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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-684/R1

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

Shandong Zeda Medical Products Co., Ltd.

Yaojia Village, Zaoyuan Town, Lanshan District, Linyi City, Shandong 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 (Dated 28.05.2021) 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

Single shift use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 5 layered, without valve, embedded nose clip, fitted with ear loops.

Brand Name: SIJIJIE **Model:** K1210
Classification: FFP2 NR

For more details, refer technical evaluation report provided to the manufacturer, dated 28.05.2021 and number 2163-KKD-684-R1.

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.

This certificate is initially issued on **20/05/2020** and updated on **28/05/2021**, will be valid for 5 years from the issue date, 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

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 28.05.2021 / 2163-KKD-684-R1

Initial Report Date and Number: 20.05.2020 / 2163-KKD-684

This technical evaluation report is updated due to changes in the mask design. The mask with new design tested for requirements of EN 149:2001+A1:2009 standard and this assessment report prepared based on the test results of the new version and the technical file updated with the new design of the product, by the manufacturer.

Manufacturer: Shandong Zeda Medical Products Co., Ltd.

Address: Yaojia Village, Zaoyuan Town, Lanshan District, Linyi City, Shandong Province, China

Introduction

This report is prepared for the, given above, manufacturer according to the test results obtained from SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center accredited by CNAS (Chinese Accreditation Service), signatory to ILAC MRA, with number L0599 for the product identified below, dated 26.05.2021 with Serial No SL52105269393601TX based on EN 149 : 2001 + A1 : 2009 standard and the technical file dated 28 May, 2021 Version 02 provided by the manufacturer.

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 No. 2163-PPE-684/R1 issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 8 pages.

Product Description: Single shift use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 5 layered, without valve, embedded nose clip, fitted with ear loops.

Component and Materials:

Component	Material	Grade / Size
1st Layer (Outer)	Non-woven Fabric (PP)	50 gsm (± 2 gsm)
2nd Layer	Melt-blown Fabric	25 gsm (± 2 gsm)
3rd Layer	Melt-blown Fabric	25 gsm (± 2 gsm)
4th Layer	Hot Air Cotton	50 gsm (± 2 gsm)
5th Layer (Inner)	Non-woven Fabric (PP)	25 gsm (± 2 gsm)
Nose Clip	Double bridge line	Length: 85mm (± 5 mm) Width: 4 mm (± 1 mm)
Ear Strap	Nylon and Spandex	Length: 195 mm (± 10 mm) Width: 5 mm (± 1 mm)

Classification: FFP2 NR

Brand Name: SIJIJIE **Model:** K1210

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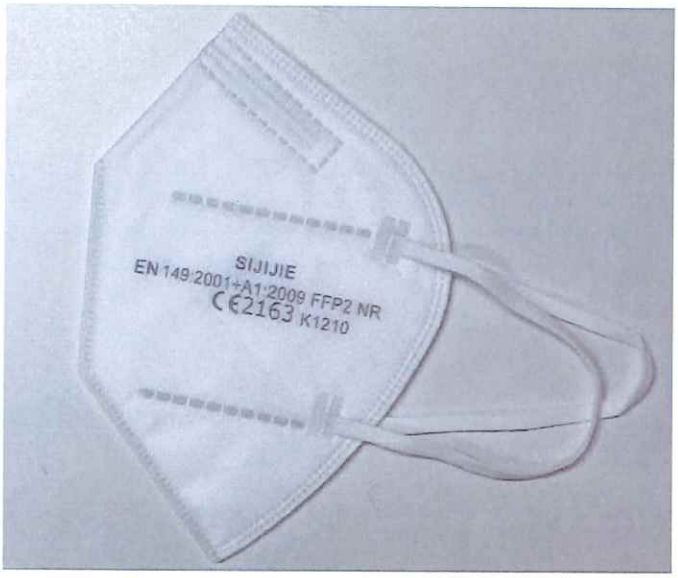

