ZHONGKANG FFP2

zhongkang Medical Device Protection Technology Co.,Ltd

MODEL：K-ZK-008

CE：2163

EN149：2001+A1:2009

Schutzklasse : FFP2

3D-Design

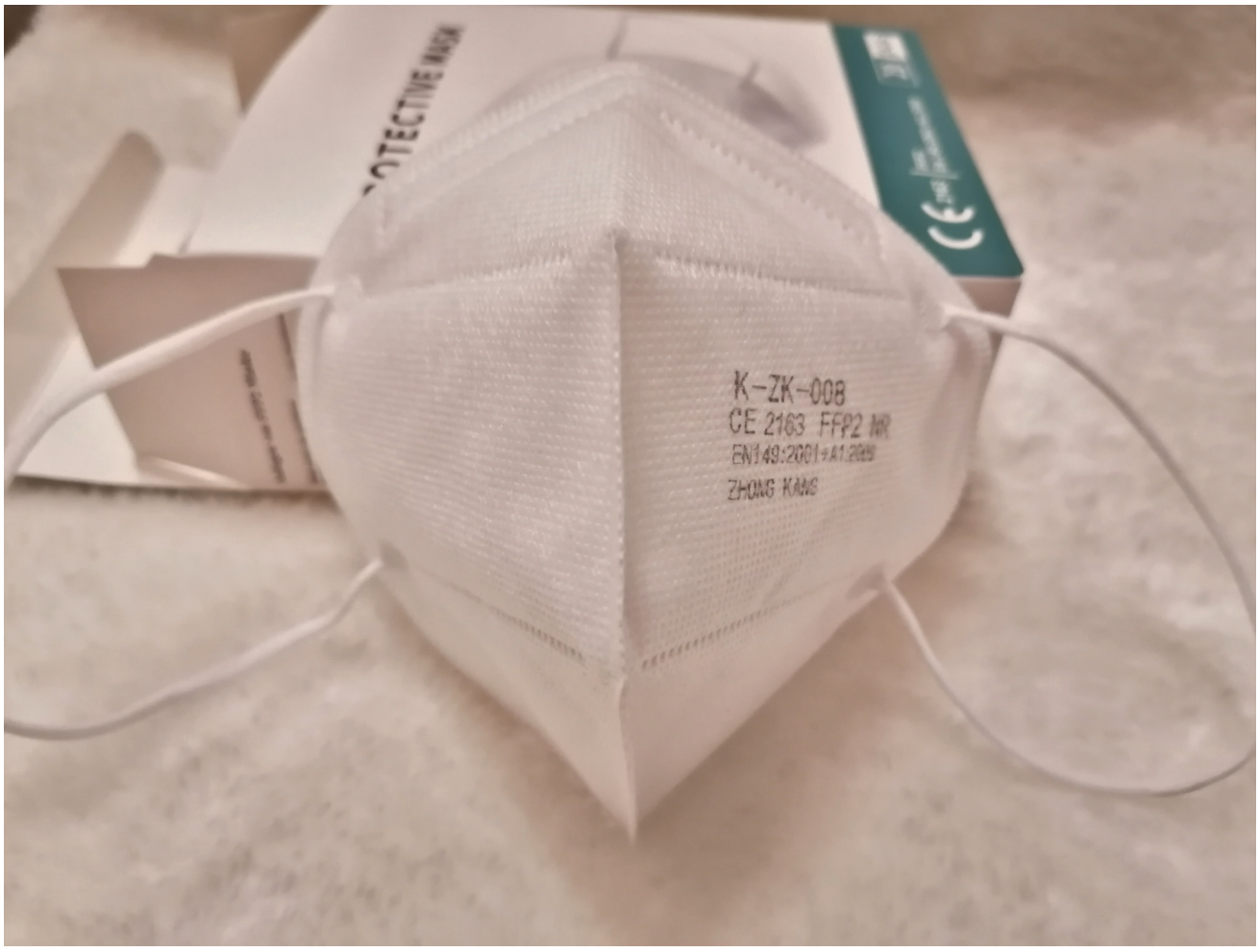
für komfortables Atmen

3-Schicht-Filtersystem
5-lagig

Spunbond,Meltbond,Nonwoven
Hochgradige Filterung von 95% aller Partikel in der Luft

Flexible Einheitsgröße

Optimale Passform: V-Form mit Nasenkontur
Ohrschlaufe mit elastischem Band für perfekten Sitz.



