

Test Report No.: 244287526a 001

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Client: **MASTERDIS GMBH**
Maria-Merian-Str.12 85521 Ottobrunn, Germany
Contact Information: Contact Person: Jan Priepke

Sample Description As Declared :

No. Of Sample	100pcs
Product Description	Filtering Half Mask FFP2
Material	Polypropylene
Colour	White
Model No.	10217
Lot No./Batch Code	2020ZS6006
Manufacture	Shenzhen Zhishan Medical Co., Ltd

Manufacture Address 2/F, Building B, Tongzhou Electronic Longgang Factory, no 1 Road 5, Baolong community, baolong street5, longgang district, Shenzhen.

Contry Of Origin	China
Test Type	Partial test
Product Type	Single shift use only
Claimed Classification	FFP2

Sample obtaining method: Sending by customer

Sample Receiving date: 2020-12-21

Delivery condition: Apparent good, Samples tested as received

Test Period: 2020-12-21 to 2021-01-13

Test Specification:

EN 149:2001 + A1:2009 Respiratory Protective Devices – Filtering Half Masks
to Protect against particles- Requirements, testing, marking

Test Result

Please refer to next page

For and on behalf of

TÜV Rheinland (Shanghai) Co., Ltd.



2021-01-14 Joyce Zhou/Assistant Technical Manager

Date

Name/Position

Test result is drawn according to the kind and extent of tests performed.

This test report relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Summary of test results

Clause	Item	M001
7.3	Visual inspection	N/R
7.4	Package	M
7.5	Material	M
7.6	Cleaning and disinfection	N/A
7.7	Practical performance	M
7.8	Finish of parts	M
7.9.1	Leakage	M
7.9.2	Penetration of filter material	M
7.10	Compatibility with skin	M
7.11	Flammability	M
7.12	Carbon dioxide content of the inhalation air	M
7.13	Head harness	M
7.14	Field of vision	M
7.15	Exhalation valve(s)	N/A
7.16	Breathing Resistance	M
7.17	Clogging	N/A
7.18	Demountable parts	M
9	Marking	N/R
10	Information to be supplied by the manufacturer	N/R

Note : M = Meet Performance Standard
 N/R = Not Request
 N/A = Not Applicable

F = Below Performance Standard
 * = No Submitted Information
 # = Refer to result page

Material list

Material No.	Material	Color/Pattern	Location
M001	Whole Product	White	Filtering Half Mask FFP2

1. Visual inspection

Test method : EN 149:2001+A1:2009 Clause 8.2

Clause	Item	M001
7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer.	N/R
7.4	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.	Pass
7.5	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.	Pass
	After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the face piece or straps.	Pass
	When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass
	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass
7.8	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs	Pass
7.18	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Pass

Remark:

N/A: Due to no relevant information/material

N/R: Due to not request

2. Practical performance

Test method : EN 149:2001+A1:2009 Clause 8.4 & 8.5

Clause	Item	M001
7.7	Wearing	Pass
7.7	Walking test	Pass
7.7	Work simulation test	Pass
7.10	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	Pass
7.13	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	Pass
7.14	The field of vision is acceptable if determined so in practical performance tests	Pass

Remark:

N/A: Due to no relevant information/material

N/R: Due to not request

3. Leakage

Test method : EN 149:2001+A1:2009 Clause 8.5
 Requirement : FFP2 :
 At least 46 out of the 50 individual exercise results for total inward leakage $\leq 11\%$
 At least 8 out of the 10 individual wearer arithmetic means for the total inward leakage $\leq 8\%$

M001									
Subject	Condition	Specimen No.	Leakage (%)					Walk	Mean
			Walk	Head Side/side	Head Up/down	Talk			
BM	As received	1	4.348	3.792	4.062	3.240	8.175	4.723	
ACH		2	5.167	5.732	6.114	7.243	5.286	5.908	
ML		3	4.968	4.734	5.926	6.148	5.305	5.416	
LLC		4	5.267	5.246	6.849	7.665	6.842	6.374	
DG		5	6.623	6.743	5.923	7.863	7.442	6.919	
SG	After conditioning	6	4.993	4.691	3.622	5.565	6.301	5.034	
YL		7	6.367	6.724	6.783	7.867	5.840	6.716	
KQ		8	5.721	6.006	7.123	7.802	5.446	6.420	
KXH		9	5.963	6.326	6.847	7.065	7.123	6.665	
YY		10	6.389	6.927	5.993	8.126	6.144	6.716	
Conclusion		Pass							

