

# 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

Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / Certification Date / Certificate Validity Date

Belge Geçerlilik Tarihi / Document Validity Period

Firma Unvanı ve Adresi / Company Name and Address

Direktifi / Directive

Marka / Model / Brand / Model

Modülü/Kategori / Module / Category

Teknik Değerlendirme Rapor No/ Technical Evaluation Report No Ürün Tipi / Product Type: : 220-21-01-R02-02

: 07.06.2022-07.06.2023

: 1 yıl / 1 year

: SEGA GRUP TEKSTİL SAN. TİC. LTD. ŞTİ. Çakmaklı Mah. Hadımköy yolu cad. No:137/1 Büyükçekmece-İSTANBUL

: SEGA-P2

: 2016/425 REGULATION

: C2 MODÜLÜ/ KATEGORİ III MODULE C2 / CATEGORY III

: MNA 220-21-01-R02-02

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

Ürünün Malzeme Bilgisi / Product Material Information: SEGA-P2 model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ SEGA-P2 model products are manufactured using fabric, elastic strap, nose clip, filter layer.

Erhan ÜSTÜNEL 07.96.2022 Karar Verjci / Approver

Okan AKEL 07.06.2022 Şirket Müdürü / General manazer



MNA Laboratuvarları San. Tic.Ltd .Şti Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul Tel: 0216 574 07 08 Faks: 0216 575 13 31 <u>www.mnalab.com</u>





# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT **CHECK AT RANDOM INTERVALS**

(MODULE C2, ANNEX VII) (220-21-01-R02-02)

Report No

: 220-21-01-R02-02

Report Date

: 26.05.2022

**Application No** 

: 220-21-01-R02-02

#### 1. COMPANY INFORMATION:

SEGA GRUP TEKSTİL SAN. TİC. LTD. ŞTİ.

Çakmaklı Mah. Hadımköy yolu cad. No:137/1 Büyükçekmece-İSTANBUL

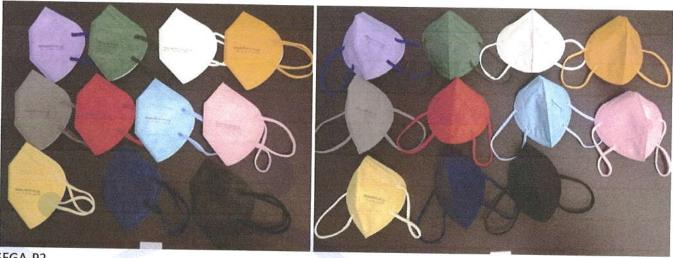
### 2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection fitler material.

#### 3. PPE TYPE IDENTIFICATION

EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles -Requirements, testing, marking

### 4. PPE PICTURES



### SEGA-P2

### 5. PPE DIMENSIONS:

SEGA-P2 model has been found to be produced using standard size.

# 6. PPE PRODUCT MATERIAL INFORMATION:

The mask is made of elastic strap, nonwoven fabric on the outer and inner layers and fitler material on the middle layer.

# 7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- A visual inspection was made according to EN 149:2001 +A1:2009 for ergonomics.
- Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials were determined by visual inspection according to EN 149:2001 +A1:2009.

### 8. ANALYSIS EVALUATION AND MARKING:

### EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFO LEVELS	ORMAN S	CE	RESULTS	PERFORMANC E LEVELS	EVALUATIO N
		FFP1	FFP2	FFP3			1.77



# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT **CHECK AT RANDOM INTERVALS**

(MODULE C2, ANNEX VII) (220-21-01-R02-02)

Part 7.3	Shall also the marking and the information	Appropriate		DAGG
Visual inspection	supplied by the manufacturer	Арргорпасе		PASS
Banned Azo Dyes	< 30 mg/kg	< 5 mg/ kg	-	PASS
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 RESULTS LEVELS	LEVELS	RESULTS	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 Inwa	ard Leakage	(%)			
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	5,1	7,0	6,8	7,6	6,2	6,5
Subject 2 (As received)	6,9	6,4	7,4	9,4	7,4	7,5
Subject 3 (As received)	6,6	6,1	7,2	10,1	8,1	7,6
Subject 4 (As received)	7,7	8,1	6,0	9,5	9,7	
Subject 5 (As received)	7,9	5,1	7,2	9,4	7,4	8,2
Subject 6 (After temperature conditioning)	7,3	7,7	4,9	9,9		7,4
Subject 7 (After temperature conditioning)	7,5	8,3	7,1	7,3	9,1	7,8
Subject 8 (After temperature conditioning)	6,8	7,1	8,3	7,2	8,1	7,5



# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS

(MODULE C2, ANNEX VII) (220-21-01-R02-02)

Subject 9 (After temperature conditioning)	6,7	6,9	6,8	7.2	0.7	7.2
Subject 10 (After temperature		0,5	0,0	7,3	8,7	7,3
conditioning)	7,5	6.7	6,5	8,8	6,8	7.2
whice facial dimensions		-/-		0,0	0,0	1,3