Produkt Fotos:

ZHONGKANG FFP2
K-ZK-008
CE2163
FFP2 NR

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Verpackung

ZHONGKANG FFP2
K-ZK-008
CE2163
FFP2 NR

Einzelverpacket

20 Stück/Packung
90 Packungen/Karton
1800 Stück / Karton

Karton Größe:
58 CM×33,8 CM×65 CM

Gewicht:
16KG/Karton

Anleitung

ZHONGKANG FFP2
K-ZK-008
CE2163
FFP2 NR

DE

ANWEISUNGEN ZUM ANLEGEN

1.Halten Sie die Halbmaske über die Nase und den Mund.
2.Ziehen Sie die Kopfbänder hinter die Ohren, und bringen sie die Bänder am Clip an. Passen Sie den Sitz an, und überprüfen Sie die Dichtheit.
3.Passen Sie den Nasenclip so an, dass er sicher um die Nase liegt, drücken Sie den Nasenclip fester an. Wiederholen Sie die Anpassungen, bis die Maske dicht ist.
4.Berühren Sie nicht die Vorderseite der Maske beim tragen.

Warnhinweise

1.Diese mit dem Zeichen „NR " versehene Maske ist zur einmaligen Verwendung bestimmt.
2.Diese Maske hilft beim Schutz vor bestimmten Partikelverunreinigungen,verhindert jedoch nicht vollständig das Risiko auf Ansteckung oder Infektion.
3.Sofern Gesichtshaar unter die Gesichtsversiegelung gerät, werden die Dichtheitsanforderungen ggf. Nicht erfüllt.
4.Wechseln Sie umgehend die Maske, wenn Ihnen das Atmen scherfällt oder die Maske beschädigt bzw. Deformiert wird.
5.Wechseln Sie die Maske, wenn die Dichtheit über dem Gesicht nicht erreicht werden kann.

Lagerung

Lagern Sie die Maske bei Nichtverwendung in einem dichten Behälter außerhalb der verunreinigten Bereiche.

Schutzschtufe

FFP2 NR mit Schtzgrad 95%

EN

FITTING INSTRUCTIONS

1.Hold the half mask over your nose and mouth.
2.Pull the headbands behind your ears and attach the straps to the clip. Adjust the seat and check for leaks.
3.Adjust the nose clip so that it fits securely around your nose, then press the nose clip tighter. Repeat the adjustments until the mask is tight.
4.Do not touch the front of the mask while wearing it.

Warning

1.This mask with the "NR" mark is for single use only.
2. This mask helps protect against certain particulate contaminants, but does not completely prevent the risk of contagion or infection.
3.If facial hair gets under the face seal, the tightness requirements may not be met.
4.Change the mask immediately if you cannot breathe or if the mask is damaged or deformed.
5.Change the mask if the tightness over the face cannot be achieved.

Storage

When not in use, store the mask in a tight container away from the contaminated areas.

Protection level

FFP2 NR with degree of protection 95%

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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1010

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

Zhongkang (Shenzhen) Medical Device Protection Technology Co., Ltd.

No. 101, Building C4, Chuangfeng Digital Technology Park, Fuyuan 2nd Road, Bao'an 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

Model: K-ZK-008
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 **10/07/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM

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CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1010/01

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

Zhongkang (Shenzhen) Medical Device Protection Technology Co., Ltd.

