

**CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED
PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)**

**MODÜL C2 - ÜRETİMİN DÂHİLÎ KONTROLÜ VE ÜRÜNÜN RASTGELE
ARALIKLARLA DENETİMLİ MUAYENESİNE DAYALI TİPE UYGUNLUK**

Belge No / Certificate No : 33-20-03-02
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 20.05.2022-20.05.2023
Belge Geçerlilik Tarihi / Document Validity Period : 1 yıl / 1 years
**Firma Unvanı ve Adresi /
Company Name and Address** : METALSUD LO GATTO SRL
Zona Industriale Loc. Aeroporto 89900 Vibo
Valentia (VV) ITALY
Marka / Model / Brand / Model : SICURA P20V
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : C2 MODÜLÜ/ KATEGORİ III
MODULE C2 / CATEGORY III
**Teknik Değerlendirme Rapor No/
Technical Evaluation Report No** : MNA 33-20-03-02

Ürün Tipi / Product Type:

- EN 149:2001+ A1:2009 Solunumla ilgili koruyucu cihazlar - Parçacıklara karşı koruma amaçlı filtrelili yarım maskeler/ Respiratory protective devices - Filtering half masks to protect against particles

Ürünün Malzeme Bilgisi / Product Material Information: SICURA P20V model ürünleri kumaş, elastik kayış, soluk verme valfi, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ SICURA P20V model products are manufactured using fabric, exhalation valve elastic strap, nose clip, filter layer.

Volkan AKIN

20.05.2022

Karar Verici / Approver



Okan AKEL

20.05.2022

Şirket Müdürü / General Manager



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Notified Body Number: 2841

Part 7.3 Visual inspection	Shall also the marking and the information supplied by the manufacturer	Appropriate	-	PASS
Banned Azo Dyes	< 30 mg/kg	Not applicable	-	Not applicable
Part 7.4 Packaging	Particle filtering half mask shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Appropriate	-	PASS
Part 7.5 Material	When conditioned in accordance 8.3.1 & 8.3.2 the particle filter half mask shall not collapse.	Appropriate	-	PASS
Part 7.6 Cleaning and disinfecting	After cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable	-	Not applicable
Part 7.7 Practical performance	No negative comments should be made by the test subject regarding any of the criteria evaluated.	Appropriate	-	PASS
Part 7.8 Finish of parts	Parts of the device likely to come into contact with the wearer shall have no sharp edge or burrs.	Appropriate	-	PASS

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.1 Total inward leakage	At least 46 out of the 50 individual exercise result	≤25	≤11	≤5	See the table below	FFP2	PASS
	At least 8 out of the 10 individual wearer arithmetic means	≤22	≤8	≤2	See the table below	FFP2	PASS

Total Inward Leakage (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As recieved)	4,6	6,5	6,3	7,1	5,7	6,0
Subject 2 (As recieved)	6,4	5,9	6,9	8,9	6,9	7,0
Subject 3 (As recieved)	6,1	5,6	6,7	9,6	7,6	7,1
Subject 4 (As recieved)	8,1	7,6	8,2	7,8	7,9	7,9
Subject 5 (As recieved)	7,4	4,6	6,7	8,9	6,9	6,9
Subject 6 (After temperature conditioning)	6,8	7,2	4,4	9,4	8,6	7,3
Subject 7 (After temperature conditioning)	7,0	7,8	6,6	6,8	8,9	7,4
Subject 8 (After temperature conditioning)	6,3	6,6	7,8	6,7	7,6	7,0

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Subject 9 (After temperature conditioning)	6,2	6,4	6,3	6,8	8,2	6,8
Subject 10 (After temperature conditioning)	7,0	6,2	6,0	8,3	6,3	6,8

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	120	145	105	61
2	128	155	112	68
3	110	128	105	55
4	123	140	133	57
5	116	128	99	58
6	120	130	91	56
7	138	151	119	65
8	110	130	96	55
9	120	131	85	58
10	135	142	125	83

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.2 Penetration of filter material	Sodium chloride, 95 L/min % , max	% 20	% 6	% 1	See the table below	FFP2	PASS
	Paraffin oil, 95 L/min % , max	% 20	% 6	% 1	See the table below	FFP2	PASS

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As received	4,5	4,7
As received	4,4	4,7
As received	4,4	4,6
After the simulated wearing treatment	4,6	4,6
After the simulated wearing treatment	4,3	4,8
After the simulated wearing treatment	4,5	4,5
Mechanical strength and temperature conditioning (120mg)	5,2	5,6
Mechanical strength and temperature conditioning (120mg)	5,3	5,4
Mechanical strength and temperature conditioning (120mg)	5,1	5,6

