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PERSONAL PROTECTIVE EQUIPMENT EU TYPE-EXAMINATION TEST REPORT

EN 149:2001+A1:2009
Particle filtering half mask

The examination and testing of Personal Protective Equipment were carried out in accordance with
MSZ EN ISO/IEC 17025:2018 standard
by GÉPTESZT Kft. Notified Body, identified under number 2233 in the EU

Customer: Siegmund Care GmbH
Address: Landsberger Straße 180 D-86507 Oberottmarshausen,
Germany

Model: siegmund air

Classification: FFP2 NR D

Exhalation valve: NO

Inhalation valve: NO

Uses: non reusable (NR)

Project number: GT522

Test report number: VD35/GT522-01/2208/EN/2233

Project worksheet number: VD34/2022/GT522-01

Date of the test: 03.08.2022 - 18.08.2022.

Samples received date: 25.07.2022.

Sample numbers: 522-1 - 522-49

Attachment: no

GÉPTESZT KFT.
EVE Vizsgáló Laboratórium
NB 2233
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Issued: Budapest, 22.08.2022.

Budai Dániel
Director of Laboratory



Relevant standards, directives and requirements:

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

Description of the sample

The fish-type mask is sold in white and black colour and contains these components:

4500-AIR (siegmond air; colour: white)

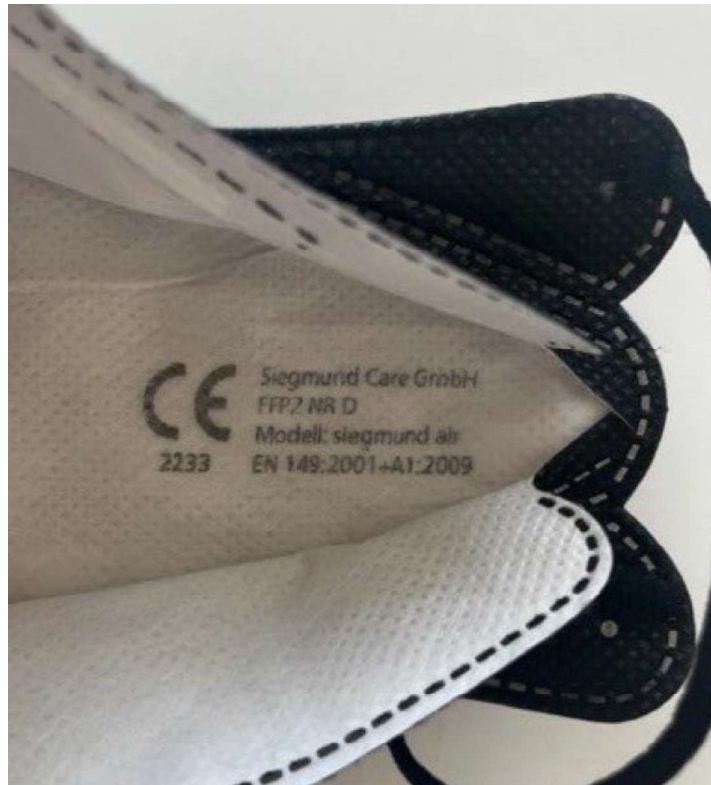
Component	Material	Specification
Outer layer 1	Spunbond 40gsm $\pm 6\%$	Polypropylene
Filter layer 2	Meltblown 25gsm $\pm 6\%$	Polypropylene
Inner layer 3	Spunbond 25gsm $\pm 6\%$	Polypropylene
Nose strip	4mm $\pm 10\%$	plastic coated double wire
Ear band	flat hollow string 4mm $\pm 10\%$	Polyamid 81% Elasthan 19%

4510-AIR (siegmond air; colour: black)

Component	Material	Specification
Outer layer 1	Spunbond 50gsm $\pm 6\%$	Polypropylenc
Filter layer 2	Meltblown 25gsm $\pm 6\%$	Polypropylene
Inner layer 3	Spunbond 25gsm $\pm 6\%$	Polypropylene
Nose strip	4mm $\pm 10\%$	plastic coated double wire
Ear band	flat hollow string 4mm $\pm 10\%$	Polyamid 81% Elasthan 19%







Short description of EU-type tests:

Requirement	Test method	Description	Result
7.4	8.2	Packaging	Passed
7.5	8.2	Material	Passed
7.6	8.11	Cleaning and disinfecting	NA
7.7	8.4	Practical performance	Passed
7.8	8.2	Finish of parts	Passed
7.9.1	8.5	Total inward leakage	Passed
7.9.2	8.11	Penetration of filter material: NaCl	Passed
7.9.2	8.11	Penetration of filter material: paraffin oil	Passed
7.10	8.4 and 8.5	Compatibility with skin	Passed
7.11	8.6	Flammability	Passed
7.12	8.7	Carbon dioxide content of the inhalation air	Passed
7.13	8.4 and 8.5	Head harness	Passed
7.14	8.4	Field of vision	Passed
7.15	8.2, 8.3.4, 8.8	Exhalation valve(s)	NA
7.16	8.9	Breathing resistance	Passed
7.17	8.10	Clogging	Passed
7.18	8.2	Demountable parts	NA
9	-	Marking	Passed
10	-	Information to be supplied by the manufacturer	Passed



Analysis and details of EU-type test results:

7.4 Packaging

Each mask is packed in a flowpack (BOPP foil 25 µm). 20/500/13500 pcs packed into carton. The packaging gives enough protection against mechanical damage or contamination.