No. 101, Building C4, Chuangfeng Digital Technology Park, Fuyuan 2nd Road, Bao'an 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
K-ZK-008	FFP2 NR	2163-PPE-1010	10.07.2020	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 **10/07/2020** and will be valid for one year, until **09/07/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
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Director

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 10.07.2020 / 2163-KKD-1010

Manufacturer: Zhongkang (Shenzhen) Medical Device Protection Technology Co., Ltd.

Address: No. 101, Building C4, Chuangfeng Digital Technology Park, Fuyuan 2nd Road, Bao'an 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 24.06.2020 with Serial Id [2020] WSZ FHL NO.6522 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 09 July, 2020 Version 01 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the client.

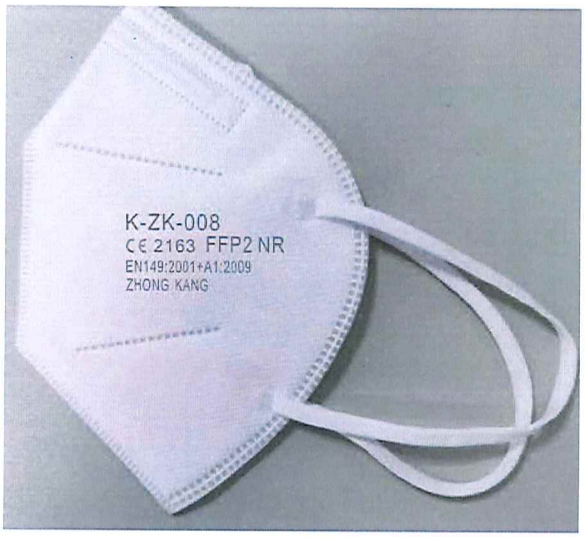
The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

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

Product Description: Particle Filtering Half Mask

Classification: FFP2 NR

Model: K-ZK-008



UNIVERSAL CERTIFICATION CE 2163 Notified Body

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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.
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. 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/ earloops 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
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	

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 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. It was reported that: All 50 exercise measurement results are smaller or equal to 11%, the values varies between 5,3 % and 7,3 %. All 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 5,8 % and 6,9 %. **According to the reported results, the product meets the limits for FFP1 and FFP2 classifications.**

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.)	-	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.)	-	0.2		
(A.R.)	-	0.1		
(S.W.)	-	0.2		
(S.W.)	-	0.1		
(S.W.)	-	0.1		
(M.S. T.C.)	-	0.3		
(M.S. T.C.)	-	0.2		
(M.S. T.C.)	-	0.2		

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

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

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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.)	-	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 and FFP2** classes.
(A.R.)	-	0.1		
(A.R.)	-	0.1		
(S.W.)	-	0.1		
(S.W.)	-	0.2		
(S.W.)	-	0.1		
(M.S. T.C.)	-	1.4		
(M.S. T.C.)	-	1.4		
(M.S. T.C.)	-	1.6		

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 0.4s		
(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.)	-	0.7125	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.)	-	0.7135			
(A.R.)	-	0.7145			

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 weared.

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 temparature 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.

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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 manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the end date of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 9.1 of the technical file. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing K-ZK-008. The mask template (drawing) indicates that the mask will carry information about the manufacturer / trademark (ZHONG KANG) 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 K-ZK-008 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 commertially available package.

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

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Test Report

Report No.: [2020] WSZ FHL NO.6522

Product Name Filtering half mask

Applicant UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co.

Manufacturer Zhongkang（Shenzhen）Medical Device protection technology Co.,Ltd

Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd.

