



Testing and Certification Center  
17, Boulevard Paul Langevin  
38600 FONTAINE - France  
Tél. +33.(0)4.76.53.52.22

**Yiwu Zhonglai labour Protective Articles  
Co., Ltd.  
Chengxi Characteristic Industrial Zone  
Chengxi Street  
YIWU CITY - Zhejiang Province  
China**

**PPE REGULATION 2016/425 – ANNEX V  
MODULE B – EU TYPE EXAMINATION  
ASSESSMENT REPORT**

**Respiratory protective device**

Report n°	<b>20.0675</b>
Technical referential	<b>European coordination sheet PPE-R/02.075 version 2</b>
Type of device	<b>PPE category III Filtering half mask to protect against COVID-19</b>
Trade mark	<b>MAIKEN</b>
Model	<b>ZLSS-77</b>

Fontaine, the 02/12/2020

Report sent for the attention of Agnes Gao to the email address [agnes.gao@cegaomeng.com](mailto:agnes.gao@cegaomeng.com)

This report includes 13 pages

The technical assessment manager  
*Immaterial original*

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DAIGAU  
Validation électronique

# Summary

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## 1.Introduction - Description of the service

This assessment report concerns PPE category III – Filtering half mask to protect against COVID-19 as defined in European coordination sheet PPE-R/02.075 version 2.

Its purpose is to assess the conformity of the PPE with the PPE REGULATION 2016/425, with a view to be placed on the European market exclusively.

The assessment was conducted in accordance with purchase order signed on 15/06/2020 placed by Yiwu Zhonglai labour Protective Articles Co., Ltd.

Company: Yiwu Zhonglai labour Protective Articles Co., Ltd. - Chengxi Characteristic Industrial Zone  
Chengxi Street - YIWU CITY - Zhejiang Province - China

## 2.Use of the report

This assessment report only concerns the equipment identified in clause 4 and described in clause 7.

Only an integral reproduction of this assessment report is authorized.

The manufacturer, or his representative, commits himself not to use this assessment report for equipment that is not strictly identical to the equipment covered by this assessment report.

## 3.Economical operator(s)

Yiwu Zhonglai labour Protective Articles Co., Ltd. - Chengxi Characteristic Industrial Zone  
Chengxi Street - YIWU CITY - Zhejiang Province - China

## 4.Identification of the equipment

Trade mark: MAIKEN

Model: ZLSS-77

## 5.Conditions for use of the equipment

This filtering half mask is designed for protection against COVID-19 only. As requested by World Health Organization recommendations, for this specific use, the nominal protection factor given by this filtering half mask is the same than the FFP2 nominal protection factor defined in EN 149:2001+A1:2009. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.

## 6.Reference specification

The assessment of conformity with Regulation 2016/425 of 9<sup>th</sup> march 2016 "Personal Protective Equipment" was conducted taking into account the provisions of European coordination sheet PPE-R/02.075 version 2 "Respiratory protective device – Filtering half mask to protect against COVID-19".

## 7. Technical Documentation

### 7.1. Identification

Identification of the assessed Technical Documentation:

1. Authorized representative – Company: Chen Xiaolan - Yiwu Zhonglai labour Protective Articles Co., Ltd.
2. Commitment signature date: 09/11/2020
3. Technical Documentation reference: ZL-PPE-001

### 7.2. Drawing



### 7.3. Description

Filtering half mask to protect against COVID-19 without exhalation valve, limited to one shift use. The half mask is foldable with a vertical fold flat shape, designed with a noseclip in aluminium and two self-adjusting ear loop harnesses in nylon and spandex. The filter media is composed of four layers in polypropylene and one layer in ethylene-propylene sidebyside.

### 7.4. Description of components

Detailed description of components in the Technical Documentation.

### 7.5. CE Marking

× Notified body in charge of assessment control to article 19c) of PPE regulation (module C2 or D):

**APAVE SUDEUROPE SAS - France**

× CE mark: **CE 0082**

× Graphic of letters C and E: **Conform**

× Height of mark: **6 mm**

× Marking clear and permanent: **Conform**

× Location of the marking: **Sprayed on the surface of the mask**

### 7.6. Packaging

Month and year of manufacture and month and year of obsolescence are indelibly and unambiguously marked on the packaging.

