

ZHI SHAN

Filtrierende Halbmaske
zum Schutz vor Partikeln
Einwegmaske FFP2

Particulate Protection
Respirator
Disposable Mask FFP2

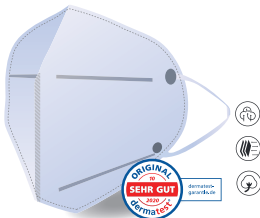


zhishan 10217
Manufacturer Shenzhen Zhishan Medical Co., Ltd
EN 149:2001+A1:2009 FFP2 NR
CE 2163

ZHI SHAN

Filterierende Halbmaske zum Schutz vor Partikeln Einwegmaske FFP2

Particulate Protection Respirator Disposable Mask FFP2



Normerfüllung

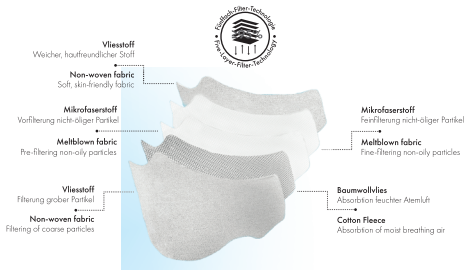
Partikelfiltrierende Atemschutzmaske mit
CE-Qualifizierung nach EN149:2001 + A1:2009

Materialien

Kopfband: elastisches Gummiband
Nasenclip: Kunststoff und leicht biegsamer
Draht Filter / Maske: Melt Blown PP, Polyester

Verwendung

Die Atemschutzmaske bietet hohen Komfort
und schützt vor festen und flüssigen
Aerosolen, Stäuben.



AUFSETZANLEITUNG

Modell-Nr.: 10217



1 Maske mit Nasenclipseite nach oben zuerst am Kinn aufsetzen.



2 Gummibänder hinter die Ohren legen, Maske ausrichten bis sie bequem sitzt.



3 Nasenclip mit den Fingern an die Nase drücken



4 Korrekten Sitz und enges Anliegen der Maske überprüfen.

SCHUTZ

Schutz gegen verschiedene Arten von Staub und nichtötlichem Nebel, bis zum zehnfachen Arbeitsplatzgrenzwert, der bei der Verarbeitung von Kohle, Eisenerz und quarzhaltigem Mineral oder durch Maschinen bei der Verarbeitung von Baumwolle, Mehl und anderen Materialien auftritt.

AUSNAHMEN

Nicht geeignet für die Umgebung, in der die von Maschinen erzeugte Staub- oder Nebelkonzentration das Zehnfache des Arbeitsplatzgrenzwertes überschreitet, wie z.B. bei Lackier- und Sandstrahlarbeiten.

Nicht geeignet für die Umgebung, in der die Konzentration von Ölparkeln oder Dampf über dem Grenzwert für die berufliche Exposition liegt. Nicht verwendbar gegen Partikel radioaktiver Stoffe, luftgetragene biologische Arbeitsstoffe der Risikogruppe 3 und Enzyme.

ACHTUNG

- Verschmutzungsbereich sofort verlassen, wenn Atembeschwerden, Schwindel oder andere Beschwerden wahrgenommen werden.
- Maske sofort wechseln, wenn sie beschädigt ist oder verstärkter Atemwiderstand verspürt wird.
- Vor dem Gebrauch, die Maske auf ihren Zustand prüfen.
- Es ist unwahrscheinlich, dass die Anforderungen an die Leckage erfüllt werden, wenn Barthaare unter der Dichtlinie am Gesicht sind.
- Die Maske sollte nicht länger als vier Stunden getragen und danach entsorgt werden. Sie darf nicht für mehr als eine Schicht benutzt werden.

STANDARD: EN 149:2001+A1:2009 (Veröffentlichungsjahr 2009)

INHALT: 50 Stück/Box

HERSTELLER: Shenzhen Zhishan Medical Co., Ltd. Baolong Street 5, Longgang Shenzhen, China

USING INSTRUCTION

Model-Nr.: 10217



Face the mask with nose bridge upside against the chin first.



Press the fingers inwardly according to the shape of the nose bridge to conform to the shape of the nose.



Pull the earband back to the ears and align the mask until it fits comfortable.



Check the correct and tight fit of the mask.

PROTECTION

It is suitable for steam odor reduction. Odor refers to the concentration not over the level of occupational exposure limit. Protection against various kinds of dust and non-oily mist of 10 times than the occupational exposure limit which occurs during processing of coal, iron ore and contain quartz mineral or by machinery during processing of cotton, flour and other materials.