3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China

Test Report

Product name	Filtering half mask	Model name	K-ZK-008
		Brand	—
Laboratory/ Add.	Jiangsu Guojian Testing Technology Co., Ltd./ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China		
Applicant/ Add/Tel	UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co./—/—		
Manufacturer/ Add/Tel	Zhongkang （Shenzhen） Medical Device protection technology Co.,Ltd/No. 101, Building C4, Chuangfeng Digital Technology Park, Fuyuan 2nd Road, Bao'an District, Shenzhen, China/—		
Sample classification	FFP2	Sample number	GW6522-2020
Sample quantity	130 pcs	Date of receipt of sample	06/06/2020
Test type	Entrusted inspection	Article/Batch/Style number	—
Date (s) of performance of tests	10/06/2020~19/06/2020	Testing location	Same as the Laboratory
Sample state	Meeting the requirements of testing	Sample description	Refer to page 3
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking		
Test items	Packaging, material, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The samples upon testing comply with FFP2 classification requirements according to the standard EN 149:2001+A1:2009. The details of test results see on Pages 3-11. Date of issue: 24/06/2020		
Note	The test results presented in this report relate only to the submitted sample as received.		

Lu Bing
Approver (name, signature)

Wan Heng
Reviewer (name, signature)

Yang Ying
Chief Tester (name, signature)

Sample description:	—
Test item particulars:	
Type of use ..... :	☐ re-useable particle filtering half mask ☒ single shift only particle filtering half mask
Classes of devices..... :	☐ FFP1 ☒ FFP2 ☐ FFP3
Exhalation valve(s)..... :	☐ Yes ☒ No
Inhalation valve(s)..... :	☐ Yes ☒ No
Designed to protect against both solid &liquid aerosols. :	☒ Yes ☐ No
Possible test case verdicts:	
- Test case does not be required to the test object..... :	NRq（Not required）
- Test case does not apply to the test object..... :	N/A (Not Applicable)
- Test object does meet the requirement..... :	P (Pass)
- Test object does not meet the requirement..... :	F (Fail)

General remarks:

The test results presented in this report relate only to the submitted sample as received.

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Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Environmental condition of the testing in this report:

1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C;

2) T.C. Temperature conditioned:

a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C;

and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
1 (7.3)	Visual inspection	Marking/ information	—	Marking and the information supplied by the manufacturer, requirements refer to Cl.9 and Cl.10	The clause were not required	NRq
2 (7.4)	Packaging	Visual inspection	—	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Particle filtering half masks packaged and protected against mechanical damage and contamination.	Pass
3 (7.5)	Material	Visual inspection	—	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Materials were suitable withstand handling and wear.	Pass
			—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure	
					Sample 2: neither facepiece nor straps have mechanical failure	
					Sample 3: neither facepiece nor straps have mechanical failure	
			—	After undergoing S.W. and T.C., none of the particle filtering half masks shall not collapse.	Sample 4: no collapse	
					Sample 5: no collapse	
					Sample 6: no collapse	
			—	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Not constitute a hazard or nuisance for the wearer	
4 (7.6)	Cleaning and disinfecting		—	Particle filtering half mask designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5.	☐ Fulfil the requirements after testing, or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	N/A
			—	With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. Testing shall be done in accordance with 8.11.	☐ Tests results refer to S. No. 7(7.9.2), or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result				Single item decision
5 (7.7)	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1: has the feeling of comfortable wearing				Pass
					Sample 2: has the feeling of comfortable wearing				
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm				
					Sample 2: All fastenings are firm				
		Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field				
					Sample 2: Having a wider visual field				
6 (7.8)	Finish of parts	Visual inspection	—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs				Pass
7 (7.9.2)	Leakage— Penetration of filter material	Sodium chloride	—	≤**6%**	A.R.[1]	0.1%	0.2%	0.1%	Pass
					S.W.[1]	0.2%	0.1%	0.1%	
					M.S+ T.C.[2]	0.3%	0.2%	0.2%	
		Paraffin oil	—	≤**6%**	A.R.[1]	0.1%	0.1%	0.1%	Pass
					S.W.[1]	0.1%	0.2%	0.1%	
					M.S+ T.C.[2]	1.4%	1.4%	1.6%	
		[1] average penetration over a time of 30s, beginning 3 min after the start of the test reported [2] max. penetration during exposure test reported; Note: The penetration of the filter of the particle filtering half mask shall meet the requirements below: Maximum penetration of sodium chloride aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1% Maximum penetration of paraffin oil aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%							

