang City, Jiangsu Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Quality Supervision and Inspection Center for Special Safety Proteciton Products accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-7901 for the product identified below, dated 21.05.2020 with Serial Id STFWT202012424 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 09 June 2020 Version 01 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the client.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

**Product Description:** Particle Filtering Half Mask
**Classification:** FFP2 NR
**Trademark:** SHENGANG **Model:** M2004

UNIVERSAL CERTIFICATION CE 2163 Notified Body



UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi. Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F.+90 216 455 80 08 info@universalcert.com

UNIVERSAL
CERTIFICATION

## ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT

**1.1. Design principles**

**1.1.1. Ergonomics**

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level. The test resuts with human subjects did not report any problem with the ergonomics of the product.

**1.1.2. Levels and classes of protection**

**1.1.2.1. Highest level of protection possible**

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

**1.1.2.2. Classes of protection appropriate to different levels of risk**

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

**1.2. Innocuousness of PPE**

**1.2.1. Absence of risks and other inherent nuisance factors**

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use. The manufacturer declares in his technical file that according to the results of risk analysis and the material properties they use in the manufacturing, the product has no hazardous content for health.

**1.2.1.1. Suitable constituent materials**

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users. The material selection is processed in the technical manufacturing process and documented.

**1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user**

Any part of the PPE that is in contact or is liable to come into contact with the user when the FFE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries is evaluated and reported in the test report.

**1.2.1.3. Maximum permissible user impediment**

Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

**1.3 Comfort and effectiveness**

**1.3.1. Adaptation of PPE to user morphology**

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

**1.3.2. Lightness and design strength**

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

**1.4. Information supplied by the manufacturer**

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE.

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination

UNIVERSAL CERTIFICATION CE 2163 Notified Body



UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No 44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

## 2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

**2.1. PPE incorporating adjustment systems**

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

**2.3. PPE for the face, eyes and respiratory system**

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

**2.4. PPE subject to ageing**

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions. The product is for single use and tested with simulated wearing conditioning.

**2.6. PPE for use in potentially explosive atmospheres**

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

**2.8. PPE for intervention in very dangerous situations**

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

**2.9. PPE incorporating components which can be adjusted or removed by the user**

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

**2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety**

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation: in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.

If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

## 3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

**3.10.1. Respiratory protection**

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.

The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.

The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.

In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.



UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ Keyap Ticaret Merkezi. Necip Fazıl Bulvarı, E2 Blok. No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

## Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to. Clauses Corresponding to the (EU) 2016/425 Regulation, Essential Health and Safety Requirements given above.

| Conforming to EN 149:2001 + A1:2009 Standard Requirements | |
|---|---|
| | **Classification: Particle Filtering Half Mask** |
| *Article* 5 | The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as:<br>Filtering Efficiency and maximum Total Inward Leakage: Classified as FFP2<br>Mask is classified for single shift use, NR |
| *Article* 7.4 | **Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage, the masks are in plastic sealed bags in the card box. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report. |
| *Article* 7.5 | **Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect the health and safety of users.<br>Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects. |
| *Article* 7.6 | **Cleaning and Disinfection:** Particle filtering half mask is not designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer. |
| *Article* 7.7 | **Practical Performance :**<br><br>The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfections reported during total inward tests about the comfort, field of vision and fastening issues. |

| Assessed Elements | Positive | Negative | Requirements in accordance with EN 149:2001 + A1:2009 and Result |
|---|---|---|---|
| 2.Head harness comfort | 2 | 0 | Positive results are obtained from the test subjects<br>No imperfections |
| 3.Security of fastenings | 2 | 0 | |
| 5.Field of vision | 2 | 0 | |

**Conditioning :** (A.R.) As Received, original

| | |
|---|---|
| *Article* 7.8 | **Finish of Parts:** The test report states that the particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs. |
| *Article* 7.9.1 | **Total Inward Leakage:**<br>The Total Inward Lekage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the condcution of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as Temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each excersize are available in the test report.<br><br>It was reported that;<br>At least 47 out of 50 exercise measurement results are smaller or equal to 11%.<br>At least 9 of 10 individual's arithmetic mean is smaller or equal to 8%. |