RESTRICTIONS

Not suitable for the environment in which the dust or mist concentration produced by machinery is 10 times over the occupational exposure limit, such as painting and sand blasting operations. It can't be used for the environment in which oily particles or steam concentration are over the occupational exposure limit. Not useable against particles of radioactive substances, airborne biological agents of risk group 3 and enzymes.

ATTENTION

- Leave the pollution area immediately when you feel difficulty in breathing, dizziness or other discomforts.
- Replace the mask when it is damaged or by feeling more breathing resistance.
- Check the mask to ensure it is in good condition before using.
- It is unlikely that the leakage requirements will be met if whiskers are on the face below the seal line.
- The mask should not be worn for more than four hours and then disposed of.

It should not be used for more than one layer.

STANDARD: EN 149:2001+A1:2009 [Release year 2009]

PACKAGE: 50 pieces/box

MANUFACTURER: Shenzhen Zhishan Medical Co., Ltd. Boolong Street 5, Longgang Shenzhen, China



EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1241

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

Shenzhen Zhishan Medical Co., Ltd.

2/F, Building B, Tongzhou Electronic Longgang Factory, No. 1 Road 5, Baolong Community,
Baolong Street 5, Longgang District, Shenzhen, 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: zhishan **Model:** 10217

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 **09/08/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1241/01

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

Shenzhen Zhishan Medical Co., Ltd.

2/F, Building B, Tongzhou Electronic Longgang Factory, No. 1 Road 5, Baolong Community,
Baolong Street 5, Longgang District, Shenzhen, 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 |
| zhishan / 10217 | FFP2 NR | 2163-PPE-1241 | 09.08.2020 | 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 **09/08/2020** and will be valid for one year, until **08/08/2021** 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.



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director

TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 09.08.2020 / 2163-KKD-1241

Manufacturer: Shenzhen Zhishan Medical Co., Ltd.

Address: 2/F, Building B, Tongzhou Electronic Longgang Factory, No. 1 Road 5, Baolong Community, Baolong Street 5, Longgang District, Shenzhen, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Guojian Testing Technology Co., Ltd. accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-10118 for the product identified below, dated 27.07.2020 with Serial Id (2020)WSZ FHL NO.7131 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 06 August, 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 Personal 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

Brand Name: zhishan **Model:** 10217



**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.

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 foreseeable conditions of use.

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.

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 PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

1.2.1.3. Maximum permissible user impediment

Any impediment 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 address of 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 question;
- 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 deadline or period of obsolescence of PPE or 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 in accordance with Article 5(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

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.

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 remain perfectly legible throughout the foreseeable useful 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 all or 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.

Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the
(EU) 2016/425 Directive

| Conforming to EN 149:2001 + A1:2009 Standard Requirements | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|---|---|---|--|------------------------|--------|---|---|---|---|--------|-------------------|-----|--------|---|-----|--------|---|-----|--------|---|-----|--------|---|-----|-------------|---|-----|-------------|---|-----|-------------|---|-----|
| Article 5 | <p>Classification: Particle Filtering Half Mask</p> <p>The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as: Filtering Efficiency and maximum Total Inward Leakage: Classified as FFP2 Mask is classified for single shift use, NR</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Article 7.4 | <p>Packing: Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. 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.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Article 7.5 | <p>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 to the health and safety of users.</p> <p>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.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Article 7.6 | <p>Cleaning and Disinfection: Particle filtering half mask is not designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Article 7.7 | <p>Practical Performance:</p> <p>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.</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Assessed Elements</th> <th style="text-align: center;">Positive</th> <th style="text-align: center;">Negative</th> <th style="text-align: center;">Requirements in accordance with EN 149:2001 + A1:2009 and Result</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">2.Head harness comfort</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> <td rowspan="3" style="text-align: center;">Positive results are obtained from the test subjects No imperfections</td> </tr> <tr> <td style="text-align: center;">3.Security of fastenings</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> </tr> <tr> <td style="text-align: center;">5.Field of vision</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> </tr> </tbody> </table> <p>Conditioning: (A.R.) As Received, original</p> | 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 No imperfections | 3.Security of fastenings | 2 | 0 | 5.Field of vision | 2 | 0 | | | | | | | | | | | | | | | | | | | | |
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| 3.Security of fastenings | 2 | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.Field of vision | 2 | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Article 7.8 | <p>Finish of Parts: Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Article 7.9.1 | <p>Total Inward Leakage:</p> <p>The Total Inward Lekage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the conduction 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.</p> <p>It was reported that: All 50 exercise measurement results are smaller or equal to 11%, the values varies between 0,6 % and 2,1 %. All 10 individual's arithmetic mean is smaller or equal to 2%, the values varies between 1,0 % and 1,7 %.</p> <p style="text-align: center;">According to the reported results, the product meets the limits for FFP2 classification.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Article 7.9.2 | <p>Penetration of filter material: Sodium Chloride Testing</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Condition</th> <th style="text-align: center;">No. of Sample</th> <th style="text-align: center;">Sodium Chloride Testing 95 L/min max (%)</th> <th style="text-align: center;">Requirements in accordance with EN 149:2001 + A1:2009</th> <th style="text-align: center;">Result</th> </tr> </thead> <tbody> <tr><td style="text-align: center;">(A.R.)</td><td style="text-align: center;">-</td><td style="text-align: center;">0.1</td><td rowspan="9" style="text-align: center;">FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %</td><td rowspan="9" style="text-align: center;">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 and FFP3 classes.</td></tr> <tr><td style="text-align: center;">(A.R.)</td><td style="text-align: center;">-</td><td style="text-align: center;">0.1</td></tr> <tr><td style="text-align: center;">(A.R.)</td><td style="text-align: center;">-</td><td style="text-align: center;">0.1</td></tr> <tr><td style="text-align: center;">(S.W.)</td><td style="text-align: center;">-</td><td style="text-align: center;">0.2</td></tr> <tr><td style="text-align: center;">(S.W.)</td><td style="text-align: center;">-</td><td style="text-align: center;">0.1</td></tr> <tr><td style="text-align: center;">(S.W.)</td><td style="text-align: center;">-</td><td style="text-align: center;">0.2</td></tr> <tr><td style="text-align: center;">(M.S. T.C.)</td><td style="text-align: center;">-</td><td style="text-align: center;">0.2</td></tr> <tr><td style="text-align: center;">(M.S. T.C.)</td><td style="text-align: center;">-</td><td style="text-align: center;">0.2</td></tr> <tr><td style="text-align: center;">(M.S. T.C.)</td><td style="text-align: center;">-</td><td style="text-align: center;">0.2</td></tr> </tbody> </table> <p>Conditioning: (M.S.) Mechanical Strength (T.C.) Temperature Conditioning (A.R.) As Received, original (S.W.) Simulated wearing treatment</p> <p style="text-align: right;">95 L/min = 1,6 dm³.sn⁻¹</p> | Condition | No. of Sample | Sodium Chloride Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result | (A.R.) | - | 0.1 | FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 % | 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 and FFP3 classes. | (A.R.) | - | 0.1 | (A.R.) | - | 0.1 | (S.W.) | - | 0.2 | (S.W.) | - | 0.1 | (S.W.) | - | 0.2 | (M.S. T.C.) | - | 0.2 | (M.S. T.C.) | - | 0.2 | (M.S. T.C.) | - | 0.2 |
| Condition | No. of Sample | Sodium Chloride Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| (A.R.) | - | 0.1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (A.R.) | - | 0.1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (S.W.) | - | 0.2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (S.W.) | - | 0.1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (S.W.) | - | 0.2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (M.S. T.C.) | - | 0.2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (M.S. T.C.) | - | 0.2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (M.S. T.C.) | - | 0.2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | |
|------------------|--|---------------|---|---|---|--|
| 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.) | - | 0.2 | FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 % | 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 and FFP3 classes. | |
| | (A.R.) | - | 0.3 | | | |
| | (A.R.) | - | 0.3 | | | |
| | (S.W.) | - | 0.3 | | | |
| | (S.W.) | - | 0.2 | | | |
| | (S.W.) | - | 0.4 | | | |
| | (M.S. T.C.) | - | 0.8 | | | |
| | (M.S. T.C.) | - | 0.9 | | | |
| | (M.S. T.C.) | - | 0.8 | | | |
| | 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. | | | | | |
| Article 7.11 | Flammability: | | | | | |
| | Condition | No. of Sample | Visual inspection | Requirements in accordance with EN 149:2001 + A1:2009 | Result | |
| | (A.R.) | - | Burn for 0.4s | Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame | Passed Filtering half masks fulfill requirements of the standard | |
| | (A.R.) | - | Burn for 0.5s | | | |
| | (T.C.) | - | Burn for 0.4s | | | |
| | (T.C.) | - | Burn for 0.4s | | | |
| | 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.) | - | 0.7130 | 0.71 [%] | 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.) | - | 0.7127 | | | |
| | (A.R.) | - | 0.7131 | | | |
| | 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 ear loops / 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 worn. | | | | | |
| Article 7.15 | Exhalation Valve(s): The model under inspection have no valves. | | | | | |
| Article 7.16 | Breathing Resistance: Inhalation The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temperature conditioning, and 3 simulated wearing treatment conditioned 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. Passed. | | | | | |