PASSED

7.5 Material

- conditioning S.W.: Sample nr: 522-16 to 522-18
None of the particle filtering half masks have suffered mechanical failure of the facepiece or straps.
- conditioning T.C.: Sample nr.: 522-41 to 522-43
Particle filtering half masks did not collapse.

PASSED

7.6 Cleaning and disinfecting (only for reusable masks)

Because the mask is non-reusable, this test was not carried out.

NA

7.7 Practical performance

The particle filtering half masks are tested by practical performance tests under realistic conditions.

1. Walking test for 10 min
2. Work simulation tests:
 - walking on the level with headroom of $(1,3 \pm 0,2)$ m for 5 min;
 - crawling on the level with headroom of $(0,70 \pm 0,05)$ m for 5 min;
 - filling a small basket 20x in 10 min;

Subjects	Colour	Samples	Conditioning	Result
KD	white	522-1	A.R.	PASSED
VBA	black	522-2	A.R.	PASSED

There were not any imperfections related to the wearer's acceptance.

PASSED

7.8 Finish of parts

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

PASSED



7.9.1 Total inward leakage

With sodium chloride aerosol. The masks were in good condition.

Number of subjects were replaced, because of not fitting/facial dimensions:0.....

Subjects facial dimensions				
Subject	Face length, mm	Face width, mm	Face depth, mm	Mouth width, mm
KD	160	120	110	53
VBA	110	115	115	55
TLI	125	165	140	75
OJ	130	105	107	54
NA	115	100	125	50
LA	123	140	105	60
BD	120	130	135	55
RE	115	138	112	48
TLA	115	130	110	53
BK	128	150	111	51

Subject	Sample	Colour	Cond.	Total inward leakage, %					Mean, %
				Walk	Head left/right	Head up/down	Talk	Walk	
KD	522-3	white	A.R.	3,44	2,63	2,14	4,40	2,28	2,98
VBA	522-4	white	A.R.	3,38	2,61	2,55	3,19	2,98	2,94
TLI	522-5	white	A.R.	3,25	3,21	2,74	3,73	2,66	3,12
OJ	522-6	black	A.R.	4,14	3,37	4,00	4,54	3,09	3,83
NA	522-7	black	A.R.	3,38	3,41	3,26	2,27	3,17	3,10
LA	522-8	white	T.C.	3,51	3,47	3,49	4,17	3,11	3,55
BD	522-9	white	T.C.	3,29	3,11	3,17	4,01	3,35	3,39
RE	522-10	black	T.C.	3,88	3,76	3,66	4,22	3,61	3,83
TLA	522-11	black	T.C.	1,65	2,22	1,83	1,70	2,28	1,94
BK	522-12	black	T.C.	3,30	2,27	2,90	2,91	2,57	2,79

50 out of the 50 individual exercise results for total inward leakage were not greater than 11 % and 10 out of the 10 individual wearer arithmetic means for the total inward leakage were not greater than 8%.

PASSED

7.9.2 Penetration of filter material: NaCl

NaCl aerosol: concentration: 4-12 mg/m³, flow: 95 l/min

The samples were subjected to the mechanical strength test and thermal conditioning in the smallest commercially available package (BOPP foil 25 µm)

Sample	Colour	Conditioning	Penetration, %	Exposure, %
522-13	black	A.R.	0,09	NA
522-14	black	A.R.	0,08	NA
522-15	white	A.R.	0,12	NA
522-16	black	S.W.	0,14	NA
522-17	white	S.W.	0,12	NA
522-18	white	S.W.	0,16	NA
522-19	black	M.S→T.C.	NA	0,21
522-20	black	M.S→T.C.	NA	0,25
522-21	white	M.S→T.C.	NA	0,22
Maximum permitted:			6 %	

The penetration of the filter material did not exceed the maximum permitted 6 % in case of any masks.

PASSED



7.9.2 Penetration of filter material: paraffin oil

Paraffin aerosol: concentration: 15-25 mg/m³, flow: 95 l/min

The samples were subjected to the mechanical strength test and thermal conditioning in the smallest commercially available package (BOPP foil 25 µm)

Sample	Colour	Conditioning	Penetration, %	Exposure, %
522-22	white	A.R.	0,91	NA
522-23	white	A.R.	0,90	NA
522-24	black	A.R.	0,78	NA
522-25	white	S.W.	0,84	NA
522-26	black	S.W.	0,98	NA
522-27	black	S.W.	0,84	NA
522-28	white	M.S→T.C.	NA	1,14
522-29	white	M.S→T.C.	NA	1,32
522-30	black	M.S→T.C.	NA	1,73
Maximum permitted:			6 %	

The penetration of the filter material did not exceed the maximum permitted 6 % in case of any masks.