**According to the reported results, the product meets the limits for FFP1 and FFP2 classification.**

**Penetration of filter material: Sodium Chloride Testing**

| Condition | No. of Sample | Sodium Chloride Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 19# | 1.14 | | |
| (A.R.) | 20# | 1.25 | | |
| (A.R.) | 21# | 1.21 | FFP1 ≤ 20 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in: 7.9.2 in range of the FFP1, FFP2 classes. |
| (S.W.) | 22# | 1.24 | | |
| (S.W.) | 23# | 1.33 | FFP2 ≤ 6 % | |
| (S.W.) | 24# | 1.41 | | |
| (M.S. T.C.) | 25# | 1.47 | FFP3 ≤ 1 % | |
| (M.S. T.C.) | 26# | 1.54 | | |
| (M.S. T.C.) | 27# | 1.62 | | |

*Article* 7.9.2

**Conditioning :** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

95 L/min = 1,6 $dm^3.sn^{-1}$



UNIVERSAL SERTIFIKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi. Necip Fazıl Bulvarı. E2 Blok. No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

*Article* 7.9.2

**Penetration of filter material: :** Paraffin Oil Testing

| Condition | No. of Sample | Paraffin Oil Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 28# | 2.52 | | |
| (A.R.) | 29# | 2.59 | | |
| (A.R.) | 30# | 2.68 | FFP1 ≤ 20 % | Filtering half masks fulfil the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1, FFP2 classes. |
| (S.W.) | 31# | 2.74 | | |
| (S.W.) | 32# | 2.79 | FFP2 ≤ 6 % | |
| (S.W.) | 33# | 2.88 | | |
| (M.S. T.C.) | 34# | 2.94 | FFP3 ≤ 1 % | |
| (M.S. T.C.) | 35# | 3.01 | | |
| (M.S. T.C.) | 36# | 3.12 | | |

**Conditioning :** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

*Article* 7.10

**Compatibility with skin:** In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported. (No negative reporting on practical performance and TIL test results)

*Article* 7.11

**Flammability :**

| Condition | No. of Sample | Visual inspection | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 37# | Didn't burn | Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame | Passed Laboratory claims that the tested items did not burn for 5 seconds and fulfils the requirement of the standard |
| (A.R.) | 38# | Didn't burn | | |
| (T.C.) | 39# | Didn't burn | | |
| (T.C.) | 40# | Didn't burn | | |

**Conditioning :** (A.R.) As Received, original
(T.C.) Temperature Conditioning

*Article* 7.12

**Carbon dioxide content of the inhalation air:**

| Condition | No. of Sample | $CO_2$ content of the inhalation air [%] by volume | An average $CO_2$ content of the inhalation air | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|---|
| (A.R.) | 41# | 0.56 | 0,55 [%] | $CO_2$ content of the inhalation air shall not exceed an average of 1,0% by volume | Passed Filtering half masks fulfil requirements of the standard |
| (A.R.) | 42# | 0.55 | | | |
| (A.R.) | 43# | 0.54 | | | |

**Conditioning :** (A.R.) As Received, original

*Article* 7.13

**Head harness:** In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the head harness are capable of holding the mask firmly enough.

*Article* 7.14

**Field of vision:** In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is weared.

*Article* 7.15

**Exhalation Valve(s):** The model under inspection have no valves.

*Article* 7.16

**Breathing Resistance:** Inhalation

The overall evaluation of the results gathered for 9 different samples 3 as received, 3 with temparature conditioning, 3 simulated wearing treatment complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min. The measurement details for each single mask tested are available in the test report.

**Passed.**

UNIVERSAL CERTIFICATION CE 2163 Notified Body



UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Kayap Ticaret Merkezi, Necip Fazıl Bulvarı E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

| | |
|---|---|
| *Article* 7.17 | **Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable. *(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)* |
| *Article* 7.18 | **Demountable Parts:** There are no demountable parts of the mask. |
| *Article* 8 | **Testing:** All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask. |
| *Article* 9 | **Marking – Packaging:** Necessary markings are available on the product package (box). The manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the end date of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 9.1 of the technical file.<br><br>The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing M2004. The mask template (drawing) indicates that the mask will carry information about the manufacturer / trademark (SHENGANG) of the manufacturer, Type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. Even the tested sample by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model drawing M2004 exists in the technical file of the manufacturer, Annex 6 of technical file. |
| *Article* 10 | **Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate. The manufacturer shall include this documented user information text in every smallest commercially available package, Annex 8 of Technical file. |

| PREPARED BY | APPROVED BY |
|---|---|
| Osman CAMCI<br>PPE Expert | Suat KAÇMAZ<br>General Manager |



UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

# 检验检测报告

# TEST REPORT

STFWT202012424

| | |
|---|---|
| Product Name | Particulate Respirator |
| Trust Unit | ZHANGJIAGANG SHENGANG MEDICAL PRODUCTS CO.,LTD. |
| Manufacturer | ——— |
| Test Category | Entrusted Inspection |

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

STFWT202012424



| | | | |
|---|---|---|---|
| Product Name | Particulate Respirator | Specification Type | M2004 |
| | | Trademark | —— |
| Trust Unit | ZHANGJIAGANG SHENGANG MEDICAL PRODUCTS CO.,LTD. | Tel | —— |
| Manufacturer | —— | Sample Grade | FFP2 |
| Sample Quantity | 70 只 | Sample Receiving Date | 2020-05-05 |
| Test Category | Entrusted inspection | Serial Number | —— |
| Samples Conditions | Meet the testing requirements | | |
| Document and Decide Accordance | EN 149：2001+A1：2009《*Respiratory protective devices -Filtering half masks to protect against particles-Requirements，testing，marking*》 | | |
| Test Conclusion | The samples were tested, the items tested meet the requirements of EN 149:2001+A1:2009 standard for FFP2 level.<br>Signature Date：2020-05-21<br>(1) | | |
| Remarks | The head harness of the mask provided by the applicant is ear hanging.<br>Compatibility with skin is not recognized by the center. The test data are only for reference.<br>The sample is not marked for reuse and does not require testing for blocking performance.<br>The test conclusion of this report is only for the items inspected and does not mean that the uninspected items or functions meet the requirements.<br>The results apply to the sample as received. | | |

Approver 陈敏 Examiner 杨森 Major tester 丁依

**7.5 Material** — **Pass[1]**

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.

**Note1: Refer to Annex A for test data.**

**7.6 Cleaning and disinfecting** — **N/A[2]**

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.

**Note2: Non-reusable respirator.**

**7.7 Practical performance** — **Pass[3]**

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

**Note3: Refer to Annex A for test data.**

**7.8 Finish of parts** — **Pass**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

**7.9.1 Total inward leakage** **Pass[4]**

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;

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

**Note4: Refer to Annex A for test data.**

**7.9.2 Penetration of filter material** **Pass[5]**

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

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



**Note5: Refer to Annex A for test data.**

**7.10 Compatibility with skin** **Pass[6]**

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.

**Note6: Refer to Annex A for test data.**

**7.11 Flammability** **Pass[7]**

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.

**Note7: Refer to Annex A for test data.**

**7.12 Carbon dioxide content of the inhalation air** **Pass[8]**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an

**Note8: Refer to Annex A for test data.**

**7.13 Head harness** **Pass[9]**

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

**Note9: Refer to Annex A for test data.**

**7.14 Field of vision** **Pass[10]**

The field of vision is acceptable if determined so in practical performance tests.

**Note10: Refer to Annex A for test data.**

**7.15 Exhalation valve** **N/A[11]**

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.

**Note11: Valve-less respirator.**

**7.16 Breathing resistance** **Pass[12]**

| 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 |

**Note12: Refer to Annex A for test data.**

**7.17 Clogging** N/A[13]

**7.17.2 Breathing resistance** N/A[13]

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

**7.17.3 Penetration of filter material**

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

N/A[13]

Note13: Non-reusable respirator.

**7.18 Demountable parts** N/A[14]

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Note14: No demountable parts.

