REGALOS

DOCUMENTATION

REF. CV-41 / SL-FK1391

MASK ULTRA PROTECTION FFP2

MASCARILLA ULTRA PROTECCIÓN FFP2
MASQUE FFP2 ULTRA PROTECTION FFP2
MASCHERINA PROTEZIONE ULTRA FFP2

MASTER BOX: 1000 pcs

CV-41

ITEM: SL-FK1391

DESCRIPTION: NAAMIO

MATERIAL:

5 PLY (40% non woven, 38% Meltblown, 22% algodón).

QUANTITY: 1.000

G.W

N.W

CNT SIZE

BATCH NUMBER:

PRODUCTION DATE:

VALIDITY:

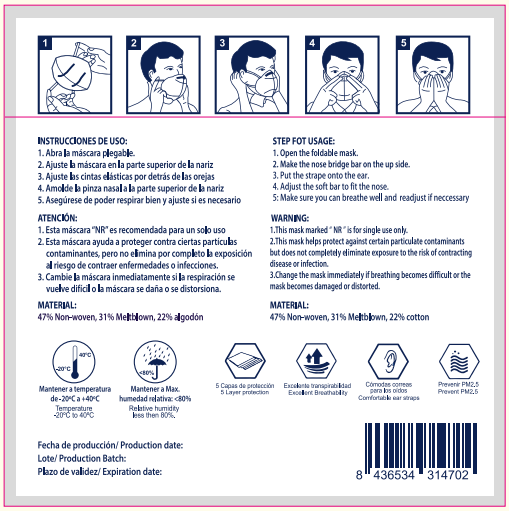
MADE IN P.R.C.

BOX: 25 pcs

L138xW138xH110mm

BAG: 1 pc

133x133 mm



GRAPHENE FREE
PRODUCTO LIBRE DE GRAFENO

NOTA IMPORTANTE:

En todos los procesos de fabricación de nuestras mascarillas, no se utiliza grafeno o derivados del mismo.

Colaboramos con

Reconocimiento a la responsabilidad ambiental

Universidad Politécnica de Cartagena

UCAM Universidad Católica de Murcia

UIMP Cartagena
Universidad Internacional Menéndez Pelayo

CIFP Carlos III FP de Calidad

AENOR ER Empresa Registrada

Asociaciones y Entidades a las que pertenecemos

COEC

Cámara Cartagena

aimfap

FYVAR

PSI

ecoembes

ecopilas

CEEIC

AECAB

Tranquilidad online

EU DECLARE OF THE CONFORMITY

CE

We

Company Name:	QUANZHOU CITY MEICHEN PROTECTIVE PRODUCTS CO.,LTD
Postal address:	NO.148,DINGXINCUO,XIN LAN VILLAGE,MEISHAN TOWN,NAN'AN QUANZHOU CITY,FUJIAN PROVINCE,CHINA
Postcode:	362321
City:	Quanzhou

Declare that the Doc is issued under our sole responsibility and belongs to the following products:

Apparatus model/Product:	Disposable protective mask FFP2
Type:	MC-001 White,black,light grey,blue and pink

Object of the declaration(identification of apparatus allowing traceability. It may include a colour image of sufficient clarity where necessary for the identification of the appearance)

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

Personal protective equipment Regulation(EU)2016/425

The following harmonised standards and technical specifications have been applied:
Title,Date of standards/specification:

EN149:2001+A1:2009

Notified body(where applicable)	4 digit notified body number
UNIVERSAL CERTIFICATION AND SURVEILLLANCE TRADE LTD,CO	2163
Certificate Number:	CE 2163-PPE-1819
Technical report numbered:	21.12.2020/2163-KKD-1819

Signed for

Quanzhou,China

Place of issue

21/12/2020

Date of issue

ALICE NING

Name,function,signature
General Manager

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1819

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

Quanzhou City Meichen Protective Products Co., Ltd.
No.148, Dingxincuo, Xin Lan Village, Meishan Town, Nan'an Quanzhou City, Fujian Province, CHINA

are tested and evaluated according to

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

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

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

Model: MC-001
Classification: FFP2 NR
Model have White, Light Grey, Black, Blue and Pink versions

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 **21/12/2020** 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

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NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1819/01

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

Quanzhou City Meichen Protective Products Co.,Ltd.
No.148, Dingxincuo, Xin Lan Village, Meishan Town, Nan'An
Quanzhou City, Fujian Province, CHINA

Continues to fulfil the requirements of

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

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
MC-001	FFP2 NR	2163-PPE-1819	21.12.2020	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 **07/02/2021** and will be valid for one year, until **06/02/2022** 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.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 21.12.2020 / 2163-KKD-1819

Manufacturer: Quanzhou City Meichen Protective Products Co., Ltd.