## 8. Correlation between the articles of PPE Regulation 2016/425 and the reference standard

The following table shows the correlation between the essential health and safety requirements of Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" and the articles of the European coordination sheet PPE-R/02.075 version 2 "Respiratory protective device – Filtering half mask to protect against COVID-19".

<b>PPE Regulation 2016/425</b> Annex II	<b>Clauses of the RfU</b>
1.1.1	3.7; 3.9
1.1.2.1	3.7; 3.9; 3.11
1.1.2.2	3.9
1.2.1	3.6; 3.11; 3.13; 3.15
1.2.1.1	3.5; 3.6; 3.7; 3.10
1.2.1.2	3.7; 3.8
1.2.1.3	3.7; 3.13
1.3.1	3.7
1.3.2	3.4; 3.5; 3.7
1.4	5
2.1	3.12
2.3	3.13
2.4	3.6; 4; 5
2.6	5
2.8	5
2.9	3.12 ; 3.16
2.12	4
3.10.1	3.6; 3.7; 3.8; 3.9; 3.11; 3.15; 4; 5

**WARNING: Other requirements and other EU Directives maybe applicable to the products falling within the scope of this Recommendation For Use.**

## 9.Examination report

Article of PPE-R/02.075 version 2	Content	Conformity			Comments
		Yes	No	N-A	
<b>Art. 3</b>	<b>Requirements</b>				
Art 3.3	<b>Visual inspection</b> The visual inspection shall also include the marking and the information supplied by the manufacturer	✓			
Art 3.4	<b>Packaging</b> Filtering half masks against COVID-19 shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	✓			
Art 3.5	<b>Material</b> Materials used shall be suitable to withstand handling and wear over the period for which the filtering half masks against COVID-19 is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	✓			
Art 3.6	<b>Cleaning and disinfecting</b> If the filtering half masks against COVID-19 is designed to be cleaned and disinfected, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Cleaning and disinfection method can be accepted only if they are scientifically proved in peer reviewed scientific publications effective against the SARS-CoV-2, or have been recommended by European Centre for Disease Prevention and Control, ECDC With reference to 3.9, after cleaning and disinfecting the filtering half masks against COVID-19 shall satisfy the penetration requirement.			✓	

Article of PPE-R/02.075 version 2	Content	Conformity			Comments
		Yes	No	N-A	
Art 3.7	<p><b>Practical performance</b></p> <p>The filtering half masks against COVID-19 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. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test houses shall provide full details of those parts of the practical performance tests which revealed these imperfections.</p> <p>Here are the comments of the test subjects:</p> <p>a) head harness comfort</p> <p>b) security of fastenings</p> <p>c) field of vision</p> <p>d) any other comments reported by the wearer on request</p> <p>During the practical performance test, the test subject should pay particular attention to the ability of the product to maintain a good faceséal. If the wearer observes that a good faceséal is not maintained, they shall be instructed to readjust the filtering half mask according to the user instructions. Should the test subject experience further difficulties with maintaining a good faceséal during the practical performance test, the filtering half mask shall be considered unsatisfactory.</p>	✓			<p>Date of test: 04/08/2020</p> <p>No imperfections determined</p> <p>No comment</p> <p>No comment</p> <p>No comment</p> <p>No comment</p> <p>No comment</p>
Art 3.8	<p><b>Finish of parts</b></p> <p>Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs</p>	✓			



Article of PPE-R/02.075 version 2	Content	Conformity*			Comments
		Yes	No	N-A	
Art 3.9	<b>Penetration of filter material</b> The Maximum penetration of sodium chloride aerosol at 95l/min of the filter of the filtering half masks against COVID-19 shall not exceed 6%.	✓			Date of test: 04/08/2020
Art 3.10	<b>Compatibility with skin</b> 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.	✓			Manufacturer statement
Art 3.11	<b>Carbon dioxide content of the inhalation air</b> The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	✓			Date of test: 04/08/2020  CO <sub>2</sub> (As Received)
					0,72%   0,77%   0,81%

\* The measurement uncertainties are not taken into account for the assessment of conformity.