S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result		Single item decision
8 (7.10)	Compatibility with skin	—	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	A.R.	5 pcs all don't cause irritation	Pass
				T.C.	5 pcs all don't cause irritation	
9 (7.11)	Flammability	—	When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.4s	Pass
					The Sample is burning. Burning time:0.4s	
				T.C.	The Sample is burning. Burning time:0.4s	
					The Sample is burning. Burning time:0.4s	
10 (7.12)	Carbon dioxide content of the inhalation air	—	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume). Remark: 3 half masks (S1, S2 and S3) A.R. tested.	Sample 1	0.7125%	Pass
				Sample 2	0.7135%	
				Sample 3	0.7145%	
				average	0.71%	
11 (7.13)	Head harness	—	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position	A.R.	All of 5 pieces particle filtering half mask meet the requirements	Pass
				T.C.	All of 5 pieces particle filtering half mask meet the requirements	
12 (7.14)	Field of vision	—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field		Pass

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
13 (7.15)	Exhalation valve(s)	Visual inspection	—	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No exhalation valve(s)	N/A
			—	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage, and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	No exhalation valve(s)	
		Flow conditioning	—	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	No exhalation valve(s)	
		Strength of attachment of exhalation valve housing	—	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.	No exhalation valve(s)	
14 (7.17)	Clogging— Breathing resistance & Penetration of filter material		—	Optional for single shift use devices, mandatory for re-usable devices. Tested by Cl. 7.17.1/2/3.	☐ Tests results refer to Table C&D, or ☒ Tests not requested for single shift use face mask	N/A
15 (7.18)	Demountable parts		—	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No demountable parts	N/A

Table A- Leakage—Total Inward Leakage

S.No. (Cl.No.)	Test item	Unit	Technical requirements[1)]	Test result							Single item decision
				Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	
16 (7.9.1)	Leakage—Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than **11%**; And in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than **8%.**	A.R.	5.7	6.5	6.6	6.8	6.1	6.3	Pass
					5.8	6.3	6.6	6.5	5.8	6.2	
					5.7	6.4	6.5	6.3	5.9	6.2	
					6.1	7.1	6.9	7.0	6.4	6.7	
					5.6	6.3	6.5	6.6	5.9	6.2	
				T.C.	5.7	6.2	6.1	6.3	5.7	6.0	
					6.2	6.6	6.8	6.9	6.3	6.6	
					6.2	6.6	7.0	6.7	6.3	6.6	
					6.2	7.1	7.3	7.2	6.6	6.9	
					5.3	6.0	6.2	6.1	5.5	5.8	

Note 1:
at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than
25 % for FFP1 11 % for FFP2 5 % for FFP3
in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than
22 % for FFP1 8 % for FFP2 2 % for FFP3.

Table A-1- Test subjects—Facial dimension

Test Subject No.	Length of face (mm)	Width of face (mm)	Depth of face (mm)	Width of mouth (mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	120	135	125	50