PASSED

7.10 Compatibility with skin

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

During the Practical performance test there were no problems.

During the Total inward leakage test there were no problems.

PASSED

7.11 Flammability

Sample	Colour	Conditioning
522-31	black	T.C.
522-32	white	T.C.
522-33	black	A.R.
522-34	white	A.R.

The materials used do not present a danger for the wearer and are not of highly flammable nature. The samples did not burn.

PASSED

7.12 Carbon dioxide content of the inhalation air

Air supplied from breathing machine: 25 cycles/min and 2,0 l/stroke, carbon dioxide content of exhaled air 5 V/V%, air flow 0,5 m/s.

Ambient carbon dioxide level: 0,081 % (less than 0,1 %.)

Sample	Colour/Size	CO ₂ , V/V%
522-35	white	0,42
522-36	black	0,35
522-37	black	0,34
Average		0,37

The carbon dioxide content of the inhalation air (dead space) did not exceed an average of 1,0 V/V %.

PASSED



7.13 Head harness

There were no adverse comments regarding security following limited practical performance and total inward leakage testing.

The product satisfied the total inward leakage requirements. See part 7.9.1. for results.

PASSED

7.14 Field of vision

Sample
522-1
522-2

During the practical performance test the field of vision was not affected adversely by wearing mask.

PASSED

7.15 Exhalation valve(s)

NA

7.16 Breathing resistance

The samples were subjected to thermal conditioning in the smallest commercially available package (BOPP foil 25 µm)

Sample	Colour	Cond.	Inhalation resistance, mbar		Exhalation resistance, mbar 160 l/min				
			30 l/min	95 l/min	ahead	vert.up wards	vert downwa rds	left	right
522-38	white	A.R.	0,28	1,16	1,83	1,82	1,83	1,81	1,82
522-39	white	A.R.	0,21	1,14	1,74	1,75	1,76	1,75	1,74
522-40	black	A.R.	0,22	1,15	1,71	1,70	1,71	1,72	1,73
522-41	white	T.C.	0,33	1,66	2,06	2,05	2,04	2,03	2,05
522-42	black	T.C.	0,29	1,59	1,98	1,99	1,99	1,98	1,97
522-43	black	T.C.	0,31	1,63	2,11	2,13	2,12	2,11	2,21
522-44	white	S.W.	0,30	1,60	2,34	2,33	2,35	2,33	2,34
522-45	white	S.W.	0,27	1,58	2,28	2,27	2,29	2,27	2,29
522-46	black	S.W.	0,22	1,46	2,24	2,26	2,25	2,24	2,25
Maximum permitted:			0,7	2,4	3,0				

None of the measured values exceeded the maximum values.

PASSED



7.17 Clogging

Clogging treatment with DRB 4/15 dolomite dust

Continuous flow through the dust chamber: 60 m³/h

	Conditioning	A.R.	T.C	T.C.	
	Sample	522-47	522-48	522-49	
	Colour	white	white	black	
	Requirement	Measured			
Temperature of the air, °C	23 ± 2 °C	25	25	25	
Relative humidity of the air, %	45 ± 15 %	31	32	30	
Concentration, mg/m ³	400±100 mg/m ³	396	397	445	
Exposure time, min	833 mgh/m ³	126	126	112	
Inhalation resistance, mbar at 95 l/min continuous flow	4 mbar	1,27	1,56	1,71	
Exhalation resistance at 95 l/min continuous flow	ahead	4 mbar	1,86	2,28	2,31
	vert. upwards		1,85	2,27	2,30
	vert. downwards		1,86	2,29	2,31
	left		1,87	2,28	2,32
	right		1,86	2,27	2,31
Paraffin aerosol concentration at 95 l/min flow		15-25 mg/m ³ ,			
Paraffin penetration, %	max. 6 %	2,41	-	-	
Paraffin exposure (120 mg), %	max. 6 %	-	3,40	4,46	

None of the measured values exceeded the maximum values

PASSED

7.18 Demountable parts

The device does not contain demountable parts.

NA

9. Marking

The marking information is complete and clearly and durably marked on the packaging.

The marking information is complete and clearly and durably marked on the particle filtering half mask.

PASSED

10. Information to be supplied by the manufacturer

Information to be supplied by the manufacturer accompany every smallest commercial available package and contain all information necessary for trained and qualified persons.

PASSED

Result of EU-type test:

The above described **siegmund air particle filtering half mask** at the time of the test **conformed to** the test requirements of EN 149:2001+A1:2009 class FFP2 NR at the close date of test report.

E N D O F T H E T E S T R E P O R T