

- 1. Table of Contents (Page 1)**
- 2. Basic Information (Page 2)**
- 3. Packaging & Pictures (Page 3-9)**
- 4. European CE Certificates (Page 10-16)**
- 5. European Test & Technical Documentation Review Report
(Page 17-28)**
- 6. CE Declaration of Conformity**

Civil Protective Mask UG FFP3 With Valve

Brand: UG

Type No.: WCL-0079

**EU Standard: EN149 2001 + A1:2009, Regulation (EU) 2016/425,
tested by UNIVERSAL (NB 2163) Finland**

**Classifications: FFP3, Protects against Bacterial, particulates and
virus, Filtration efficiency $\geq 99\%$**

Inspection: The Netherlands Ministry of Labor and the Tax

Investigation Bureau provide the passed proof

**Features: Against COVID-19, purchased by British and German
Federal Ministry of Health**

**Material: Total 5 layers, PP nonwoven(outer layer), Melt-blown
fabric(3 layers), PP nonwoven(Inner layer)**

Mask Specifications: Universal, 15.50x10.50cm

**Head-mounted Design: Breathable and comfortable for
prolonged wearing**

Date of manufacture: From October 2020

Expiration date: 2 years

**Packing specifications: 1 pc./PE bag, 10 pcs./box, 30
boxes/carton, 40 cartons/euro pallet**

P2



P3



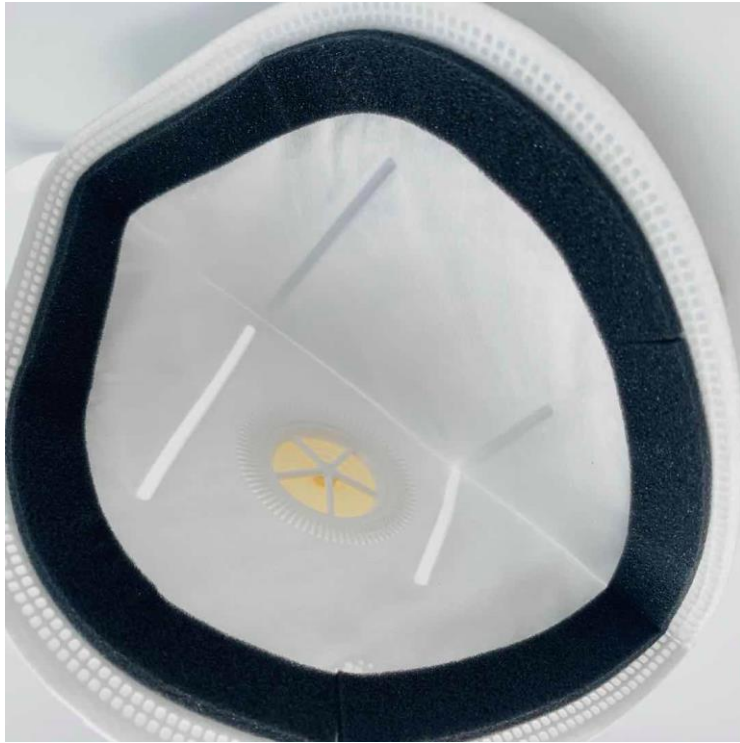
P4



P5



P6

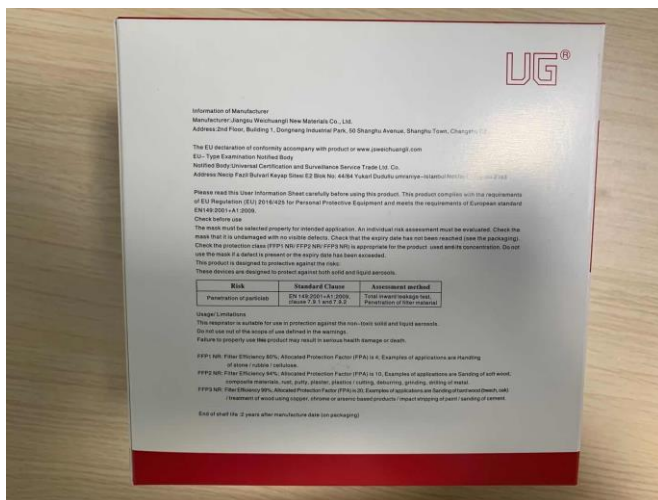


P7



P8





P10

UNIVERSAL

Verify the validity with the QR code



UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1415

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

Jiangsu Weichuangli New Materials Co., Ltd

2nd Floor, Building 1, Dongneng Industrial Park, 50 Shanghu Avenue, Shanghu Town, Changshu City
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: WCL-0079