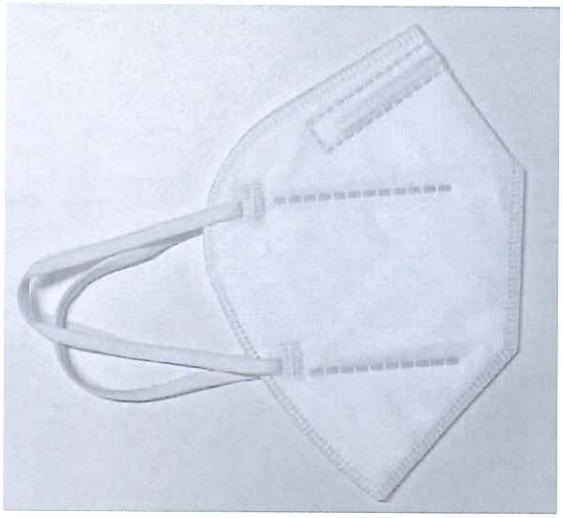

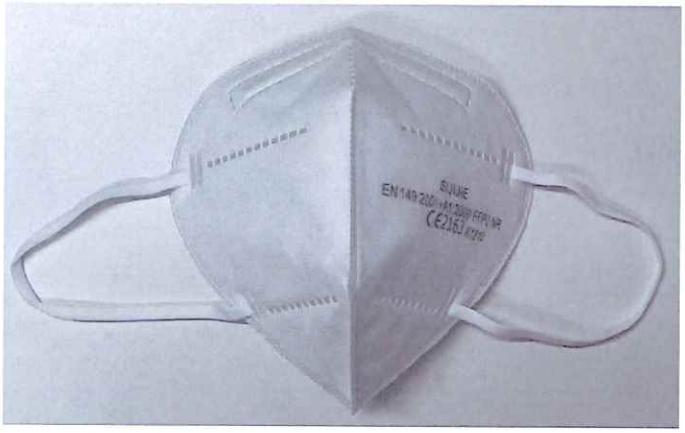

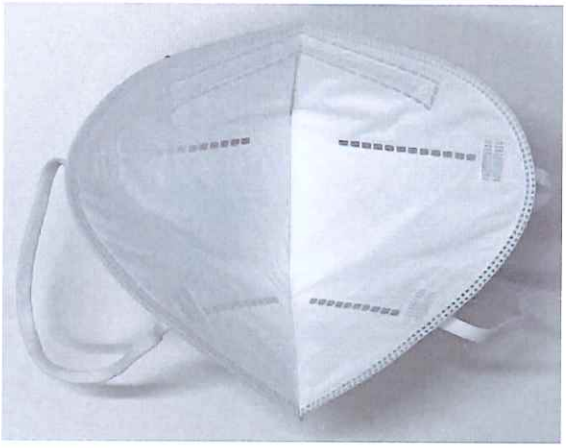

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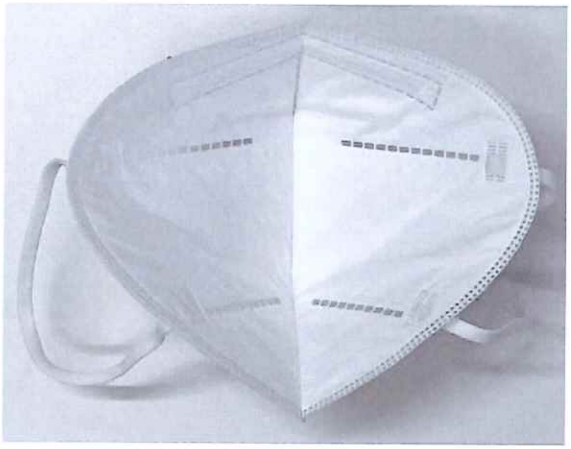

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ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT

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 prossible 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 fore seeable 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 permessible 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

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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 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.