| | |
|--------------|--|
| 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 on the product. |
| 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 the 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 expiration date, 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. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing 10217. The mask template (drawing) indicates that the mask will carry information about the name and trademark (Shenzhen Zhishan Medical Co., Ltd. / zhishan) 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 10217 drawing 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, Annex 8. The manufacturer shall include this documented user information text in every smallest commercially available package. |

| PREPARED BY | APPROVED BY |
|--|--|
| Osman CAMCI PPE Expert  | Suat KAÇMAZ Director   |



Zhishan Medical

**EU DECLARATION OF CONFORMITY
PERSONAL PROTECTIVE EQUIPMENT REGULATION
(EU) 2016/425**

We,

Shenzhen Zhishan Medical Co., Ltd, No.1, Baolong 5th Road, , Baolong street, Longgang District, Shenzhen, China being the manufacturer established in the Community (European Union), hereby declare the following Personal Protective Equipment (PPE):

Product: Particulate Halfmask FFP2
Model: 10217
EAN: 4250284209545

is in conformity with the provisions of Regulation (EU) 2016/425, including fulfilment of the applicable essential health and safety requirements set out in Annex 11, and with the National Standard transposing the harmonised European Standard Number:

EN 149:2001 +A 1 :2009

and is identical to the PPE which is the subject of EU type-examination (Module B of Regulation (EU) 2016/425) referenced on the certificate number 2163-PPE-1241 (Issue Date: 09/08/2020) issued by the Notified Body UNIVERSAL, Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye / İSTANBUL / TÜRKİYE and is subject to the procedures set out in Module D of Regulation (EU) 2016/425 under the surveillance of UNIVERSAL (Notified Body number 2163).

Annie Wu
General Managing

09th Aug 1st 2020



Annie Wu

Dermatest[®] GmbH Engelstr. 37 48143 Münster

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Muenster, 21.12.2020

Dermatological report on human Patch Test for primary skin irritation and
to detect existing sensitisations of human subjects after single
application of

FFP2 Zhishan Maske (inner layer)

Customer: Shenzhen Zhishan Medical Co., Ltd
2/F, Building B, Tongzhou Electronic Longgang Factory
no 1 Road 5, Baolong community, Baolong street 5,
Longgang district, Shenzhen
China

Test Panel: 30 panellists of either sex,
all without visible skin diseases or known hypersensitivity

**Concentration
of the product:** undiluted



PRINCIPLE AND METHODS

The objective of the study is to detect primary skin irritation potential and/ or existing allergic sensitisation to the test substance.

The test substance is applied to the skin of the panellist via an occlusive patch at a suitable concentration.

The patch limits contact of the panellist's skin with the test substance to a local area and exposure is exaggerated due to the occlusive conditions. The skin is checked at 24, 48 and 72 hours.

The occlusion eases the absorption of the suspected topical allergen allowing it to penetrate the stratum corneum to the viable (effector) cells of the skin and thus presenting a local challenge to the immune system.

If the threshold level of sensitivity is reached, a positive reaction could potentially be induced.

A positive reaction to a correctly applied patch provides evidence of primary irritation to the substance tested, but is not necessarily evidence of sensitisation.

Patch testing provokes allergic skin reactions in already sensitised panellists.

PROCEDURES

Prospective panellists receive a complete explanation of study procedures. If they wish to participate and agree to the conditions of the study, panellists sign a written, informed consent and provide a medical history.

20 mg/ 20 µl of the undiluted test product is applied to an adhesive plaster (Curatest® F Folien-Testpflaster, Fa. Lohmann & Rauscher GmbH & Co. KG) and affixed to clinically healthy skin on the upper back. Textile products are affixed with a sample size of 0,8 cm Ø with the adhesive plaster on the upper back.

After a 24 hour exposure period, the plaster is removed and the exposed skin is dermatologically assessed and graded. The second and third assessments are performed after 48 and 72 hours respectively.

