CENTRALNY INSTYTUT OCHRONY PRACY
- PAŃSTWOWY INSTYTUT BADAWCZY
ul. Czerniakowska 16, 00-701 Warszawa

Zakład Ochron Osobistych

Nr 450/PZ/2021/NO

TEMAT:

Przygotowanie raportu z badań 143/PB-COV/2021/NO w języku angielskim

ZLECENIODAWCA:

Sandex M.Szandecki, J.Szandecka Sp.j.

ul. Majowa 6,

05-092 Łomianki

NIP: 1180202839

Data rozpoczęcia: 07.05.2021 r. **Data zakończenia:** 27.05.2021 r.

	Imię i nazwisko
Główny wykonawca	Małgorzata Okrasa

KIEROWNIK
ZAKŁADU OCHRON OSOBISTYCH
dr hab. inż. Katarzyna Majchrzycka
prof. nadzw. CIOP-PIB

1. Przedmiot zlecenia

Przedmiotem zlecenia było przygotowanie na prośbę Zleceniodawcy sprawozdania z badań nr 143/PB-COV/2021/NO w języku angielskim.

Miejsce wykonania zlecenia: Zakład Ochron Osobistych CIOP-PIB
Pracownia Sprzętu Ochrony Układu Oddechowego
90-133 Łódź, ul. Wierzbowa 48

Data sporządzenia sprawozdania: 27.05.2021 r.

Uwagi: Bez pisemnej zgody CIOP-PIB sprawozdanie nie może być powielane fragmentarycznie, lecz tylko w całości.

Koniec sprawozdania

CENTRAL INSTITUTE FOR LABOUR PROTECTION
– NATIONAL RESEARCH INSTITUTE
Czerniakowska 16, 00-701 Warszawa

AB 038

DEPARTMENT OF PERSONAL PROTECTIVE EQUIPMENT

LABORATORY OF RESPIRATORY PROTECTIVE DEVICES

TEST REPORT

Contract to perform testing No.: *143/PB-COV/2021/NO*

Subject of the contract: *Testing of Maska Premium SX00021 filtering half mask*

Ordering Party: *Sandex M.Szandecki, J.Szandecka Sp.j.*
ul. Majowa 6
05-092 Łomianki
Poland

Date of issuing the test report:

Main performer: *Renata Głodek*

Authorized by:
KIEROWNIK
ZAKŁADU OCHRON OSOBISTYCH
dr hab. inż. Katarzyna Majchrzycka
prof. nadzw. CIOP-PIB

Approved by:

Copy No.: 3

The report from the tests includes the results of tests carried out within the scope of the accreditation as well as unaccredited tests. The results of tests that are beyond the scope of accreditation are marked with ""*

Test object:
Forty three filtering half masks model MASKA PREMIUM SX00021 were tested. Test object is shown in figure 1. The filtering half masks were delivered by Sandex M.Szandecki, J.Szandecka Sp.j.; ul. Majowa 6; 05-092 Łomianki, Poland.

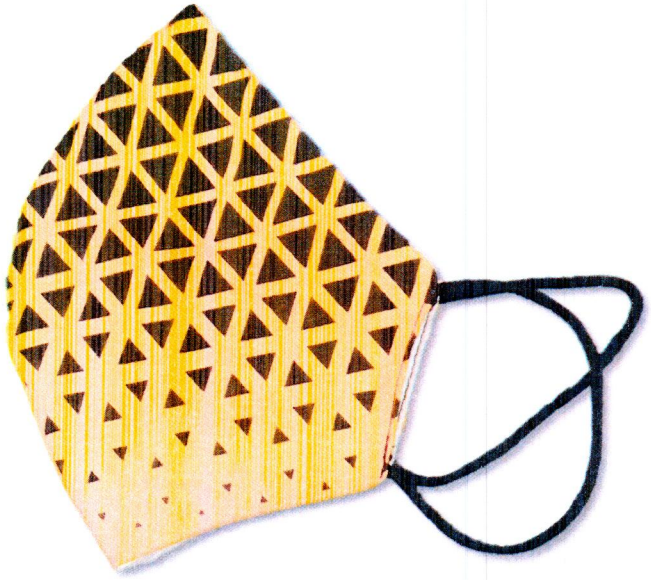

Fig. 1. Filtering half mask model MASKA PREMIUM SX00021 (Sandex M.Szandecki, J.Szandecka Sp.j.).