Filtering half mask

Classification: FFP3 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 **07/09/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director

TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 07.09.2020 / 2163-KKD-1415

Manufacturer: Jiangsu Weichuangli New Materials Co., Ltd

Address: 2nd Floor, Building 1, Dongneng Industrial Park, 50 Shanghu Avenue, Shanghu Town, Changshu City 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 09.07.2020 with Serial Id WLH0741-2020 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 21 August, 2020 Version 01 provided by the manufacturer.

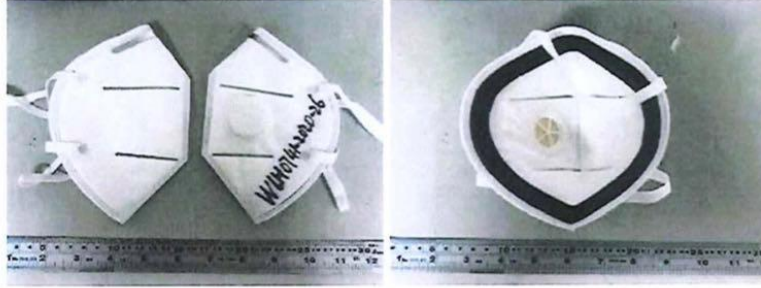
The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personal Protective Equipment Regulation and found to be appropriate.

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

Product Description: Particle Filtering Half Mask

Classification: FFP3 NR

Model: WCL-0079





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

1.1. Design principles

1.1.1. Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level.

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

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

1.1.2.2. Classes of protection appropriate to different levels of risk

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

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other inherent nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

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

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

1.2.1.3. Maximum permissible user impediment

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

1.3. Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

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

1.3.2. Lightness and design strength

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

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

1.4. Information supplied by the manufacturer

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

- a) In addition to the name and address of the manufacturer and/or his authorized representative established in the Community
- b) Storage, use, cleaning, maintenance, servicing and disinfection, cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
- c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
- d) Suitable PPE accessories and the characteristics of appropriate spare parts;
- e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
- f) The obsolescence deadline or period of obsolescence of PPE or certain of its components;
- g) The type of packaging suitable for transport;
- h) The significance of any markings (see 2.12)
- i) Where appropriate the references of the Directives applied in accordance with Article 5(6) (b);
- j) The name, address and identification number of the notified body involved in the design stage of the PPE

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





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

2.1. PPE incorporating adjustment systems

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

2.3. PPE for the face, eyes and respiratory system

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

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

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

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

2.4. PPE subject to ageing

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

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

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

2.6. PPE for use in potentially explosive atmospheres

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

2.8. PPE for intervention in very dangerous situations

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

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

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

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

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

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

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

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

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10.1. Respiratory protection