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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	**Classification:** Particle Filtering Half Mask 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**
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 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. Details given in Annex 9.1 of technical file.
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 to the health and safety of users. Manufacturer declares that the material do not have any adverse effect for the wearers health in Section 7 of the technical file. 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:** 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/ ear loops comfort, security of fastenings and field of vision. Also no imperfactions 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
Head harness comfort	2	0	Positive results are obtained from the test subjects **No imperfections**
Security of fastenings	2	0	
Field of vision	2	0	

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

Article 7.8	**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.
Article 7.9.1	**Total Inward Leakage:** The Total Inward Leakage 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. It was reported that: All 50 exercise measurement results are smaller or equal to 11 %, the values varies between 3.12 % and 6.52 %. All 10 individual's arithmetic mean is smaller or equal to 8 %, the values varies between 3.32 % and 5.66 %. **According to the reported results, the product meets the limits for FFP2 classification.**
Article 7.9.2	**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.)	1	0.129	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2 and FFP3** classes.
(A.R.)	2	0.153		
(A.R.)	3	0.137		
(S.W.)	4	0.182		
(S.W.)	5	0.120		
(S.W.)	6	0.165		
(M.S. T.C.)	7	0.376		
(M.S. T.C.)	8	0.433		
(M.S. T.C.)	9	0.391		

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

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

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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.)	10	0.237	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1 and FFP2** classes.
(A.R.)	11	0.265		
(A.R.)	12	0.341		
(S.W.)	13	0.253		
(S.W.)	14	0.264		
(S.W.)	15	0.259		
(M.S. T.C.)	16	1.497		
(M.S. T.C.)	17	1.337		
(M.S. T.C.)	18	1.465		

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.)	1	Burn for 0 s	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.)	2	Burn for 0 s		
(T.C.)	3	Burn for 0 s		
(T.C.)	4	Burn for 0 s		

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.)	1	0.5825	0,58 [%]	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.)	2	0.5811			
(A.R.)	3	0.5834			

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 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):
No exhalation valve exists.

Article 7.16

Breathing Resistance: Inhalation

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 simulated wearing treatment conditioned samples 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.

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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 name and trademark of the manufacturer is stated to exist on the carton boxes. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the year of end 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. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing Annex 6. The mask template (drawing) indicates that the mask will carry information about the trademark (SIJIJIE) of the manufacturer, type of mask, the reference to EN 149:2001+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. The tested samples by the laboratory carry necessary marking information, as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production given in the technical file. K1210 drawing, which exists in the technical file of the manufacturer; as Annex 6.
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 commertially available package.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert	**Suat KAÇMAZ** Director

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CONFORMITY TO TYPE CERTIFICATE

Certificate No: 2163-PPE-684/02

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

Shandong Zeda Medical Products Co., Ltd.
Yaojia Village, Zaoyuan Town, Lanshan District, Linyi City, Shandong 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 Nr.	Date	Issuing NB Nr.
SIJIJIE / K1210	FFP2 NR	2163-PPE-684/R1	28.05.2021	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 **28/05/2021** and will be valid for one year, until **27/05/2022** 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.

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Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

SHANDONG ZEDA MEDICAL PRODUCTS CO.,LTD
YAOJIA VILLAGE, ZAOYUAN TOWN, LANSHAN DISTRICT, LINYI CITY, SHANDONG PROVINCE, CHINA

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52105257269701TX DATE:2021-05-18 ISSUED BY SGS (Shanghai)
UPDATED CLIENT'S INFORMATION/ SAMPLE INFORMATION.

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Filtering half mask
Sample Color	:	(A)White
Composition	:	(A)40%non-woven fabric 30%hot air cotton 30%melt-blown fabric
Style No.	:	K1210
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 28, 2021
Testing Period	:	Apr 28, 2021 - May 18, 2021
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Conclusion:

Sample No.	Recommendation Level
(A)	FFP2 NR

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

SGS does not verify authenticity of any Brand/Trademark of products. Buyers must check if the product is genuine with the Brand/Trademark owner directly.

Test Result

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

Clause 7.4 Packaging
(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Comply	Pass

Clause 7.5 Material
(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
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.	Comply	Pass
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.	Comply	
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting
(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
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. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance
(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass

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Clause 7.8 Finish of Parts
(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

Clause 7.9.1 Total Inward Leakage
(EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3	Detail refer to Appendix 1	Meet FFP1, Meet FFP2