#### Sodium chloride penetration of filter material tests results

Conditioning	As Received		
Exposure (120mg)	0,3	0,2	0,2
Penetration (3min)	0,3	0,2	0,2

Values in %

Article of PPE-R/02.075 version 2	Content	Conformity*			Comments																						
		Yes	No	N-A																							
Art 3.12	<p><b>Head harness</b></p> <p>The head harness shall be designed so that the filtering half mask can be donned and removed easily.</p> <p>The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the filtering half mask firmly in position.</p>	✓			Self-Adjusting ear loop harness																						
Art 3.13	<p><b>Field of vision</b></p> <p>The field of vision is acceptable if determined so in practical performance tests</p>	✓			See Art 3.7																						
Art 3.14	<p><b>Exhalation valve(s)</b></p> <p>A filtering half masks against COVID-19 may have one or more exhalation valve(s), which shall function correctly in all orientations</p> <p>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 filtering half masks against COVID-19 to comply with 3.9.</p> <p>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.</p> <p>When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10 N applied for 10s.</p>			✓ ✓ ✓ ✓																							
Art 3.15	<p><b>Breathing resistance</b></p> <p>The breathing resistances apply to valved and valveless filtering half masks and shall meet the requirements FFP2 of Table 2.</p> <p style="text-align: center;">Tableau 2 – Breathing resistance</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="3">Classification</th> <th colspan="3">Maximum permitted resistance (mbar)</th> </tr> <tr> <th colspan="2">inhalation</th> <th>exhalation</th> </tr> <tr> <th>30 l/min</th> <th>95 l/min</th> <th>160 l/min</th> </tr> </thead> <tbody> <tr> <td>FFP1</td> <td>0.6</td> <td>2.1</td> <td>3.0</td> </tr> <tr> <td>FFP2</td> <td>0.7</td> <td>2.4</td> <td>3.0</td> </tr> <tr> <td>FFP3</td> <td>1</td> <td>3</td> <td>3.0</td> </tr> </tbody> </table>	Classification	Maximum permitted resistance (mbar)			inhalation		exhalation	30 l/min	95 l/min	160 l/min	FFP1	0.6	2.1	3.0	FFP2	0.7	2.4	3.0	FFP3	1	3	3.0				Date of test: 04/08/2020
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FFP3	1	3	3.0																								
Art 3.16	<p><b>Demountable parts</b></p> <p>All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.</p>	✓		✓																							

\* The measurement uncertainties are not taken into account for the assessment of conformity.

#### Breathing resistance tests results

Conditioning	As Received		
	at 30l/min	0,42	0,23
at 95l/min	1,33	1,03	1,15
at 160l/min	2,00	1,70	1,71

Values in mbar

Article of PPE-R/02.075 version 2	Content	Conformity			Comments
		Yes	No	N-A	
<b>Art. 4</b>	<b>Marking</b>				
Art 4.1	<b>Packaging</b> The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent. - The name, trademark or other means of identification of the manufacturer or supplier. - Type-identifying marking. - The intended use, which must be stated only as "Filtering half mask to protect against COVID-19" - The number and version of This RFU. Eg ; PPE-R/02.075 version 2 - At least the month and year of end of shelf life. The end of shelf life may be informed by a pictogram. - The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using a pictogram. - The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram.	✓ ✓ ✓ ✓ ✓ ✓ ✓			
Art 4.2	<b>Filtering half mask</b> Filtering half-mask against COVID-19 complying with this Recommendation for use shall be clearly and durably marked with the following: - The name, trademark or other means of identification of the manufacturer or supplier. - Type-identifying marking. - The intended use, which must be stated only as "COVID-19" - The number and version of This RFU. Eg ; PPE-R/02.075 version 2 - Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.	✓ ✓ ✓ ✓ ✓		✓	
<b>Regulation</b>	CE Marking (CE + Notified body in charge of module C2 or D) ; The CE marking shall be affixed visibly, legibly and indelibly to the PPE ; For PPE subject to 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 ; Name and address of the manufacturer ; Type, batch or serial number or other means of identification	✓ ✓ ✓ ✓ ✓			



## 10. Conclusion

The PPE category III – Filtering half mask to protect against COVID-19 identified in paragraph 4 meets the Essential Health and Safety Requirements of PPE Regulation 2016/425 of 9<sup>th</sup> march 2016.

The assessment of conformity takes into account the compliance of the PPE with the provisions of European coordination sheet PPE-R/02.075 version 2, and with the conformity of manufacturer's technical documentation.

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