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

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

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

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

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

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

UFR-383 12.12.2018 Rev.01



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

Conforming to EN 149:2001 + A1:2009 Standard Requirements																																					
Article 5	<p>Classification: Particle Filtering Half Mask</p> <p>The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as: Filtering Efficiency and Maximum Total Inward Leakage: Classified as FFP3</p> <p>Mask is classified for single shift use, NR</p>																																				
Article 7.4	<p>Packing: Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report.</p>																																				
Article 7.5	<p>Material: Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users.</p> <p>Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.</p>																																				
Article 7.6	<p>Cleaning and Disinfection: Particle filtering half mask is not designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.</p>																																				
Article 7.7	<p>Practical Performance:</p> <p>The test report indicates that the human subjects did not face any difficulty in performing the exerccises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfections reported during total inward tests about the comfort, field of vision and fastening issues.</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th>Assessed Elements</th> <th>Positive</th> <th>Negative</th> <th>Requirements in accordance with EN 149:2001 + A1:2009 and Result</th> </tr> </thead> <tbody> <tr> <td>2.Head harness comfort</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> <td rowspan="3" style="text-align: center;">Positive results are obtained from the test subjects No imperfections</td> </tr> <tr> <td>3.Security of fastenings</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> </tr> <tr> <td>5.Field of vision</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> </tr> </tbody> </table> <p>Conditioning: (A.R.) As Received, original</p>	Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result	2.Head harness comfort	2	0	Positive results are obtained from the test subjects No imperfections	3.Security of fastenings	2	0	5.Field of vision	2	0																						
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3.Security of fastenings	2	0																																			
5.Field of vision	2	0																																			
Article 7.8	<p>Finish of Parts: Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.</p>																																				
Article 7.9.1	<p>Total Inward Leakage:</p> <p>The Total Inward Leakage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the conduction of the exerccises 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 exerccise are available in the test report.</p> <p>It was reported that: At least 47 out of the 50 exercise measurement results are smaller or equal to 5%, the values varies between 0,7% and 7,4%. At least 8 out of the 10 individual's arithmetic mean is smaller or equal to 2%, the values varies between 1,6% and 3,8%.</p> <p style="text-align: center;">According to the reported results, the product meets the limits for FFP3 classification.</p>																																				
Article 7.9.2	<p>Penetration of filter material: Sodium Chloride Testing</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th>Condition</th> <th>No. of Sample</th> <th>Sodium Chloride Testing 95 L/min max (%)</th> <th>Requirements in accordance with EN 149:2001 + A1:2009</th> <th>Result</th> </tr> </thead> <tbody> <tr> <td>(A.R.)</td> <td style="text-align: center;">-26</td> <td style="text-align: center;">0.06</td> <td rowspan="3" style="text-align: center;">FFP1 ≤ 20 %</td> <td rowspan="9" style="text-align: center;">Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1, FFP2 and FFP3 classes.</td> </tr> <tr> <td>(A.R.)</td> <td style="text-align: center;">-27</td> <td style="text-align: center;">0.21</td> </tr> <tr> <td>(A.R.)</td> <td style="text-align: center;">-28</td> <td style="text-align: center;">0.09</td> </tr> <tr> <td>(S.W.)</td> <td style="text-align: center;">-14</td> <td style="text-align: center;">0.09</td> <td rowspan="3" style="text-align: center;">FFP2 ≤ 6 %</td> </tr> <tr> <td>(S.W.)</td> <td style="text-align: center;">-15</td> <td style="text-align: center;">0.12</td> </tr> <tr> <td>(S.W.)</td> <td style="text-align: center;">-16</td> <td style="text-align: center;">0.11</td> </tr> <tr> <td>(M.S. T.C.)</td> <td style="text-align: center;">-20</td> <td style="text-align: center;">0.22</td> <td rowspan="3" style="text-align: center;">FFP3 ≤ 1 %</td> </tr> <tr> <td>(M.S. T.C.)</td> <td style="text-align: center;">-21</td> <td style="text-align: center;">0.18</td> </tr> <tr> <td>(M.S. T.C.)</td> <td style="text-align: center;">-22</td> <td style="text-align: center;">0.11</td> </tr> </tbody> </table> <p>Conditioning: (M.S.) Mechanical Strength (T.C.) Temperature Conditioning (A.R.) As Received, original (S.W.) Simulated wearing treatment</p> <p style="text-align: right;">95 L/min = 1,6 dm³.sn⁻¹</p>	Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result	(A.R.)	-26	0.06	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1, FFP2 and FFP3 classes.	(A.R.)	-27	0.21	(A.R.)	-28	0.09	(S.W.)	-14	0.09	FFP2 ≤ 6 %	(S.W.)	-15	0.12	(S.W.)	-16	0.11	(M.S. T.C.)	-20	0.22	FFP3 ≤ 1 %	(M.S. T.C.)	-21	0.18	(M.S. T.C.)	-22	0.11
Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result																																	
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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.)	-29	0.16	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.)	-30	0.28		
	(A.R.)	-31	0.36		
	(S.W.)	-17	0.41		
	(S.W.)	-18	0.50		
	(S.W.)	-19	0.59		
	(M.S. T.C.)	-23	0.14		
	(M.S. T.C.)	-24	0.40		
(M.S. T.C.)	-25	0.20			
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.)	-32	Burn for 0.6s	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.)	-33	Burn for 0.5s		
	(T.C.)	-09	Burn for 0.7s		
(T.C.)	-10	Burn for 0.4s			
(T.C.)	-10	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
	(A.R.)	-32	0.33	0.35[%]	CO ₂ content of the inhalation air shall not exceed an average of 1.0% by volume
	(A.R.)	-33	0.37		
(A.R.)	-34	0.35			
(A.R.)	-34	0.35			
Conditioning: (A.R.) As Received, original					
Article 7.13	Head harness: In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.				
Article 7.14	Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is worn.				
Article 7.15	Exhalation Valve: The valve on the mask was functioning tested during the visual inspection. Total 12 valved sample (3 as received, 3 after temperature conditioning and 3 after the test for simulated wearing and 3 after the flow conditioning) tested and the results are valid for FFP3 protection class. See results on 7.16 The samples tested in accordance to 7.9 were functional those subjected to temperature, mechanical and flow conditioned processes. No problem with the functionality of the valves noted while subjected to 300 L/min flow for 30 seconds. The valve tested withstand to a 10 N force applied to the valve horizontally. Filtering half masks fulfill requirements of the standard for FFP3 protection class..				
	Breathing Resistance: Inhalation The overall evaluation in the figures gathered for 12 different samples 3 as received, 3 with temperature conditioning, 3 simulated wearing, 3 after the flow conditioning treatment complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.				
Article 7.16	Passed.				