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	4.32	3.97	3.57	4.70	4.40	4.19
Luo	2	A.R.	5.50	5.44	5.19	5.56	4.10	5.16
Lu	3	A.R.	4.20	4.81	4.67	4.85	3.39	4.38
Wang	4	A.R.	3.12	3.43	3.16	3.53	3.34	3.32
Bao	5	A.R.	5.26	5.45	5.51	5.73	4.83	5.36
Ding	6	T.C.	3.57	3.74	3.32	3.89	3.20	3.54
Li	7	T.C.	5.15	5.58	5.11	6.24	5.27	5.47
Chen	8	T.C.	3.79	3.38	3.41	4.34	3.95	3.77
Song	9	T.C.	4.89	4.46	4.28	4.94	4.53	4.62
Ye	10	T.C.	5.31	5.90	5.53	6.52	5.05	5.66

Facial Dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50

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Ding	134	150	110	52
Liu	120	135	117	50
Ye	126	137	105	52

Note: A panel of ten clean-shaven persons (without beards or sideburns) were selected covering the spectrum of facial characteristics of typical users of the filtering half masks submitted by applicant (excluding significant abnormalities). It is to be expected that exceptionally some persons cannot be satisfactorily fitted with a particle filtering half mask. Such exceptional subjects shall not be used for testing particle filtering half masks.

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

<table>
<tr><th>Test Requirement</th><th>Results</th><th>Comment</th></tr>
<tr><td>The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.
<table>
<tr><th rowspan="2">Classification</th><th colspan="2">Maximum penetration of test aerosol</th></tr>
<tr><th>Sodium chloride test 95 l/min
%
max.</th><th>Paraffin oil test 95 l/min
%
max.</th></tr>
<tr><td>FFP1</td><td>20</td><td>20</td></tr>
<tr><td>FFP2</td><td>6</td><td>6</td></tr>
<tr><td>FFP3</td><td>1</td><td>1</td></tr>
</table></td><td>Detail refer to Appendix 2</td><td>Meet FFP1, Meet FFP2</td></tr>
</table>

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	1	0.129
		2	0.153
		3	0.137
	Simulated wearing treatment	4	0.182
		5	0.120
		6	0.165
	Mechanical strength +Temperature conditioned	7	0.376
		8	0.433
		9	0.391
Paraffin oil test	As received	10	0.237
		11	0.265
		12	0.341
	Simulated wearing treatment	13	0.253
		14	0.264
		15	0.259
	Mechanical strength +Temperature conditioned	16	1.497
		17	1.337
		18	1.465
Flow conditioning：Single filter: 95.0 L/min			

Clause 7.10 Compatibility with Skin

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
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.	No irritation or any other adverse effect to health	Pass

Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature 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.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result
As received	1	NIL
	2	NIL
Temperature conditioned	3	NIL
	4	NIL

Clause 7.12 Carbon Dioxide Content of The Inhalation Air

(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result	
As received	1	0.5825	Mean value:0.58
	2	0.5811	
	3	0.5834	

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Clause 7.13 Head Harness
(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

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

Clause 7.14 Field of Vision
(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.15 Exhalation Valve(s)
(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to No exhalation valve	N.A.
(b) 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.	Not applicable due to No exhalation valve	
(c) 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.	Not applicable due to No exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve	

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Clause 7.16 Breathing Resistance
(EN 149:2001+A1:2009, Clause 8.9)

Test Requirement	Results	Comment
The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of the following table.	Detail refer to Appendix 5	Meet FFP1, Meet FFP2, Meet FFP3

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

Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

	Flow rate(l/min)		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30	0.5	0.4	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.4	0.4	0.4	0.5	0.5
		95	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.8	1.8	1.8	1.8	1.9	1.8	1.8
	Exhalation	160	2.7	2.7	2.7	2.8	2.8	2.8	2.8	2.8	2.8	2.7	2.7	2.7	2.8	2.8	2.8
	Flow rate(l/min)		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Simulated wearing treatment	Inhalation	30	0.5	0.5	0.4	0.4	0.5	0.5	0.5	0.5	0.4	0.4	0.4	0.5	0.5	0.5	0.5
		95	1.8	1.9	1.9	1.9	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.8	1.8	1.8
	Exhalation	160	2.7	2.8	2.8	2.8	2.7	2.7	2.7	2.7	2.8	2.8	2.8	2.8	2.7	2.7	2.8
	Flow rate(l/min)		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Temperature conditioned	Inhalation	30	0.4	0.4	0.5	0.5	0.5	0.5	0.4	0.4	0.5	0.5	0.5	0.5	0.4	0.4	0.4
		95	1.9	1.9	1.8	1.8	1.9	1.9	1.9	1.9	1.8	1.8	1.8	1.9	1.9	1.9	1.9
	Exhalation	160	2.8	2.8	2.8	2.7	2.7	2.7	2.7	2.8	2.8	2.8	2.8	2.7	2.7	2.8	2.8