Address: No.148, Dingxincuo, Xin Lan Village, Meishan Town, Nan'an Quanzhou City, Fujian Province, CHINA

Introduction

This report is prepared for the, given above, manufacturer according to the test results obtained from Zhejiang Academy Of Science And Technology For Inspection And Quarantine accredited by CNAS (Chinese Accreditation Service), signatory to ILAC MRA, with number L0354 for the product identified below, dated 24.11.2020 with Serial No JKF20030909R1 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 10.12.2020 Version 0 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 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: Single shift use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 5 layers, without valve, with inside nose clip, fitted with ear loops.

Component and Materials:

Component	Material	Grade / Size
Outer Layer	Non-woven Fabric	50 gsm (± 2.0 gsm)
Filter Layer I	Melt-blown Fabric	25 gsm (± 2.0 gsm)
Filter Layer II	Melt-blown Fabric	25 gsm (± 2.0 gsm)
Filter Layer III	Hot Air Cotton Fabric	45 gsm (± 2.0 gsm)
Inner Layer	Non-woven Fabric	25 gsm (± 2.0 gsm)
Ear Strap	Spandex Elastic Band	Length: 200 mm ± 2 mm Width: 5 mm ± 0.5 mm
Nose Bridge	Polypropylene / Galvanized iron wire	Length: 85 mm ± 1 mm Width: 5 mm ± 0.5 mm

Classification: FFP2 NR

Model: MC-001

Colored samples of the mask

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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 4 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.
The model have colored ones manufactured by use of colored spunbond fabrics in the most outer layer of the mask, with the earloops as well.
Based on the test result in the test report of Shanghai Global Testing Services Co., Ltd., Report numbers THFJ20112528004R1-1EN for white, light grey, black, blue and pink REACH SVHC content reports.
Based on the results the colored materials (spunbond fabric) used in the most outer layer of the mask is considered to be safe for use on the mask.
Annexed sample photos of the colored masks.

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
1.Face piece fitting	2	0	Positive results are obtained from the test subjects **No imperfections**
2.Head harness comfort	2	0	
3.Security of fastenings	2	0	
4.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 5.454 % and 11.038 %.
All 10 individual's arithmetic mean is smaller or equal to 8 %, the values varies between 6.582 % and 7.769 %.

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.)	11	0,058	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.)	12	0,003		
(A.R.)	13	0,006		
(S.W.)	14	0,003		
(S.W.)	15	0,005		
(S.W.)	16	0,003		
(M.S. T.C.)	17	0,010		
(M.S. T.C.)	18	0,022		
(M.S. T.C.)	19	0,020		

95 L/min = 1,6 $dm^3 \cdot s^{-1}$

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

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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.)	20	0,003	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.)	21	0.002		
(A.R.)	22	0.035		
(S.W.)	23	0.071		
(S.W.)	24	0.332		
(S.W.)	25	0.150		
(M.S. T.C.)	26	0.147		
(M.S. T.C.)	27	0.081		
(M.S. T.C.)	28	0.221		

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.)	29	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.)	30	Burn for 0 s		
(T.C.)	31	Burn for 0 s		
(T.C.)	32	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.)	33	0.26	0,28 [%]	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.)	34	0.31			
(A.R.)	35	0.27			

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 4 of the technical file. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing Annex 3. The mask template (drawing) indicates that the mask will carry information about the brandname 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. The tested samples by the laboratory do not carry necessary marking information, as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production given in the technical file. MC-001 drawing, which exists in the technical file of the manufacturer, as Annex 3 olmalı of technical file. The manufacturer shall pay attention on the colored samples that the markings shall be easily readable on the mask.
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 1. 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 UNIVERSAL CERTIFICATION CE 2163 Notified Body

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TESTING
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TEST REPORT

Report No.: JKF20030909R1

Applicant : QUANZHOU CITY MEICHEN PROTECTIVE PRODUCTS CO.,LTD

Zhejiang Academy of Science and Technology for Inspection and Quarantine
Add: No. 398, Jianshe 3 Road, Xiaoshan District, Hangzhou, Zhejiang, China
Tel: +86 0571 8352 7187/185/193 Website: www.zaiq.org.cn