Article 7.17	Clogging: This test is not applied to Particle Filtering Half Mask which is not reusable. (For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)
Article 7.18	Demountable Parts: There are no demountable parts on the product.
Article 8	Testing: All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask.
Article 9	Marking – Packaging: Necessary markings are available on the product package (box). The name and trademark of the manufacturer 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 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 Appendix B of the technical file. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing WCL-0079. The mask template (drawing) indicates that the mask will carry information about the trademark and the name (UG / Jiangsu Weichuangli New Materials Co., Ltd.) 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 sample by the laboratory carries necessary marking information as stated in the technical documentation, manufacturer shall follow marking instructions for serial production. Model WCL-0079 drawing exists in the technical file of the manufacturer, Appendix C of technical file.
Article 10	Information to be supplied by the manufacturer: In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate. The manufacturer shall include this documented user information text in every smallest commercially available package.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert 	Suat KAÇMAZ Director  



China academy of safety science and technology (CASST) is accredited for compliance with ISO/IEC 17025.
 The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.
 CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT

EN 149:2001+A1:2009
Filtering half masks to protect against particles

Report no: WLH0741-2020
Product: Flat Fold Respirator Mask
Model(s): WCL-0079
Main components: Mask body, with exhalation valve
Date(s) of tests: 24th Jun~09th Jul 2020

Client	Manufacturer
TÜV Rheinland / CCIC (Qingdao) Co., Ltd. 4F, No. 2 Bldg., No.175 Zhuzhou Road, Qingdao, Shandong Province, China Client order: / Order(s) received: Jun, 2020	Jiangsu Weichuangli New Material Co., Ltd. 2nd Floor, Building 1, Dongneng Industrial Park, 50 Shanghu Avenue, Shanghu Town, Changshu City, Jiangsu Province, China Contact: / E-mail: / Phone: /

Conditions:
This report shall not be reproduced except in full, without the written approval of CASST.
The results described in this test report refer to the mentioned test samples, exclusively. A copy of the test report, complete or in extracts, is not allowed without any written permission of the CASST.
Any objection should be submitted within 2 weeks from the date of receipt of the report, and it will not be accepted after the deadline.
Specimens will be disposed of 4 weeks from the date of this report, unless otherwise instructed.

Signed: 
 张明明/Zhang Mingming, Authorized Signatory

Issued: 2020-07-09

Page 1 of 11

Summary of assessment*

Clause		Assessment
	Model:	WCL-0079
7.4	Packaging	NRq
7.5	Material	Pass
7.6	Cleaning and disinfecting	NAp
7.7	Practical performance	Pass
7.8	Finish of parts	Pass
7.9.1	Total inward leakage	Pass
7.9.2	Penetration of filter material: Sodium chloride	Pass
7.9.2	Penetration of filter material: Paraffin oil	Pass
7.10	Compatibility with skin	Pass
7.11	Flammability	Pass
7.12	Carbon dioxide content of the inhalation air	Pass
7.13	Head harness	Pass
7.14	Field of vision	Pass
7.15	Exhalation valve(s)	Pass
7.16	Breathing resistance	Pass
7.17	Clogging	NRq
7.18	Demountable parts	NAp
9	Marking	NRq
10	Information to be supplied by the manufacturer	NRq

Key

	Shading shows the clauses requested.
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "Result details" section for more information.
Fail	Requirement not satisfied. Refer to the "Result details" section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

* Assessment relates only to those specimens which were tested and are the subject of this report.