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.10 Compatibility with skin	Materials shall not be known to be likely to cause irritation or any other adverse effect to health				Appropriate	-	PASS
Part 7.11 Flammibility	Mask shall not burn or not to continue to burn for more than 5 s				Flame not seen	-	PASS
Part 7.12	Shall not exceed an average of % 1				0,71	-	PASS

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Carbondioxide content of the inhalation air		0,73 0,73		
Part 7.13 Head harness	It can be donned and removed easily	Appropriate	-	PASS
Part 7.14 Field of vision	The field of vision shall acceptable in practical performance test.	Appropriate	-	PASS
Part 7.15 Exhalation valve(s)	It shall withstand axially a tensile force of 10 N apply for 10 s. If fitted, shall continue to operate correctly after a continuous exhalation flow of 300 L/min over a period of 30 s.	Not applicable	-	Not applicable

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.16 Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1,0 mbar	See the table below	FFP2	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3,0 mbar	See the table below	FFP2	PASS
	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar	See the table below	FFP2	PASS

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0,5	1,4
As recieved	0,5	1,3
As recieved	0,4	1,4
After temperature conditioning	0,3	1,2
After temperature conditioning	0,4	1,2
After temperature conditioning	0,4	1,3
After the simulated wearing treatment	0,5	1,3
After the simulated wearing treatment	0,5	1,3
After the simulated wearing treatment	0,4	1,4

Breathing Resistance 160L/min (mbar)	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As recieved	2,2	2,1	2,2	2,2	2,2
As recieved	2,2	2,2	2,2	2,1	2,1
As recieved	2,1	2,2	2,1	2,1	2,1
After temperature conditioning	2,1	2,0	2,1	2,0	2,0
After temperature conditioning	2,0	2,0	2,0	2,0	2,0
After temperature conditioning	2,1	2,1	2,1	2,1	2,0
After the simulated wearing treatment	2,1	2,0	2,0	2,0	2,1
After the simulated wearing treatment	2,1	2,1	2,1	2,1	2,1
After the simulated wearing treatment	2,0	2,0	2,0	2,0	2,0
After flow conditioning	2,1	2,1	2,1	2,1	2,0
After flow conditioning	2,1	2,0	2,0	2,0	2,1

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After flow conditioning	2,1	2,1	2,1	2,1	2,1
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TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.17 Clogging	After clogging the inhalation resistances shall not exceed. (valved)	4 mbar	5 mbar	7 mbar	Not applicable	-	Not applicable
	The exhalation resistance shall not exceed 3 mbar at 160 L/ min continuous flow. (valved)				Not applicable	-	Not applicable
	After clogging the inhalation and exhalation resistances shall not exceed. (valveless)	3 mbar	4 mbar	5 mbar	Not applicable	-	Not applicable
Part 7.18 Demountable part	All demountable parts (if fitted) shall be readily connected and secured were possible by hand.				Not applicable	-	Not applicable
Part 9 Marking	The packaging information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.				Appropriate	-	PASS

9. DECISION

Analysis and examinations SICURA P20V model coded personal protective equipment; Respiratory Protective Devices EN 149:2001 +A1:2009- Filtered Half Masks for Protection Against Particles - Properties, Experiments and Marking standards are evaluated. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports (M-2022-0431)
- User Instruction

CONTROLLER : VOLKAN AKIN

SIGN :

DATE : 20.05.2022



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Purpose of Analysis	: Special request
Sample Send Org.	: METALSULD Lo Gatta S.r.l.
Address	: Metalsud Lo Gatto S.r.l. Zona Industriale-Localita Aeroporto Zip Code 89900 City Vibo Valentia(VV) Italy
Sample Acceptance Date	: 2022-05-05 16:34:10
Analysis Date	: 2022-05-05 18:00:48
Sample Quantity	: 80 Pieces
Sample Description	: SICURA P20V
Other informations	:

Flammability

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Flammability	No flame seen.	Shall not burn for more than 5 sec after removal from the flame	EN 13274-4	PASS	-

Penetration Of Filter Material

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Penetration Of Filter Material	Check the table for results.	FFP1 \leq 20 FFP2 \leq 6 FFP3 \leq 1	EN 149+A1 Part 8.11, EN 13274-7	PASS(FFP2)	-

	Sodium Chloride (%)	Paraffin Oil (%)
As received 1	4,5	4,7
As received 2	4,4	4,7
As received 3	4,4	4,6
After the simulated wearing treatment 1	4,6	4,6
After the simulated wearing treatment 2	4,3	4,8
After the simulated wearing treatment 3	4,5	4,5
Mechanical strength and temperature conditioning (120 mg) 1	5,2	5,6
Mechanical strength and temperature conditioning (120 mg) 2	5,3	5,4
Mechanical strength and temperature conditioning (120 mg) 3	5,1	5,6

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Carbon Dioxide Content Of The Inhalation Air