Report No.：JKF20030909R1
Report date：2020-11-24

The information are provided by client(applicant):				
Sample Information	Sample Name：	Filtering half mask		
	Style No.：	MC-001		
Customer Information	Applicant：	QUANZHOU CITY MEICHEN PROTECTIVE PRODUCTS CO.,LTD		
	Address/Tel：	NO.148,DINGXINCUO,XIN LAN VILLAGE,MEISHAN TOWN,NAN’ AN QUANZHOU CITY,FUJIAN PROVINCE,CHINA.		
The information are confirmed by testing organization:				
Test Information	Date of sample received:	2020-11-18	Testing period：	2020-11-18 to 2020-11-23
	Quantity：	100 Pieces		
	Sample description：	White mask		
	Basis of judgment：	EN 149:2001+A1:2009 FFP2 NR Respiratory protective devices—Filtering half masks to protect against particles —Requirements, testing, marking		
Test Conclusion	The items tested meet the requirements of EN 149:2001+A1:2009 FFP2 NR			
Test Result	Please refer to next pages.			
Remark	This report (which has modified Address) is to replace the original report (report number JKF20030909 issued on 2020-11-23), the original report also void.			

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Test Results:

Clause 7.5 Material

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

Requirement	Results	Rating
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. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. 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	Pass

Clause 7.6 Cleaning and disinfecting

（EN 149:2001+A1:2009 Clause 8.4 & 8.5 & 8.11）

Requirement	Results	Rating
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）

Requirement	Results	Rating
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

Clause 7.8 Finish of parts

（EN 149:2001+A1:2009 Clause 8.2）

Requirement	Results	Rating
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

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Clause 7.9.1 Total inward leakage

（EN 149:2001+A1:2009 Clause 8.5）

Requirement	Results	Rating
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	48 out of the 50 individual exercise≤11% 10 out of the 10 individual wearer arithmetic means ≤8%	Pass

Table 7.9.1-A Inward leakage test data

Subject	Sample No.	Condition	Walk (%)	Head side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
CQQ	1	As received	5.693	5.844	6.180	10.074	6.527	6.864
WLJ	2		6.275	6.295	6.642	10.695	7.126	7.406
WG	3		6.594	6.702	7.021	10.742	7.416	7.695
ZJH	4		6.681	6.917	7.207	10.732	7.308	7.769
TLB	5		6.665	6.840	7.181	11.038	7.122	7.769
ZMY	6	Temperature conditioned	6.425	6.538	6.995	11.026	6.972	7.591
LJF	7		6.145	6.221	6.713	10.533	6.768	7.276
HML	8		5.964	5.948	6.351	10.008	6.482	6.951
RK	9		5.701	5.731	6.072	9.724	6.249	6.696
ZD	10		5.454	5.640	5.972	9.651	6.193	6.582

Table 7.9.1-B Facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
CQQ	136	167	125	65
WLJ	132	159	110	60
WG	120	152	109	57
ZJH	122	150	104	50
TLB	125	152	111	57
ZMY	137	150	120	60
LJF	125	135	90	55
HML	124	130	115	55
RK	112	161	146	50
ZD	116	160	115	55

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Clause 7.9.2 Penetration of filter material

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

Requirement	Results	Rating
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Table 7.9.2	Pass

Classification	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Table 7.9.2 Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	11	0.058
		12	0.003
		13	0.006
	Simulated wearing treatment	14	0.003
		15	0.005
		16	0.003
	Mechanical strength+ Temperature conditioned	17	0.010
		18	0.022
		19	0.020
Paraffin oil test	As received	20	0.003
		21	0.002
		22	0.035
	Simulated wearing treatment	23	0.071
		24	0.332
		25	0.150
	Mechanical strength+ Temperature conditioned	26	0.147
		27	0.081
		28	0.221
Flow conditioning: single filter: 95.0 L/min			

Clause 7.10 Compatibility with skin

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

Requirement	Results	Rating
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）

Requirement	Results	Rating
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.	Detail refer to Table 7.11	Pass

Table 7.11 Flammability

Condition	Sample No.	Result
As received	29	Not burn
	30	Not burn
Temperature conditioned	31	Not burn
	32	Not burn

Clause 7.12 Carbon dioxide content of the inhalation air

（EN 149:2001+A1:2009 Clause 8.7）

Requirement	Results	Rating
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).	Detail refer to Table 7.12	Pass

Table 7.12 Carbon dioxide content of the inhalation air

Condition	Sample No.	Result (%)	
As received	33	0.26	Mean value: 0.28
	34	0.31	
	35	0.27	