Product characteristics

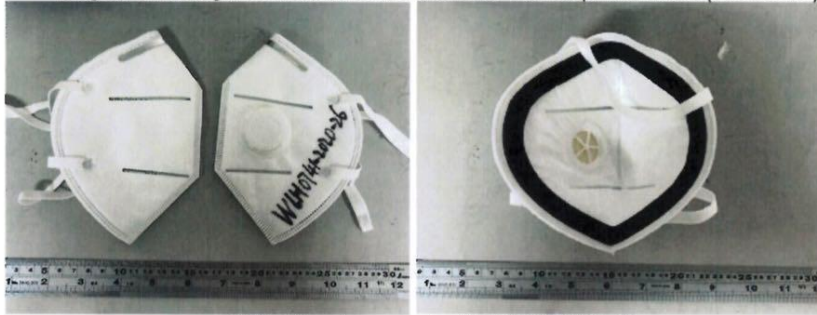
Property	Characteristic
Model	WCL-0079
Classification claimed	FFP3 NR
Exhalation valve(s)	Single

Submission details

Product	Quantity	Date received	Specimen No.
Flat Fold Respirator Mask (WCL-0079)	110	24 th Jun 2020	WLH0741-2020 -01 to -110

Photographs of the products tested

Jiangsu Weichuangli New Material Co., Ltd.'s Flat Fold Respirator Mask (WCL-0079)



CASSTspecimennumberWLH0741-2020-26

Procedures

Specimens were selected at random from the submission(s) detailed above.

Testing was performed in accordance with EN 149:2001 incorporating Corrigendum No. 1 (January 2003), and amendment A1 (2009) unless otherwise specified below. Reference should be made to the standard when reading this report.

Unless stated otherwise, specimens were tested in the condition as received.

Result details**7.4 Packaging****NRq**

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.

7.5 Material**Pass¹**

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.

Note1: In accordance with the requirement.

Specimens -14, -15, -16 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.

Specimens -01, -02, -03 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

7.6 Cleaning and disinfecting**NAP²**

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.

Note2: Single shift use only.

7.7 Practical performance**Pass³**

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

Note3: No imperfections.

Specimen and subject details:

Specimen	Subject
-41	ZMM
-42	SM

7.8 Finish of parts**Pass⁴**

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

Note4: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 Total inward leakage (%)**Pass⁵**

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.

Note5: 46 out of the 50 individual exercise results were not greater than 5%; 8 of the 10 individual wearer arithmetic means were not greater than 2%. Detailed data are showed below.

Subject	Specimen	Cond	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
ZMM	-41	AR	1.5	2.8	2.8	0.5	1.4	1.8
SM	-42	AR	1.2	2.3	2.4	1.8	1.5	1.9
GJB	-43	AR	1.6	3.2	1.7	2.2	0.9	1.9
ZH	-44	AR	1.0	2.0	2.1	1.5	1.2	1.6
JLX	-45	AR	2.2	5.7	7.2	1.9	2.0	3.8
LZM	-04	TC	0.7	2.5	2.7	1.2	0.9	1.6
TJ	-05	TC	1.2	2.4	2.5	1.1	1.8	1.8
YZF	-06	TC	1.0	7.4	7.3	1.6	1.2	3.7
LCF	-07	TC	1.2	2.4	2.3	1.7	1.7	1.9
TS	-08	TC	1.0	2.1	3.1	0.8	1.1	1.6
Maximum permitted			5					2

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
ZMM	114	157	119	50
SM	116	144	109	49
GJB	109	154	109	57
ZH	102	152	113	55
JLX	119	152	109	59
LZM	118	157	124	44
TJ	105	151	110	52
YZF	113	151	106	48
LCF	119	165	121	56
TS	97	146	102	51

7.9.2 Penetration of filter material**Pass**

The penetration of the filter of the particle filtering half mask shall meet the requirements:

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

Sodium chloride test results: (Pass)

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
-26	A.R.	0.06	
-27		0.21	
-28		0.09	
-14	S.W.	0.09	
-15		0.12	
-16		0.11	
-20	M.S. + T.C.	0.22	0.23
-21		0.18	0.21
-22		0.11	0.16
Maximum permitted		1	

Paraffin oil test results: (Pass)

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
-29	A.R.	0.16	
-30		0.28	
-31		0.36	
-17	S.W.	0.41	
-18		0.50	
-19		0.59	
-23	M.S. + T.C.	0.14	0.17
-24		0.40	0.41
-25		0.20	0.22
Maximum permitted		1	

7.10 Compatibility with skin**Pass⁶**

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Note6: Specimens -41, -42, -43, -44, -45 (A.R.) and specimens -04, -05, -06, -07, -08 (T.C.) were tested. No irritation or any other adverse effect to health.