All assessments are conducted 30 minutes after removal of the test plaster.

Where a positive reaction is observed, but it is unclear whether the observed reaction is due to sensitisation or irritation, subsequent readings can be performed.

All assessments are performed under standard lighting conditions.

The panellists are instructed to keep the test sites dry.

Patch test
FFP2 Zhishan Maske (inner layer)

PANELLISTS

The test panel included 30 adult male and female subjects.

This test group includes test persons with various skin types, such as: (very) dry, oily, mixed, normal and sensitive.

INCLUSION CRITERIA

Subjects aged 18 years and above with healthy skin in the test area

EXCLUSION CRITERIA

- Acute diseases
- Pregnancy and lactation period
- Sensitisation to ingredients of the test plaster
- Severe illnesses
- Application of pharmaceutical products and skin care products with active ingredients until 4 weeks before testing
- Intake of drugs that possibly can interfere with skin reactions (steroids, antiallergics, topical immuno modulator, etc.)
- Extremely tanned skin

RESULTS

Table 1: Results of patch testing for the test substance
 Concentration of the product: undiluted

| No. | Name | Gender | Age | Diagnosis | 24 h | 48 h | 72 h |
|-----|------|--------|-----|--------------|------|------|------|
| 1. | BeUl | f | 64 | healthy skin | - | - | - |
| 2. | BöAn | f | 60 | healthy skin | - | - | - |
| 3. | BüTa | f | 43 | healthy skin | - | - | - |
| 4. | DeKl | m | 40 | healthy skin | - | - | - |
| 5. | FIFi | m | 24 | healthy skin | - | - | - |
| 6. | GüEs | f | 32 | healthy skin | - | - | - |
| 7. | HeKa | f | 28 | healthy skin | - | - | - |
| 8. | HuBe | f | 42 | healthy skin | - | - | - |
| 9. | JuFa | m | 27 | healthy skin | - | - | - |
| 10. | KaHa | f | 63 | healthy skin | - | - | - |
| 11. | KeMo | m | 25 | healthy skin | - | - | - |
| 12. | Kllr | f | 54 | healthy skin | - | - | - |
| 13. | LaBi | f | 27 | healthy skin | - | - | - |
| 14. | LaMo | f | 34 | healthy skin | - | - | - |
| 15. | LeJe | f | 34 | healthy skin | - | - | - |
| 16. | LuRe | f | 63 | healthy skin | - | - | - |
| 17. | MaSe | f | 59 | healthy skin | - | - | - |
| 18. | NäNi | f | 25 | healthy skin | - | - | - |
| 19. | NiGe | m | 30 | healthy skin | - | - | - |
| 20. | NiJo | f | 30 | healthy skin | - | - | - |
| 21. | NuAg | f | 23 | healthy skin | - | - | - |
| 22. | NuVi | f | 20 | healthy skin | - | - | - |
| 23. | RaBe | f | 55 | healthy skin | - | - | - |
| 24. | SaEr | m | 40 | healthy skin | - | - | - |
| 25. | SaMe | f | 36 | healthy skin | - | - | - |
| 26. | SaHi | f | 67 | healthy skin | - | - | - |
| 27. | SaMa | m | 70 | healthy skin | - | - | - |
| 28. | ScJa | f | 35 | healthy skin | - | - | - |
| 29. | SiKa | f | 39 | healthy skin | - | - | - |
| 30. | WoSo | f | 60 | healthy skin | - | - | - |

RESULTS

Table 2: RESULTS of patch testing for the CONTROL
 Concentration of the product: blank patch test