Place of testing: Department of Personal Protective Equipment CIOP-PIB
Laboratory of Respiratory Protective Devices
Wierzbowa 48, 90-133 Łódź, Poland

Samples registry number: NO1/16/2021
Samples receiving date: 17.02.2021
Date of completing the tests: 14.03.2021 – 31.03.2021

Identification of test methods:

Penetration of sodium chloride:	method and requirements in accordance with EN 149:2001+A1:2009
Penetration of paraffin oil mist:	method and requirements in accordance with EN 149:2001+A1:2009
Breathing resistance:	method and requirements in accordance with EN 149:2001+A1:2009
Flammability:	method and requirements in accordance with EN 149:2001+A1:2009
Practical performance test:	method and requirements in accordance with EN 149:2001+A1:2009
Total inward leakage:	method and requirements in accordance with EN 149:2001+A1:2009
CO_2 content in inhaled air:	method and requirements in accordance with EN 149:2001+A1:2009

Non-accredited tests:
Visual inspection: method and requirements in accordance with EN 149:2001+A1:2009

Before tests according to requirements of the standard, filtering half masks were submitted to:
- mechanical strength test according to 8.3.3 of EN 149:2001+A1:2009,
- temperature conditioning according to 8.3.2 of EN 149:2001+A1:2009,
- simulated wearing treatment according to 8.3.1 of EN 149:2001+A1:2009.

Note:
This test report consists of twelve (13) pages.
This test report may not be copied fragmentarily, but only as the whole unless there is CIOP-PIB permission.

TEST RESULTS OF PENETRATION OF SODIUM CHLORIDE according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

No. of sample		Penetration of NaCl, % (flow rate 1.6 dm^3s^{-1})		Requirements in accordance with EN 149:2001+ A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard[1]
		Measured value	Uncertainty (U95)		
51	MS, TC	0.41	0.04	FFP1 < 20% FFP2 < 6% FFP3 < 1%	Filtering half masks fulfill requirements given in p. 7.9.2 of the EN 149:2001+ A1:2009 standard for NaCl penetration in the range of the first, the second and the third protection class (FFP1, FFP2, FFP3).
57	MS, TC	0.19	0.02		
59	MS, TC	0.43	0.04		
93	AR	0.36	0.03		
94	AR	0.35	0.03		
95	AR	0.19	0.02		
60	SW	0.61	0.05		
61	SW	0.56	0.05		
62	SW	0.16	0.02		

Given results relate to delivered samples only.

MS – sample after the mechanical strength test
TC – sample after temperature conditioning
AR – sample as received
SW – sample after the simulated wearing treatment

[1]) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF PENETRATION OF PARAFFIN OIL MIST according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

No. of sample	Penetration of paraffin oil mist, % (flow rate 1.6 dm^3s^{-1})		Requirements in accordance with EN 149:2001+ A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard[1]
	Measured value	Uncertainty (U95)		
52 MS, TC	2,73	0,22	FFP1 ≤ 20% FFP2 ≤ 6% FFP3 ≤ 1%	Filtering half masks fulfill requirements given in p. 7.9.2 of the EN 149:2001+ A1:2009 standard for paraffin oil mist penetration in the range of the first and the second protection class (FFP1, FFP2).
53 MS, TC	1,43	0,12		
58 MS, TC	1,32	0,11		
90 AR	0,51	0,05		
91 AR	0,29	0,03		
92 AR	0,47	0,04		
54 SW	0,89	0,08		
55 SW	0,46	0,04		
56 SW	0,98	0,08		

Given results relate to delivered samples only.

MS – sample after the mechanical strength test
TC – sample after temperature conditioning
AR – sample as received
SW – sample after the simulated wearing treatment

[1]) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF INHALATION RESISTANCE
according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

No. of sample	Inhalation resistance, Pa						
	Flow rate 0.5 dm^3s^{-1}		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Flow rate 1.6 dm^3s^{-1}		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard[1]
	Measured value	Uncertainty (U95)		Measured value	Uncertainty (U95)		
87 AR	51	2	FFP1 ≤ 60 Pa FFP2 ≤ 70 Pa FFP3 ≤ 100 Pa	183	7	FFP1 ≤ 210 Pa FFP2 ≤ 240 Pa FFP3 ≤ 300 Pa	Filtering half masks fulfill requirements given in p. 7.16 of the EN 149:2001 + A1:2009 standard for inhalation resistance in the range of the first, the second and the third protection class (FFP1, FFP2, FFP3).
88 AR	47	2		179	7		
89 AR	47	2		185	7		
66 TC	48	2		178	7		
77 TC	49	2		184	7		
78 TC	48	2		183	7		
54 SW	50	2		189	7		
55 SW	52	2		190	7		
56 SW	51	2		188	7		

Given results relate to delivered samples only.