Table B- Breathing Resistance

S.No. (Cl.No.)	Test item		Unit	Technical requirements[1)]	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
17 (7.16)	Breathing resistance	Inhalation 30 L/min	mbar	≤0.7	A.R.	0.5	0.5	0.5	0.5	0.4	Pass
						0.4	0.5	0.5	0.5	0.5	
						0.4	0.5	0.5	0.5	0.4	
					S.W.	0.5	0.4	0.5	0.4	0.5	
						0.4	0.5	0.5	0.5	0.4	
						0.5	0.5	0.4	0.5	0.5	
					T.C.	0.5	0.5	0.5	0.5	0.4	
						0.4	0.5	0.5	0.5	0.5	
						0.5	0.4	0.5	0.4	0.5	
		Inhalation 95 L/min		≤2.4	A.R.	1.9	1.9	1.9	1.9	1.8	Pass
						1.8	1.9	1.9	1.9	1.9	
						1.9	1.8	1.9	1.8	1.9	
					S.W.	1.8	1.9	1.9	1.9	1.8	
						1.9	1.9	1.9	1.9	1.8	
						1.8	1.9	1.9	1.9	1.9	
					T.C.	1.9	1.8	1.9	1.8	1.9	
						1.8	1.9	1.9	1.9	1.8	
						1.9	1.9	1.8	1.9	1.9	
		Exhalation 160 L/min		≤3.0	A.R.	2.4	2.4	2.4	2.4	2.3	Pass
						2.3	2.4	2.4	2.4	2.4	
						2.4	2.3	2.4	2.3	2.4	
					S.W.	2.4	2.4	2.3	2.4	2.4	
						2.3	2.4	2.4	2.4	2.3	
						2.4	2.3	2.4	2.3	2.4	
					T.C.	2.4	2.4	2.4	2.4	2.3	
						2.3	2.4	2.4	2.4	2.4	
						2.4	2.3	2.4	2.3	2.4	

Note 1: Limitation may need be changed according to classification, refer to Table 2 — Breathing resistance of EN 149:2001 +A1:2009 for the Technical requirements.

Table C- Clogging Test—Breathing resistance

S.No. (Cl.No.)	Test item[1) 2)]		Unit	Technical requirements[1) 2)] (mbar)	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
18 (7.17)	Clogging test— Breathing resistance	Inhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						
		Exhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						

Note 1: Valved particle filtering half masks
After clogging the inhalation resistances shall not exceed FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar at 95 l/min continuous flow;
The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Note 2: Valveless particle filtering half masks
After clogging the inhalation and exhalation resistances shall not exceed FFP1: 3 mbar, FFP2: 4 mbar FFP3: 5 mbar at 95 l/min continuous flow.

Table D- Clogging Test—Penetration of filter material

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

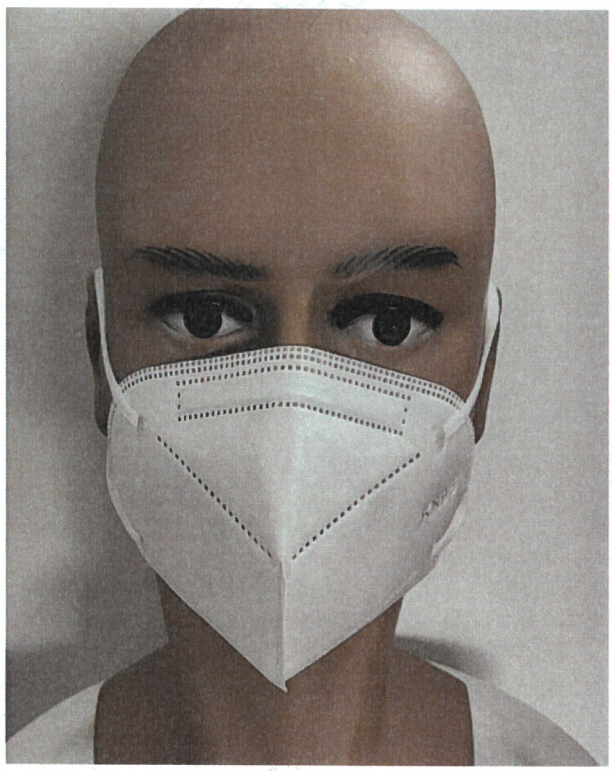
Note: Maximum penetration of test aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%

Abbreviations :		
A.R. As received	M.S. Mechanical strength	S.W. Simulated wearing treatment
T.C. Temperature conditioned	F.C. Flow conditioned	C.D. Cleaning and Disinfecting

Annex A- Estimates of the uncertainty of measurement

Test item	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%

Annex B- Sample Photo



The end