| No. | Name | Gender | Age | Diagnosis | 24 h | 48 h | 72 h |
|-----|------|--------|-----|--------------|------|------|------|
| 1. | BeUl | f | 64 | healthy skin | - | - | - |
| 2. | BöAn | f | 60 | healthy skin | - | - | - |
| 3. | BüTa | f | 43 | healthy skin | - | - | - |
| 4. | DeKl | m | 40 | healthy skin | - | - | - |
| 5. | FIFi | m | 24 | healthy skin | - | - | - |
| 6. | GüEs | f | 32 | healthy skin | - | - | - |
| 7. | HeKa | f | 28 | healthy skin | - | - | - |
| 8. | HuBe | f | 42 | healthy skin | - | - | - |
| 9. | JuFa | m | 27 | healthy skin | - | - | - |
| 10. | KaHa | f | 63 | healthy skin | - | - | - |
| 11. | KeMo | m | 25 | healthy skin | - | - | - |
| 12. | Kllr | f | 54 | healthy skin | - | - | - |
| 13. | LaBi | f | 27 | healthy skin | - | - | - |
| 14. | LaMo | f | 34 | healthy skin | - | - | - |
| 15. | LeJe | f | 34 | healthy skin | - | - | - |
| 16. | LuRe | f | 63 | healthy skin | - | - | - |
| 17. | MaSe | f | 59 | healthy skin | - | - | - |
| 18. | NäNi | f | 25 | healthy skin | - | - | - |
| 19. | NiGe | m | 30 | healthy skin | - | - | - |
| 20. | NiJo | f | 30 | healthy skin | - | - | - |
| 21. | NuAg | f | 23 | healthy skin | - | - | - |
| 22. | NuVi | f | 20 | healthy skin | - | - | - |
| 23. | RaBe | f | 55 | healthy skin | - | - | - |
| 24. | SaEr | m | 40 | healthy skin | - | - | - |
| 25. | SaMe | f | 36 | healthy skin | - | - | - |
| 26. | SaHi | f | 67 | healthy skin | - | - | - |
| 27. | SaMa | m | 70 | healthy skin | - | - | - |
| 28. | ScJa | f | 35 | healthy skin | - | - | - |
| 29. | SiKa | f | 39 | healthy skin | - | - | - |
| 30. | WoSo | f | 60 | healthy skin | - | - | - |

INTERPRETATION CRITERIA

The assessment is based on the morphologic changes detailed in the modified guidelines of ICDRG (Fregert S (1981/ 2nd edition) Manual of Contact Dermatitis. On behalf of the International Contact Dermatitis Research Group and the North American Contact Dermatitis Group, Munksgaard Publishers, Copenhagen).

Table 3: Grading of the patch test reactions

| Symbol | Morphology | Meaning |
|--------|--|----------------------------------|
| - | no reaction | negative |
| ? | only erythema, no infiltration | doubtful |
| + | erythema, infiltration, possibly discrete papules | weak positive reaction |
| ++ | erythema, infiltration, papules, vesicles | strong positive reaction |
| +++ | erythema, infiltration, papules, confluent vesicles | extreme severe positive reaction |
| ir | different changes (soap effect, vesicles, bulla, necrosis) | irritative |
| nt | | not tested |

GENERAL DERMATOLOGICAL INTERPRETATION CRITERIA:

The distinction between irritation and allergy is of importance. As a general rule, a positive reaction is said to be „allergic“ if it has been graded as “+” to “+++ “ up to 72 hours or beyond.

Understanding the dynamics of the reaction may aid the assessment.

Allergic test reactions could persist ("Plateau-type") or even worsen ("Crescendo-type") on the day after the plaster has been removed). A "Decrescendo"-type (decrease of reaction after removal of plaster) on the other hand, indicates irritation.

If delayed reactions only develop 10-14 days after application, ("iatrogenic") sensitisation should be considered.

Irritative and allergic reactions present erythema and could also cause infiltration.

Papules, vesicles and bullae could demonstrate irritation as well as allergy, whereas pustules and necrosis point to severe irritation reactions.

Both reactions could spread beyond the original application site.

Moreover the individual expression of a reaction lies within a wide range.

Patch test
FFP2 Zhishan Maske (inner layer)

CONCLUSION

No evidence of any skin disorder was detected in the test area of any of the 30 panellists after conducting patch testing for 24, 48 and 72 hours according to the internationally recognised guidelines of ICDRG (International Contact Dermatitis Research Group).

It can be concluded that the use of the product will not cause any unwanted skin reactions due to an irritating effect.


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Dr. med. Werner Voss
Investigating specialist
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Literature:

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China

Muenster, 21.12.2020

Certificate

for the Product

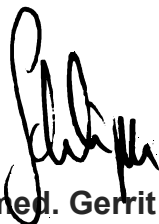
FFP2 Zhishan Maske (inner layer)

Dermatological test on humans in 2020

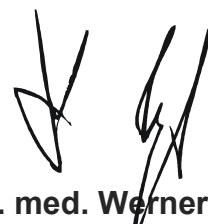
The dermatological test performed by us on your product under the control of dermatological specialists was passed for this product with the rating of

„excellent“

This product did not lead to toxic-irritative intolerance reactions in patch testing carried out in accordance with international guidelines. The preparation can therefore be declared as dermatologically tested.



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