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

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Clause 7.17 Clogging
(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement	Results	Comment
Clause 7.17.2 Breathing resistance Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow. Valveless particle filtering half masks: After clogging the inhalation and exhalation resistances shall not exceed: FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow	Optional for single shift device only	N.A.
Clause 7.17.3 Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.	Optional for single shift device only	N.A.

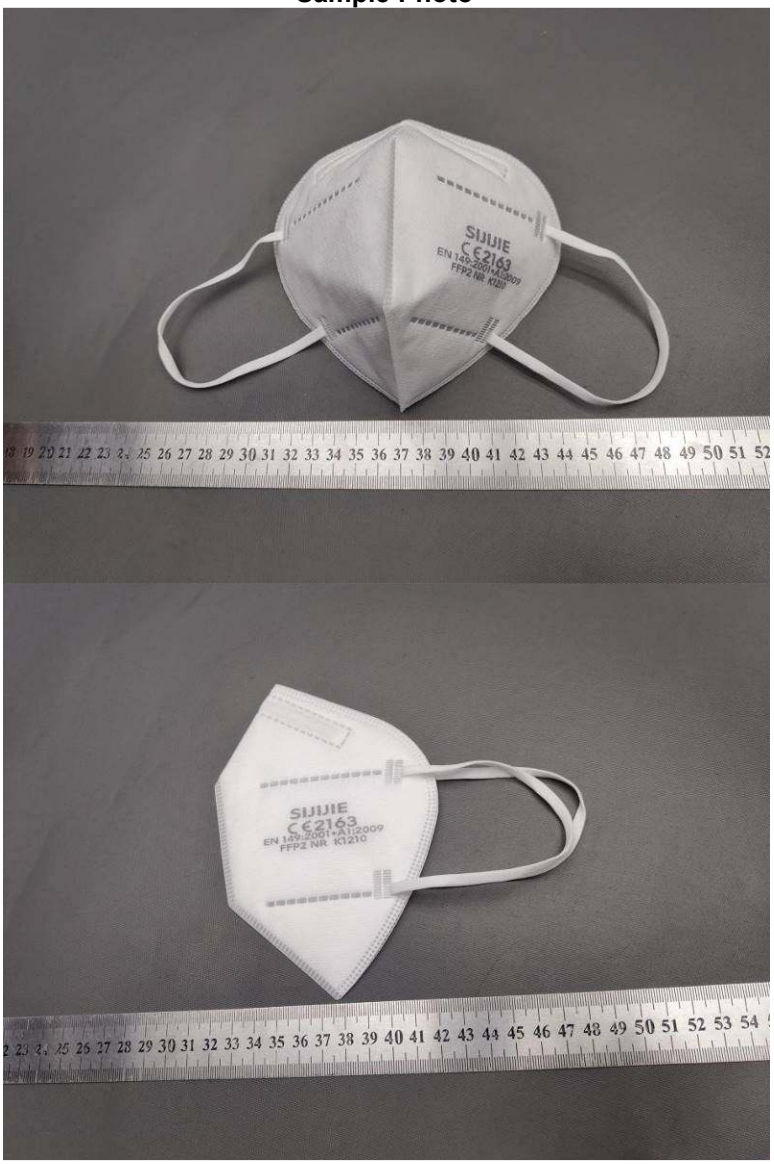
Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
	%	%
	max.	max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Clause 7.18 Demountable Parts
(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No demountable parts	N.A.

Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%

Sample Photo



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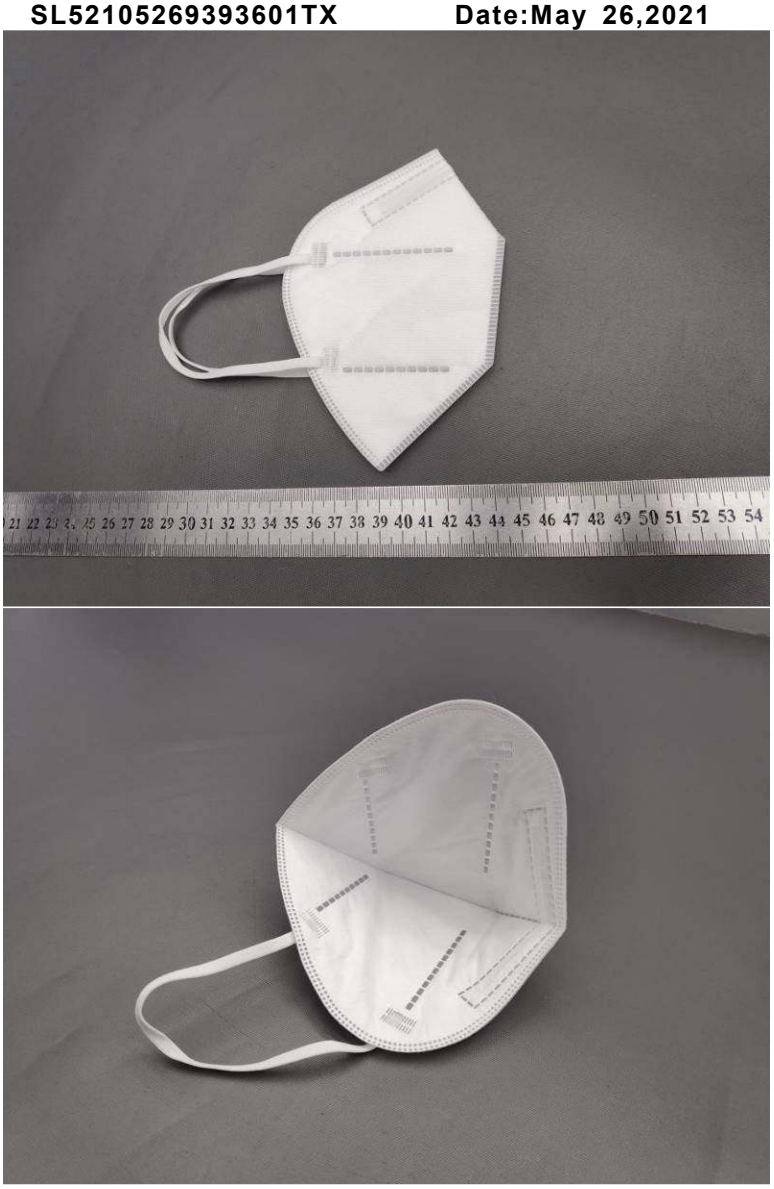

Product information is provided by applicant without verification of authentication of the brand.

End of Report

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SIJIE

Certificate of Compliance

Statement on DEHP, Fiberglass, Latex and Graphene Free PPE (Personal Protection Equipment)

SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD., hereby declares that all of our products are free from DEHP, Fiberglass, Latex and Graphene.

Certificado de cumplimiento

Declaración sobre EPIs (equipo de protección individual) libres de DEHP, fibra de vidrio, látex y Grafeno.

SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD., declara que todos nuestros productos están libres de DEHP, fibra de vidrio, látex y grafeno.

Date/Fecha: 2021.04.17

Signature/Firma: Yi xiu Zhang

SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD. 山东泽达医疗用品有限公司

General Manage of SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD.

DECLARACIÓN UE DE CONFORMIDAD

Nº. 20210529/1

1. **Equipo de Protección Individual (EPI):**
   Media Máscara facial filtrante FFP2 NR (Modelo: K1210)

2. **Nombre y dirección del fabricante:**
   Nombre: SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD
   Dirección: Yaojia Village, Zaoyuan Town, Lanshan District, Linyi City, Shandong Province, China

3. **La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante:**
   SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD

4. **Objeto de la declaración:**
   Media Máscara facial filtrante FFP2 NR (Modelo: k1210). Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas.