Clause 7.13 Head harness

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

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

Clause 7.14 Field of vision

（EN 149:2001+A1:2009 Clause 8.4）

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

Clause 7.15 Exhalation valve

（EN 149:2001+A1:2009 Clause 8.2 & 8.9.1 & 8.3.4 & 8.8）

Requirement	Results	Rating
A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9. Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 L/min over a period of 30 s. When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.	Not applicable (No exhalation valve)	N/A

Clause 7.16 Breathing resistance

（EN 149:2001+A1:2009 Clause 8.9

Requirement	Results	Rating
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Table 7.16	Pass

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30L/min	95L/min	160L/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Table 7.16 Breathing resistance (mbar)

Test item	Condition	Sample No.	A	B	C	D	E
Inhalation (30 L/min)	As received	36	0.42	0.42	0.43	0.42	0.41
		37	0.38	0.39	0.40	0.39	0.38
		38	0.39	0.39	0.40	0.39	0.39
	Simulated wearing treatment	39	0.36	0.37	0.36	0.36	0.36
		40	0.38	0.38	0.38	0.37	0.37
		41	0.36	0.37	0.37	0.37	0.37
	Temperature conditioned	42	0.38	0.38	0.37	0.37	0.38
		43	0.34	0.34	0.34	0.34	0.34
		44	0.35	0.35	0.36	0.35	0.36

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Test item	Condition	Sample No.	A	B	C	D	E
Inhalation (95 L/min)	As received	36	1.28	1.26	1.27	1.29	1.28
		37	1.37	1.35	1.35	1.34	1.36
		38	1.33	1.35	1.33	1.34	1.35
	Simulated wearing treatment	39	1.24	1.24	1.23	1.24	1.24
		40	1.26	1.25	1.26	1.27	1.26
		41	1.26	1.26	1.25	1.26	1.25
	Temperature conditioned	42	1.27	1.27	1.27	1.27	1.27
		43	1.23	1.23	1.22	1.23	1.23
		44	1.28	1.27	1.27	1.27	1.27
Exhalation (160 L/min)	As received	36	1.94	1.95	1.95	1.96	1.95
		37	2.05	2.03	2.03	2.05	2.04
		38	2.00	2.01	2.01	2.00	2.01
	Simulated wearing treatment	39	1.91	1.91	1.90	1.91	1.91
		40	1.95	1.94	1.94	1.95	1.95
		41	1.96	1.96	1.98	1.99	1.99
	Temperature conditioned	42	1.95	1.97	1.97	1.95	1.96
		43	1.91	1.90	1.89	1.88	1.89
		44	1.93	1.95	1.95	1.94	1.93

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

Clause 7.17 Clogging

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

Requirement	Results	Rating
7.17.2Breathing resistance: **7.17.2.1 Valved particle filtering half masks** After clogging the inhalation resistances shall not exceed FFP1:4mbar, FFP2:5mbar, FFP3:7mbar at 95 L/min continuous flow; The exhalation resistance shall not exceed 3mbar at 160 L/min continuous flow. **7.17.2.2 Valveless particle filtering half masks** After clogging the inhalation and exhalation resistances shall not exceed FFP1:3mbar, FFP2:4mbar, FFP3:5mbar at 95 L/min continuous flow. **7.17.3Penetration of filter material:** All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.	Optional for single shift device only	Not required

Clause 7.18 Demountable parts

（EN 149:2001+A1:2009 Clause 8.2）

Requirement	Results	Rating
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Comply	Pass

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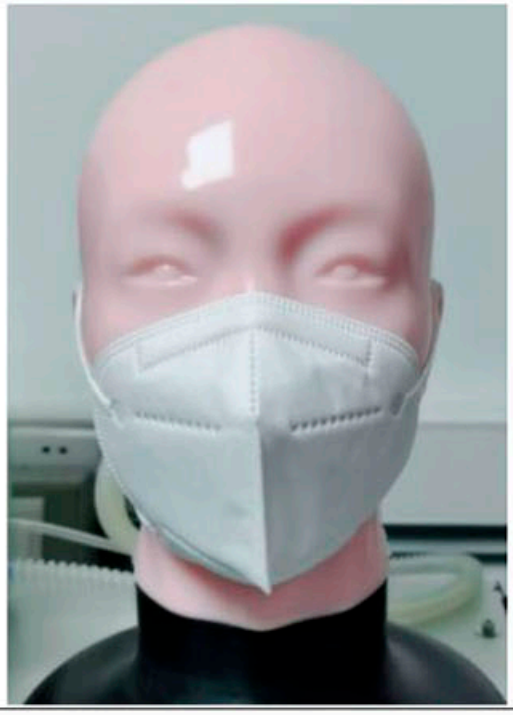
Sample photo



*** End of Report***

STATEMENT

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