Facial Dimension Of Subject (mm)										
Subject	BM	ACH	ML	LLC	DG	SG	YL	KQ	KXH	YY
Face length	135	127	120	120	130	135	115	120	130	130
Face width	160	159	133	140	145	155	135	135	155	165
Face Depth	130	122	115	115	132	132	118	115	120	143
Mouth Width	52	55	52	50	50	55	48	50	52	50

4. Flammability

Test method : EN 149:2001+A1:2009 Clause 8.6
 Requirement : $\leq 5s$

M001				
Item	Condition	Specimen No	Test results	Conclusion
Afterflame time (s)	As received	1	1.0	Pass
		2	1.0	
	After conditioning	3	1.2	
		4	1.1	

5. Carbon Dioxide Content Of The Inhalation Air

Test method : EN 149:2001+A1:2009 Clause 8.7
 Requirement : $\leq 1\%$

M001.						
Item	Condition	Test results				Conclusion
Content (%)	As received	Specimen 1	Specimen 2	Specimen 3	Mean	Pass
		0.60	0.61	0.62	0.61	

6. Breathing Resistance

Test method	:	EN 149:2001+A1:2009 Clause 8.9
	:	FFP2:
Requirement		Inhalation: 30l/min: ≤0.7mbar
		Inhalation: 95l/min: ≤2.4mbar
		Exhalation: 160l/min: ≤3.0mbar

M001																
Flow rate (l/min)		Resistance (mbar)														
As received		Specimen 1					Specimen 2					Specimen 3				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	95	1.3	1.3	1.3	1.3	1.3	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3
Exhalation	160	2.2	2.2	2.2	2.2	2.2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1
Simulated wearing treatment		Specimen 4					Specimen 5					Specimen 6				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	95	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3
Exhalation	160	2.1	2.1	2.1	2.1	2.1	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1
Temperature conditioned		Specimen 7					Specimen 8					Specimen 9				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	95	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3
Exhalation	160	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0
Conclusion		Pass														

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

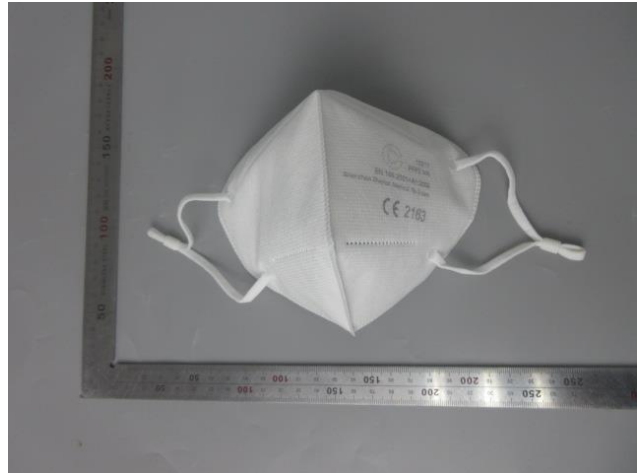
7. Penetration Of Filter Material

Test method : EN 149:2001+A1:2009 Clause 8.11

Requirement : FFP2:≤6%

M001			
Aerosol	Condition	Specimen No.	Penetration (%)
Sodium chloride Penetration	As received	1	0.036
		2	0.049
		3	0.087
	Simulated wearing treatment	4	0.023
		5	0.028
		6	0.057
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	7	0.052
		8	0.068
		9	0.079
Paraffin oil Penetration	As received	10	0.139
		11	0.122
		12	0.131
	Simulated wearing treatment	13	0.146
		14	0.120
		15	0.124
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	16	0.326
		17	0.928
		18	0.153
Conclusion	Pass		

Photo:



- END -