AR – sample as received
TC – sample after temperature conditioning
SW – sample after the simulated wearing treatment

[1]) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF EXHALATION RESISTANCE
according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

No. of sample	The dummy head positions	Exhalation resistance, Pa (flow rate 2.7 dm^3s^{-1})		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard[1]
		Measured value	Uncertainty (U95)		
87 AR	Facing directly ahead	184	7	FFP1 ≤ 300 Pa FFP2 ≤ 300 Pa FFP3 ≤ 300 Pa	Filtering half masks fulfill requirements given in p. 7.16 of the EN 149:2001 + A1:2009 standard for exhalation resistance in the range of the first, the second and the third protection class (FFP1, FFP2, FFP3).
	Facing vertically upwards	184	7		
	Facing vertically downwards	180	7		
	Lying on the right side	181	7		
	Lying on the left side	181	7		
88 AR	Facing directly ahead	190	7		
	Facing vertically upwards	193	7		
	Facing vertically downwards	191	7		
	Lying on the right side	193	7		
	Lying on the left side	195	7		
89 AR	Facing directly ahead	204	8		
	Facing vertically upwards	208	8		
	Facing vertically downwards	200	7		
	Lying on the right side	205	8		
	Lying on the left side	207	8		

Given results relate to delivered samples only.

AR – sample as received

[1]) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF EXHALATION RESISTANCE
according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

No. of sample	The dummy head positions	Exhalation resistance, Pa (flow rate 2.7 dm^3s^{-1})		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard[1]
		Measured value	Uncertainty (U95)		
66 TC	Facing directly ahead	164	6	FFP1 ≤ 300 Pa FFP2 ≤ 300 Pa FFP3 ≤ 300 Pa	Filtering half masks fulfill requirements given in p. 7.16 of the EN 149:2001 + A1:2009 standard for exhalation resistance in the range of the first, the second and the third protection class (FFP1, FFP2, FFP3).
	Facing vertically upwards	165	6		
	Facing vertically downwards	158	6		
	Lying on the right side	160	6		
	Lying on the left side	159	6		
77 TC	Facing directly ahead	221	8		
	Facing vertically upwards	229	9		
	Facing vertically downwards	220	8		
	Lying on the right side	221	8		
	Lying on the left side	219	8		
78 TC	Facing directly ahead	180	7		
	Facing vertically upwards	186	7		
	Facing vertically downwards	183	7		
	Lying on the right side	179	7		
	Lying on the left side	180	7		

Given results relate to delivered samples only.

TC – sample after temperature conditioning

[1]) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF EXHALATION RESISTANCE
according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

No. of sample	The dummy head positions	Exhalation resistance, Pa (flow rate 2.7 dm^3s^{-1})		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard[1]
		Measured value	Uncertainty (U95)		
54 SW	Facing directly ahead	220	8	FFP1 ≤ 300 Pa FFP2 ≤ 300 Pa FFP3 ≤ 300 Pa	Filtering half masks fulfill requirements given in p. 7.16 of the EN 149:2001 + A1:2009 standard for exhalation resistance in the range of the first, the second and the third protection class (FFP1, FFP2, FFP3).
	Facing vertically upwards	224	8		
	Facing vertically downwards	218	8		
	Lying on the right side	223	8		
	Lying on the left side	221	8		
55 SW	Facing directly ahead	146	6		
	Facing vertically upwards	148	6		
	Facing vertically downwards	151	6		
	Lying on the right side	149	6		
	Lying on the left side	150	6		
56 SW	Facing directly ahead	205	8		
	Facing vertically upwards	214	8		
	Facing vertically downwards	202	8		
	Lying on the right side	208	8		
	Lying on the left side	211	8		

Given results relate to delivered samples only.

SW – sample after the simulated wearing treatment

[1]) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF FLAMMABILITY according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

No. of sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Estimation of conformity / nonconformity with the standard
80 AR	Filtering half mask did not burn	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame.	Filtering half masks fulfill requirements given in p 7.11 of the EN 149:2001 + A1:2009 standard.
81 AR	Filtering half mask did not burn		
67 TC	Filtering half mask did not burn		
75 TC	Filtering half mask did not burn		

Given results relate to delivered samples only.