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Carbon Dioxide Content Of The Inhalation Air	Check the table for results.	Maximum %1	EN 149+A1 Part 8.7	PASS(FFP2)	-

	CO2 (%)
Sample 1	0,71
Sample 2	0,73
Sample 3	0,73

Breathing Resistance

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Breathing Resistance	Check the table for results.	Check the table for limits	EN 149+A1 Part 8.9	PASS(FFP2)	-

Classification	30 L/min max basınç (mbar)	95 L/min max basınç (mbar)	160 L/min max basınç (mbar)
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

Inhalation	30 L/min	95 L/min
As received 1	0,5	1,4
As received 2	0,5	1,3
As received 3	0,4	1,4
After temperature conditioning 1	0,3	1,2
After temperature conditioning 2	0,3	1,2
After temperature conditioning 3	0,4	1,3
After the simulated wearing treatment 1	0,5	1,3
After the simulated wearing treatment 2	0,5	1,3
After the simulated wearing treatment 3	0,4	1,4

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After the flow conditioning 1	0,4	1,3
After the flow conditioning 2	0,5	1,4
After the flow conditioning 3	0,5	1,4

Exhalation 160L/min	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As received 1	2,2	2,1	2,2	2,2	2,2
As received 2	2,2	2,2	2,2	2,1	2,1
As received 3	2,1	2,2	2,1	2,1	2,1
After temperature conditioning 1	2,1	2,0	2,1	2,0	2,0
After temperature conditioning 2	2,0	2,0	2,0	2,0	2,0
After temperature conditioning 3	2,1	2,1	2,1	2,1	2,0
After the simulated wearing treatment 1	2,1	2,0	2,0	2,0	2,1
After the simulated wearing treatment 2	2,1	2,1	2,1	2,1	2,1
After the simulated wearing treatment 3	2,0	2,0	2,0	2,0	2,0
After the flow conditioning 1	2,1	2,1	2,1	2,1	2,0
After the flow conditioning 2	2,1	2,0	2,0	2,0	2,1
After the flow conditioning 3	2,1	2,1	2,1	2,1	2,1

Total Inward Leakage

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Total Inward Leakage	Check the table for results.	Check the table for limits	EN 149+A1 Part 8.5	PASS(FFP2)	-

	At least 46 out of the 50 individual exercise result shall be not greater than	At least 8 out of the 10 individual wearer arithmetic means shall be not greater than
FFP1	≤25	≤22
FFP2	≤11	≤8
FFP3	≤5	≤2

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	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	4,6	6,5	6,3	7,1	5,7	6,0
Subject 2 (As received)	6,4	5,9	6,9	8,9	6,9	7,0
Subject 3 (As received)	6,1	5,6	6,7	9,6	7,6	7,1
Subject 4 (As received)	8,1	7,6	8,2	7,8	7,9	7,9
Subject 5 (As received)	7,4	4,6	6,7	8,9	6,9	6,9
Subject 6 (After temperature conditioning)	6,8	7,2	4,4	9,4	8,6	7,3
Subject 7 (After temperature conditioning)	7,0	7,8	6,6	6,8	8,9	7,4
Subject 8 (After temperature conditioning)	6,3	6,6	7,8	6,7	7,6	7,0
Subject 9 (After temperature conditioning)	6,2	6,4	6,3	6,8	8,2	6,8
Subject 10 (After temperature conditioning)	7,0	6,2	6,0	8,3	6,3	6,8

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*The analysis is within the scope of accreditation.

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6. A decision rule is a rule that determines how measurement uncertainty is to be taken into account when specifying compliance with a specified specification. TLM-052 Decision Rule According to the implementation instruction, the decision rule chosen in agreement with the customer will be applied if necessary.
7. Limit Values are determined by taking from analysis methods.
8. The laboratory is not responsible if the information provided by the CUSTOMER affects the validity of the results.
9. Test and / or measurement results, expanded measurement uncertainties (if any) and test methods are given in the following pages, which are the supplementary part of this certificate.
10. Water Repellency Determination Hydrostatic Pressure Determination T S ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13965-2 (Strength Test Device E / N: 50) Analysis and resistance to liquid chemical permeation TS EN 659 -A1 Part 3.18 (Liquid Chemical Transfer Device E / N: 107) Analysis is carried out in the conditioning room and ISO 139 PART 3.2 conditions (23 ± 2 ° C temperature and $50 \pm 4\%$ relative humidity) are applied for ambient conditions.

Selin Gergin

Numune Kabul ve Raporlama Sorumlusu

2022-05-20 17:34:16

Erhan Üstünel

Laboratuvar Sorumlusu

2022-05-20 17:30:56



VOLKAN AKIN
Laboratuvar Müdürü
2022-05-20 17:32:50