7.11 Flammability**Pass**

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.

Specimen	Condition	Results
-32	A.R.	burn for 0.6 s
-33		burn for 0.5 s
-09	T.C.	burn for 0.7 s
-10		burn for 0.4 s

7.12 Carbon dioxide content of the inhalation air**Pass**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).

Specimen	CO ₂ (%)
-32	0.33
-33	0.37
-34	0.35
Maximum permitted	1.0

7.13 Head harness**Pass⁷**

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.

Note7: Specimens -41, -42, -43, -44, -45 (A.R.) and specimens -04, -05, -06, -07, -08 (T.C.) were tested. Head harness (head straps) can be donned and removed easily, adjustable or self-adjusting, and have sufficiently robust to hold the face mask firmly. The product satisfied the total inward leakage requirements. See 7.9.1 for results.

7.14 Field of vision**Pass⁸**

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

Note8: Specimens -41 and -42 (A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 Exhalation valve**Pass⁹**

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.

Note9:

There were no observed problems during testing of function in all orientations. See 7.16 for results.

The valve was protected against dirt and mechanical damage by a shroud.

The product satisfied leakage requirements. See 7.9.1 for results.

There were no observed problems when assessing operation after high exhalation flow.

See 7.16 for results.

The valve housing withstood 10 N applied for 10 s. Specimens -38 (A.R.), -40 (T.C.) and -39 (M.S.) Were tested.

7.16 Breathing resistance**Pass¹⁰**

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min×2.0 l/stroke)
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note10: FFP3 Filtering face mask. Test results are detailed below.

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)				
		At 30 l/min	At 95 l/min	Breathing machine (25 cycles/min×2.0 l/stroke)				
				A	B	C	D	E
-35	A.R.	0.48	1.52	1.82	1.86	1.84	1.87	1.85
-36		0.48	1.50	1.83	1.79	1.82	1.84	1.86
-37		0.50	1.54	1.84	1.82	1.85	1.85	1.86
-11	T.C.	0.45	1.43	1.74	1.75	1.72	1.76	1.71
-12		0.45	1.41	1.71	1.73	1.75	1.76	1.74
-13		0.46	1.47	1.83	1.79	1.72	1.76	1.78
-17	S.W.	0.52	1.60	1.91	1.87	1.85	1.83	1.81
-18		0.50	1.56	1.86	1.84	1.81	1.83	1.87
-19		0.49	1.53	1.82	1.86	1.81	1.76	1.79
-46	A.R. + F.C.	0.49	1.51	1.79	1.83	1.76	1.80	1.77
-47	T.C. + F.C.	0.51	1.54	1.81	1.87	1.82	1.85	1.84
-48		0.46	1.45	1.79	1.72	1.77	1.82	1.81
Maximum permitted		1.0	3.0	3.0				

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

7.17 Clogging

NRq¹¹

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 95 l/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 95 l/min continuous flow.

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 given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.

Note11: Single shift use only.

7.18 Demountable partsNAP¹²

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

Note12: No demountable parts were used.

9 Marking

NRq

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then:

"NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or

"R" if the particle filtering half mask is re-usable. Example: FFP2 R D."

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then:

"NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or

"R" if the particle filtering half mask is re-usable. Example: FFP2 R D."

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space (see 9.2.4).

Examples FFP3 NR D, FFP2 R D"

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified

10 Information to be supplied by the manufacturer

NRq

10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.

10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.

10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on:

application/limitations; the meaning of any colour coding; checks prior to use; donning, fitting; use; maintenance (e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.

10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.

10.5 Warning shall be given against problems likely to be encountered, for example:

- fit of particle filtering half mask (check prior to use);
- it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;
- air quality (contaminants, oxygen deficiency);
- use of equipment in explosive atmosphere.

10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.

10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift."

End of Test Report.