## Annex A: Summarization of Test Data

| Clause | | Result | | | Assessment |
|---|---|---|---|---|---|
| 7.5 | Material | Simulated wearing treatment | 1# | No mechanical failure | Pass |
| | | | 2# | No mechanical failure | |
| | | | 3# | No mechanical failure | |
| | | Temperature conditioned | 4# | No mechanical failure | |
| | | | 5# | No mechanical failure | |
| | | | 6# | No mechanical failure | |
| 7.9 | Practical performance | As received | 7# | No mechanical failure | Pass |
| | | | 8# | No mechanical failure | |
| 7.9.1 | Total inward leakage | Individual exercise result | | | Pass |
| | | As received | 9# | 47 out of the 50 individual exercise results ≤ 11% | |
| | | | 10# | 47 out of the 50 individual exercise results ≤11% | |
| | | | 11# | 47 out of the 50 individual exercise results ≤ 11% | |
| | | | 12# | 47 out of the 50 individual exercise results ≤11% | |
| | | | 13# | 47 out of the 50 individual exercise results ≤ 11% | |
| | | Temperature conditioned | 14# | 47 out of the 50 individual exercise results ≤11% | |
| | | | 15# | 47 out of the 50 individual exercise results ≤ 11% | |
| | | | 16# | 47 out of the 50 individual exercise results ≤11% | |
| | | | 17# | 47 out of the 50 individual exercise results ≤ 11% | |
| | | | 18# | 47 out of the 50 individual exercise results ≤11% | |
| | | Individual wearer arithmetic means | | | |
| | | As received | 9# | 9 individual wearer arithmetic means≤ 8% | |
| | | | 10# | 9 individual wearer arithmetic means≤ 8% | |
| | | | 11# | 9 individual wearer arithmetic means≤ 8% | |
| | | | 12# | 9 individual wearer arithmetic means≤ 8% | |
| | | | 13# | 9 individual wearer arithmetic means≤ 8% | |
| | | Temperature conditioned | 14# | 9 individual wearer arithmetic means≤ 8% | |
| | | | 15# | 9 individual wearer arithmetic means≤ 8% | |
| | | | 16# | 9 individual wearer arithmetic means≤ 8% | |
| | | | 17# | 9 individual wearer arithmetic means≤ 8% | |
| | | | 18# | 9 individual wearer arithmetic means≤ 8% | |

| Clause | | Result | | | Assessment |
|---|---|---|---|---|---|
| 7.9.2 | Penetration of filter material/% | Sodium chloride test(95L/min) | | | Pass |
| | | As received | 19# | 1.14 | |
| | | | 20# | 1.25 | |
| | | | 21# | 1.21 | |
| | | Simulated wearing treatment | 22# | 1.24 | |
| | | | 23# | 1.33 | |
| | | | 24# | 1.41 | |
| | | M.S.+T.C. | 25# | 1.47 | |
| | | | 26# | 1.54 | |
| | | | 27# | 1.62 | |
| | | Paraffin oil test(95L/min) | | | |
| | | As received | 28# | 2.52 | |
| | | | 29# | 2.59 | |
| | | | 30# | 2.68 | |
| | | Simulated wearing treatment | 31# | 2.74 | |
| | | | 32# | 2.79 | |
| | | | 33# | 2.88 | |
| | | M.S.+T.C. | 34# | 2.94 | |
| | | | 35# | 3.01 | |
| | | | 36# | 3.12 | |
| 7.10 | Compatibility with skin | As received | 9# | No irritation or any other adverse effect to health | Pass |
| | | | 10# | No irritation or any other adverse effect to health | |
| | | | 11# | No irritation or any other adverse effect to health | |
| | | | 12# | No irritation or any other adverse effect to health | |
| | | | 13# | No irritation or any other adverse effect to health | |
| | | Temperature conditioned | 14# | No irritation or any other adverse effect to health | |
| | | | 15# | No irritation or any other adverse effect to health | |
| | | | 16# | No irritation or any other adverse effect to health | |
| | | | 17# | No irritation or any other adverse effect to health | |
| | | | 18# | No irritation or any other adverse effect to health | |
| 7.11 | Flammability | As received | 37# | Didn't burn | Pass |
| | | | 38# | Didn't burn | |
| | | Temperature conditioned | 39# | Didn't burn | |
| | | | 40# | Didn't burn | |

| Clause | | Result | | | | Assessment |
|---|---|---|---|---|---|---|
| | Carbon dioxide content of the inhalation air/% | As received | | | | Pass |
| | | 41# | 42# | 43# | Mean value | |
| | | 0.56 | 0.55 | 0.54 | 0.55 | |
| | Head hardness | As received | | | | Pass |
| | | 9# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | | 10# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | | 11# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | | 12# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | | 13# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | | Temperature conditioned | | | | |
| | | 14# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | | 15# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | | 16# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | | 17# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | | 18# | Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly. | | | |
| | Field of vision | As received | 7# | Passed the practical performance tests | | Pass |
| | | | 8# | Passed the practical performance tests | | |