AR – sample as received
TC – sample after temperature conditioning

TEST RESULTS OF PRACTICAL PERFORMANCE TEST according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

Assessed elements	Positive assessment	Negative assessment	Requirements in accordance with EN 149:2001 + A1:2009	Estimation of conformity / nonconformity with the standard
The face piece fitting	4	0	Filtering half masks should not have imperfections related to wearer´s acceptance.	Filtering half masks fulfill requirements given in p. 7.7 of the EN 149:2001 + A1:2009 standard.
Head harness comfort	4	0		
Security of fastenings	4	0		
Speech clearness	4	0		
Field of vision	4	0		
Materials compatibility with skin	4	0		

Given results relate to delivered samples only – 68 AR, 69 AR samples were tested.

AR – sample as received

TEST RESULTS OF TOTAL INWARD LEAKAGE
according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

Test subject	No. of sample	Total inward leakage, %										Average total inward leakage, %	
		A		B		C		D		E			
		Measured value	Uncertainty (U95)	Measured value	Uncertainty (U95)	Measured value	Uncertainty (U95)	Measured value	Uncertainty (U95)	Measured value	Uncertainty (U95)	Measured value	Uncertainty (U95)
1	82 AR	2.12	0.07	2.16	0.07	2.14	0.07	5.72	0.18	3.84	0.12	3.20	0.72
2	83 AR	1.46	0.05	2.72	0.09	2.30	0.07	2.17	0.07	2.08	0.07	2.14	0.21
3	84 AR	0.76	0.03	0.30	0.01	0.48	0.02	1.13	0.04	0.63	0.02	0.66	0.15
4	85 AR	0.39	0.02	0.21	0.01	0.27	0.01	0.41	0.02	0.24	0.01	0.31	0.05
5	86 AR	0.41	0.02	0.10	0.01	0.11	0.01	0.94	0.03	0.56	0.02	0.42	0.16
6	63 TC	2.16	0.07	1.68	0.06	1.78	0.06	2.76	0.09	1.58	0.05	1.99	0.22
7	64 TC	0.56	0.02	0.68	0.03	0.59	0.02	0.64	0.02	1.09	0.04	0.71	0.10
8	73 TC	1.16	0.04	0.43	0.02	1.35	0.05	0.50	0.02	0.36	0.02	0.76	0.21
9	74 TC	2.27	0.07	2.19	0.07	3.60	0.11	3.08	0.10	3.96	0.12	3.02	0.36
10	76 TC	4.04	0.13	4.40	0.14	3.87	0.12	4.87	0.15	4.28	0.13	4.29	0.19

Given results relate to delivered samples only. A – walking, B – head left to right, C – head up and down, D – speech, E – walking

TC – sample after temperature conditioning
AR – sample as received

Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard[1]
at least 46 out of the 50 individual results shall be not greater than 25% for FFP1; 11% for FFP2; 5% for FFP3 and at least 8 out of the 10 individual wearer means shall be not greater than 22% for FFP1; 8% for FFP2; 2% for FFP3	Filtering half masks fulfill requirements given in p. 7.9.1 of the EN 149:2001 + A1:2009 standard in the range of the first and the second protection class (FFP1, FFP2).

[1]) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF CO_2 CONTENT IN INHALED AIR according to EN 149:2001+ A1:2009

Test object: filtering half masks model MASKA PREMIUM SX00021

No. of sample	CO_2 content in the inhaled air, % vol.		Average CO_2 content in the inhaled air, % vol.		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard[1]
	Measured value	Uncertainty (U95)	Measured value	Uncertainty (U95)		
70 AR	0.78	0.04	0.72	0.04	CO_2 content of the inhalation air shall not exceed an average of 1.0% by volume.	Filtering half masks fulfill requirements given in p. 7.12 of the EN 149:2001 + A1:2009 standard.
71 AR	0.71	0.04				
72 AR	0.67	0.04				

Given results relate to delivered samples only.

AR – sample as received

[1]) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF VISUAL INSPECTION according to EN 149:2001+A1:2009*)

Test object: filtering half masks model MASKA PREMIUM SX00021

Inspected parameter	Clause No. of EN 149:2001 + A1:2009 containing requirements	Estimation of conformity / nonconformity with the standard
Marking	7.3	Not applicable
Packaging	7.4	Filtering half masks fulfill requirements
Material	7.5	Filtering half masks fulfill requirements
Cleaning and disinfecting	7.6	Not applicable
Finish of parts	7.8	Filtering half masks fulfill requirements
Exhalation valve(s)	7.15	Not applicable
Demountable parts	7.18	Not applicable

Given results relate to delivered samples only. All samples were evaluated.

END OF TEST REPORT