



中国认可  
国际互认  
检测  
TESTING  
CNAS L10118



国检检测  
CHINA COMPONENTS TEST

# Test Report

Report No.: [2020] WSZ FHL NO.8858

Product Name Filtering half mask

Applicant DK medical GmbH

Manufacturer WUXI YUSHOU MEDICAL APPLIANCES CO.,LTD.

Test Type Entrusted inspection



Jiangsu Guojian Testing Technology Co.,Ltd

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





# Test Report

Product name	Filtering half mask	Model name	YSK-P2
		Brand	—
Laboratory/Add	Jiangsu Guojian Testing Technology Co., Ltd/ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China		
Applicant/Add/Tel	DK medical GmbH/Joh.-Peter-Melchior-Str. 22 40885 Ratingen-Germany/—		
Manufacturer/Add/Tel	WUXI YUSHOU MEDICAL APPLIANCES CO.,LTD./No.115,Nongxinhe Road, Xishan District, Wuxi City, Jiangsu Province, China/—		
Sample classification	FFP2	Sample number	GW8858-2020
Sample quantity	100 pcs	Date of receipt of sample	07/12/2020
Test type	Entrusted inspection	Article/Batch/Style number	—
Date(s) of performance of tests	12/12/2020~15/12/2020	Testing location	Same as the Laboratory
Sample state	Meeting the requirements of testings	Sample description	Refer to page 3
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices -Filtering half masks to protect against particles -Requirements,testing,marking		
Test item(s)	Clogging—Breathing resistance, clogging test-Penetration of filter material		
Test result	The details of test results see on Pages 3-5.		
Note	The test results presented in this report relate only to the submitted sample as received.		

Su Hequn

苏赫群

Approver(name,signature)

Wan Heng

万恒

Reviewer(name,signature)

Yang Ying

杨莹

Chief Tester(name,signature)



<b>Sample description:</b>	White
<b>Test item particulars:</b>	
Type of useuse .....	<input type="checkbox"/> re-useable particle filtering half mask <input checked="" type="checkbox"/> single shift only particle filtering half mask
Classes of devices.....	<input type="checkbox"/> FFP1 <input checked="" type="checkbox"/> FFP2 <input type="checkbox"/> FFP3
Exhalation valve(s).....	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Inhalation valve(s).....	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Designed to protect against both solid & liquid aerosols. :	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>Possible test case verdicts:</b>	
- Test case does not required to the test object..... :	NRq(Not required)
- Test case does not apply to the test object..... :	N/A (Not Applicable)
- Test object does meet the requirement..... :	P (Pass)
- Test object does not meet the requirement..... :	F (Fail)
<b>General remarks:</b>	
<p>The test results presented in this report relate only to the submitted sample as received.</p> <p>This report shall not be reproduced, except in full, without the written approval of the issuing Laboratory can provide assurance that parts of a report are not taken out of context.</p> <p>Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods.</p> <p>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</p>	
<b>Environmental condition of the testing in this report:</b>	
<p>1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C;</p> <p>2) T.C. Temperature conditioned:</p> <p>a) for 24 h to a dry atmosphere of 70 °C;                      b) for 24 h to a temperature of -30 °C;</p> <p>and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.</p>	

**Table A- Clogging Test—Breathing resistance**

S.No. (Cl.No.)	Test item <sup>1)2)</sup>	Unit	Technical requirements <sup>1)2)</sup>	Test result						Single item decision	
				Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side		
1 (7.17)	Clogging test—	Inhalation 95 L/min	mbar	≤4	A.R.	3.3	3.2	3.3	3.3	3.2	Pass
					T.C.	3.3	3.3	3.3	3.2	3.3	
		3.4	3.3	3.4		3.3	3.3				
	Breathing resistance	Exhalation 95 L/min	mbar	≤4	A.R.	2.7	2.6	2.7	2.7	2.7	Pass
					T.C.	2.7	2.7	2.7	2.6	2.7	
				2.6		2.6	2.6	2.6	2.6		

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

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

**Table B- Clogging Test—Penetration of filter material**

S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result		Single item decision	
2 (7.17)	Clogging test- Penetration of filter material	Sodium chloride	—	≤ <u>6%</u>	A.R.	0.4%	Pass
					T.C.	0.5%	
		Paraffin oil	—	≤ <u>6%</u>	A.R.	0.6%	Pass
					T.C.	0.5%	
				0.6%			

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

**Abbreviations :**

A.R. As received

M.S. Mechanical strength

S.W. Simulated wearing treatment

T.C. Temperature conditioned

F.C. Flow conditioned

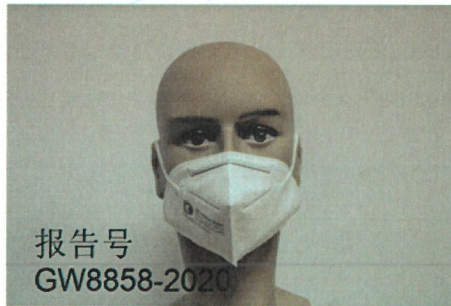
C.D. Cleaning and Disinfecting



**Annex A- Estimates of the uncertainty of measurement**

Test item	Uncertainty
Penetration of filter material	1.00%
Breathing resistance	1.90%

**Annex B- Sample Photo**



The end