5. **El objeto de la declaración descrito en el punto 4 anterior es conforme con la legislación de armonización de la Unión aplicable:**
   Reglamento (UE) 2016/425 relativo a los equipos de protección individual y por el que se deroga la Directiva 89/686/CEE del Consejo.

6. **Referencias a las normas armonizadas aplicables utilizadas, incluidas sus fechas, o referencias a las otras especificaciones técnicas, incluidas sus fechas, respecto a las cuales se declara la conformidad:**
   Norma armonizada: EN 149:2001+A1:2009. Clasificación: FFP2 NR

7. **El Organismo Notificado Universal Uygunluk Degerlendirme Hizmetleri ve Tic. A.Ş., número 2163 ha efectuado el examen UE de tipo (módulo B) y ha expedido el certificado de examen UE de tipo (2163-PPE-684/R1)**

8. **El EPI está sujeto al procedimiento de evaluación de la conformidad con el tipo basada en el aseguramiento de la calidad del proceso de producción (módulo C2) bajo la supervisión del organismo notificado Universal Uygunluk Degerlendirme Hizmetleri ve Tic. A.Ş., número 2163 (2163-PPE-684/02)**

Firmado en nombre de: SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD
Yaojia Village, Zaoyuan Town, Lanshan District, Linyi City, Shandong Province, China

Lugar y fecha:
Linyi City, China 2021.05.29

SHANDONG ZEDA MEDICAL PRODUCTS CO. 山东泽达医疗用品有限公司

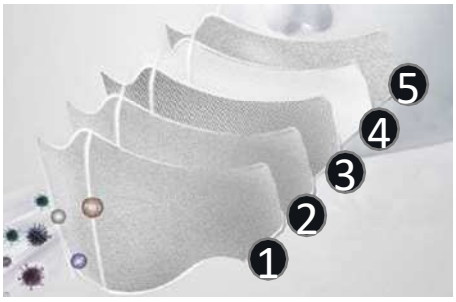
Signature/Firma: Yi xiu Zhang
Position :General Manger

SIJIE CE 2163

EN 149:2001+ A1:2009
FFP2 NR K1210

Media Máscara Facial Filtrante FFP2 NR
Modelo: K1210

Antibacteriana e hipoalergénica. Inodora. No estéril. Libre de látex, DEHP y fibras de vidrio. Apta para uso sanitario. Con 3 capas de tejido no tejido y 2 de tejido de polipropileno fundido soplado. Diseño 3D que aumenta el espacio para boca y nariz y mejora el ajuste al contorno de la cara. Material poroso conformado para ajuste facial completo. Uso previsto: Proteger de la inhalación de aerosoles, sólidos y líquidos a la persona que la lleva puesta.



Cinco Capas de Protección

3 capas de:
Tejido no tejido

2 capas de :
Tejido de polipropileno fundido soplado

Color Blanco
Talla única adulto

Especificaciones

Eficiencia de filtración de partículas PFE 0.3 µm ≥ 97%
Propiedades de las gomas: Elásticas y sujeción tras las orejas
Ajuste facial: Sellado facial total
Exenta de ingredientes tóxicos, látex, silicona, PVC, DEHP, fibra de vidrio, grafeno, etc.
Hidrofóbica. Resistente a salpicaduras

Recomendaciones uso

Mascarilla filtrante no reutilizable, usable hasta 12 horas o un turno de trabajo.
No deben compartirse.
Vidal útil: 3 años desde fecha de fabricación.

Material

Melt Blown:
Polipropileno
Poliuretano-Ácido poliláctico

Resto de capas:
Tejido no tejido (PP)

Gomas
Elastano

Clip nasal:
Aluminio

Embalaje

55 uds (55 bolsas x 1ud) Peso: (5gr/ud)

Dimensiones-peso caja
130x115x175mm – 400gr
Caja master
30 cajas (1650uds) 670x360x380mm (13,5Kg)

Certificados

Norma EN 149:2001+A1:2009

Dispositivos de protección respiratoria. Medias máscaras filtrantes para proteger contra partículas
Módulo B 2163-PPE-684/R1
Módulo C2 2163-PPE-684/02

Fabricante

SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD
Yaojia Village, Zaoyuan Town, Lanshan District, Linyi City, Shandong Province, China