| Clause | | Result | | | | | Assessment |
|---|---|---|---|---|---|---|---|
| | | | | Inhalation | | Exhalation | |
| | | | | 30 l/min | 95 l/min | 160 l/min | |
| | | As received | | | | | |
| 7.16 | Breathing resistance (mbar) | 41# | A | 0.3 | 1.0 | 1.4 | Pass |
| | | | B | 0.3 | 1.0 | 1.4 | |
| | | | C | 0.3 | 1.1 | 1.5 | |
| | | | D | 0.3 | 1.0 | 1.4 | |
| | | | E | 0.3 | 1.0 | 1.4 | |
| | | 42# | A | 0.3 | 1.0 | 1.4 | |
| | | | B | 0.3 | 1.1 | 1.5 | |
| | | | C | 0.3 | 1.0 | 1.4 | |
| | | | D | 0.3 | 1.0 | 1.4 | |
| | | | E | 0.3 | 1.0 | 1.4 | |
| | | 43# | A | 0.3 | 1.0 | 1.4 | |
| | | | B | 0.3 | 1.0 | 1.4 | |
| | | | C | 0.3 | 1.0 | 1.4 | |
| | | | D | 0.3 | 1.1 | 1.5 | |
| | | | E | 0.3 | 1.0 | 1.4 | |
| | | Simulated wearing treatment | | | | | |
| | | 44# | A | 0.3 | 1.0 | 1.4 | |
| | | | B | 0.3 | 1.0 | 1.4 | |
| | | | C | 0.3 | 1.0 | 1.4 | |
| | | | D | 0.3 | 1.0 | 1.4 | |
| | | | E | 0.3 | 1.1 | 1.5 | |
| | | 45# | A | 0.3 | 1.0 | 1.4 | |
| | | | B | 0.3 | 1.0 | 1.4 | |
| | | | C | 0.3 | 1.1 | 1.4 | |
| | | | D | 0.3 | 1.0 | 1.5 | |
| | | | E | 0.3 | 1.0 | 1.4 | |
| | | 46# | A | 0.3 | 1.0 | 1.4 | |
| | | | B | 0.3 | 1.1 | 1.5 | |
| | | | C | 0.3 | 1.0 | 1.4 | |
| | | | D | 0.3 | 1.0 | 1.4 | |
| | | | E | 0.3 | 1.0 | 1.4 | |

| Clause | | Result | | | | | Assessment |
|---|---|---|---|---|---|---|---|
| | | | | Inhalation | | Exhalation | |
| | | | | 30 l/min | 95 l/min | 160 l/min | |
| | | Temperature conditioned | | | | | |
| 7.16 | Breathing resistance | 47# | A | 0.3 | 1.1 | 1.5 | Pass |
| | | | B | 0.3 | 1.0 | 1.4 | |
| | | | C | 0.3 | 1.0 | 1.4 | |
| | | | D | 0.3 | 1.0 | 1.4 | |
| | | | E | 0.3 | 1.0 | 1.4 | |
| | | 48# | A | 0.3 | 1.0 | 1.4 | |
| | | | B | 0.3 | 1.1 | 1.4 | |
| | | | C | 0.3 | 1.0 | 1.5 | |
| | | | D | 0.3 | 1.0 | 1.4 | |
| | | | E | 0.3 | 1.0 | 1.4 | |
| | | 49# | A | 0.3 | 1.0 | 1.4 | |
| | | | B | 0.3 | 1.0 | 1.4 | |
| | | | C | 0.3 | 1.1 | 1.5 | |
| | | | D | 0.3 | 1.0 | 1.4 | |
| | | | E | 0.3 | 1.0 | 1.4 | |
| 7.16 | Breathing resistance | A: facing directly ahead<br>B: facing vertically upwards<br>C: facing vertically downwards<br>D: lying on the left side<br>E: lying on the right side | | | | | |

Remarks: M.S.: Mechanical strength; T.C.: Temperature conditioning; N/A: Not applicable

**Original Sample**

======= End of Report =======

# 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。

2、复制检验检测报告未重新加盖检验检测报告专用章无效。

3、检验检测报告无主检、审核、批准人签字无效。

4、检验检测报告涂改无效。

# Points For Attention

1、This Report Is Invalid If Without “The Test Report Special Seal” Or The Official Seal Of The Institute.

2、The Reproduction Is Invalid If Without Being Confirmed By The Test Report Special Seal.

3、This Report Is Invalid If Without Signature Of The Major Tester And The Examiner And The Approver.

4、This Report Is Invalid If In Any Form By Any Means Altered.

地址：江苏省泰州市高港区临港经济园临港大道 166 号

Add: Lingang Road 166, Lingang Economic Park , Gaogang, Taizhou.Jiangsu

电话（Tel）：0523-86989959

0523-86989939

邮编（Post）：225300

网址（Web）：www.jstfzx.com

邮箱（E-mail）：1735889887@qq.com

监督电话 (Complain Tel)：0523-86989901