Importador

SOLFIX ENGINEERING, S.L.
C/ Fco. Medina Mendoza, nº 10A, Puerta 29 19171 Cabanillas del Campo (Guadalajara)
Web: www.solfixair.es – Email: comercialcovid19@sol-fix.es

Made In China.
Fabricado en China

SIJIE CE 2163

EN 149:2001+ A1:2009
FFP2 NR K1210

INSTRUCCIONES DE LAS MASCARILLAS

IMPORTANTE:

Antes de leer la información que se detalla a continuación compruebe qué tipo de mascarilla tiene intención de utilizar. Es responsabilidad del usuario elegir el modelo de mascarilla que le proporcione el nivel de protección adecuado frente al tipo y concentración del contaminante o contaminantes presentes en la zona de trabajo en la que va a desarrollar su actividad. Las máscaras filtrantes cumplen con la siguiente certificación EN 149:2001+A1:2009.

INSTRUCCIONES DE USO:

- Coloque la mascarilla y verifique la estanquidad antes de entrar en el área contaminada.
- Lleve la mascarilla puesta durante todo el tiempo de exposición a los contaminantes.
- Use la mascarilla de acuerdo a las regulaciones aplicables de salud y seguridad.
- Deseche la mascarilla y sustitúyala por una nueva si: la mascarilla se retira mientras está en el área contaminada, si la obstrucción excesiva de la mascarilla causa dificultad o incomodidad para respirar, si la mascarilla se daña (para mascarillas que protegen contra vapores, el olor del vapor se vuelve detectable).
- Salga del área contaminada si se marea, nota irritación u otro malestar.
- Válida sólo para un uso. No se necesita mantenimiento. No lo almacene/reutilice después de cada uso.
- Deseche la mascarilla después de cada uso (1 turno de trabajo como máximo).
- No apto para niños. Solo uso en adultos.

INSTRUCCIONES DE COLOCACIÓN:

1. Coloque la mascarilla en la mano, permitiendo que las bandas cuelguen libremente.
2. Sostenga la mascarilla debajo de la barbilla con la pieza metálica de aluminio nasal mirando hacia afuera.
3. Coloque las bandas por detrás de las orejas.
4. Moldee la pieza metálica de aluminio nasal a la forma de la cara, pasando las puntas de los dedos de ambas manos desde la parte superior de la nariz hacia ambos lados mientras presiona hacia adentro.
5. Verifique la estanqueidad (ajuste facial), como sigue: Coloque ambas manos sobre la mascarilla y exhale. Debe haber presión positiva dentro de la mascarilla. Si siente que el aire escapa alrededor de los bordes vuelva a ajustar el respirador apretando en la nariz.

LIMITACIONES DE USO:

No use las mascarillas, ni entre o permanezca en la zona de riesgo si:

- La mascarilla está deteriorada
- La concentración de oxígeno es inferior al 19,5% (en volumen)
- Desconoce la naturaleza y/o concentración del agente contaminante o si ésta es inmediatamente peligrosa para la salud y/o la vida.
- La concentración de partículas supera los límites fijados por la legislación aplicable o si ésta es superior a 12,5 veces el valor TLV/MAC/OEL del contaminante(s).
- Detecta la presencia de gases o vapores en la zona de riesgo, en cuyo caso deberá emplear una mascarilla con carbón activo y en ese caso la concentración del contaminante deberá ser inferior a su valor TL/MAC/OEL.

AVISO IMPORTANTE:

No usar en caso de incendio. Estos EPI no aportan oxígeno. No usar en atmósferas con baja concentración de oxígeno, por ejemplo, en tanques o zonas poco ventiladas. No utilizar en atmósferas explosivas. En caso de usuarios con alguna característica física especial o vello facial abundante (barbas, bigotes o patillas) es muy probable que no se alcancen los requisitos necesarios para conseguir un correcto ajuste de la mascarilla. Durante el transporte mantener el equipo en su embalaje original y alejado de riesgos mecánicos y químicos.

ALMACENAMIENTO:

Mantenga las mascarillas sin usar en su embalaje cerrado y guárdelas en un área seca no contaminada entre 0 y +50ºC a una humedad relativa por debajo del 50%.

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