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width
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	PERFORMAN LEVELS		PERFORMANCE LEVELS		SULTS PERFORMANCE EVALUAT LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.2 Penetration of filter	Sodium chloride, 95 L/min %, max	% 20	% 6	%1	See the table below	FFP2	PASS
material	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	3,2	3,7
As received	3,1	3,9
As received	3,1	3,9
After the simulated wearing treatment	3,5	3,4
After the simulated wearing treatment	3,0	3,0
After the simulated wearing treatment	3,3	3,4
Mechanical strength and temperature conditioning (120mg)	5,1	5,5
Mechanical strength and temperature conditioning (120mg)	5,3	5,8
Mechanical strength and temperature conditioning (120mg)	5,1	5,8

TESTS	PARAMETER	PERFC LEVEL	ORMAN S	CE	RESULTS	PERFORMANCE LEVELS	EVALUATION
<b>建筑市间建</b>	19-26 At 10	FFP1	FFP2	FFP3			1
Part 7.10 Compatibility with skin	Materials shall no cause irritation or health				Appropriate	- /	PASS
Part 7.11 Flammibility	Mask shall not bur for more than 5 s	n or not to	continu	e to burn	Flame not seen	- \ / /	PASS
Part 7.12	Shall not exceed a	n average o	of % 1		0,74 0,70	-	PASS

U-FRM-056.REV.01./18.03.2022



# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS

(MODULE C2, ANNEX VII) (220-21-01-R02-02)

Carbondioxide content of the inhalation air		0,77	102-02	
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	- 8	Not applicable

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.16 Breathing	Inhalation 30L/min	0,6 mbar	0,7 mbar	1,0 mbar	See the table below	FFP2	PASS
Resistance	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 received	0,6	1,8
As received	0,5	1,7
As received	0,5	1.7
After temperature conditioning	0,5	1,7
After temperature conditioning	0,6	1,8
After temperature conditioning	0,6	
After the simulated wearing treatment	0,6	1,8
After the simulated wearing treatment	0,5	1,7
After the simulated wearing treatment	0,5	1,7

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 received	2,9	2,9	2,8	2,8	2,8
As received	2,8	2,8	2,8	2,8	2,9
As received	2,9	2,9	2,9	2,9	
After temperature conditioning	2,9	2,8	2,9	2,8	2,9
After temperature conditioning	2,8	2,8	2,8		2,8
After temperature conditioning	2,9	2,9		2,8	2,8
After the simulated wearing treatment	2,9		2,9	2,9	2,8
		2,8	2,8	2,8	2,9
After the simulated wearing treatment	2,9	2,9	2,9	2,9	2,9
After the simulated wearing treatment	2,8	2,8	2,8	2,8	2,8



# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS

Notified Body Number: 2841

(MODULE C2, ANNEX VII) (220-21-01-R02-02)

TESTS	PARAMETER		ORMAN		RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3		And the second second second second	
Part 7.17 Clogging	After clogging the inhalation resistances shall not exceed. (valved)	4 mba r	5 mba r	7 mbar	Not applicable	-	Not applicable
	The exhalation resist 3 mbar at 160 L/ r (valved)				Not applicable	-	Not applicable
	After clogging the inhalation and exhalation resistances shall not exceed. (valveless)	3 mba r	4 mba r	5 mbar	Not applicable	-	Not applicable
Part 7.18 Demountable part	All demountable par readily connected possible by hand.				Not applicable		Not applicable
Part 9 Marking	and durably marke commercially availa legible through it transparent.	d on the smallest			Appropriate	-	PASS

### 9. DECISION

Analysis and examinations SEGA-P2 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-2022-0345, M-2022-0346)
- User Instruction

CONTROLLER

: ERHAN ÜSTÜN

**SIGNATURE** 

.

DATE

: 07.06.2022



Report Nu. : M-2022-0345 Date : 2022-05-26 13:11:41 Page : 1 / 5 Rev:

Purpose of Analysis : Special request

Sample Send Org. : Sega Grup Tekstil Sanayi ve Ticaret Limited Şirketi

Address : Çakmaklı mah. Hadımköy Yolu Cad. No: 137/1 Büyükçekmece İstanbul

Sample Acceptance Date : 2022-04-07 11:42:38

Analysis Date : 2022-04-07 14:33:47

Sample Quantity : 80 Pieces
Sample Description : SEGA-P2

Other informations :

## **Flammability**

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Flammability	Flame not seen.	Shall not burn for more than 5 sec after removal from the flame	EN 13274-4	PASS(FFP2)	-

### **Penetration Of Filter Material**

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

	Sodium Chloride (%)	Paraffin Oil (%)
As received 1	3,2	3,7
As received 2	3,1	3,9
As received 3	3,1	3,9
After the simulated wearing treatment 1	3,5	3,4
After the simulated wearing treatment 2	3,0	3,0
After the simulated wearing treatment 3	3,3	3,4
Mechanical strength and temperature conditioning (120 mg) 1	5,1	5,5
Mechanical strength and temperature conditioning (120 mg) 2	5,3	5,8
Mechanical strength and temperature conditioning (120 mg) 3	5,1	5,8

Report Nu. : M-2022-0345 Date : 2022-05-26 13:11:41	Page : 2 / 5	Rev:
---	--------------	------

# **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	0,74
Sample 2	0,70
Sample 3	0,77

# **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	0,6	1,8
As received 2	0,5	1,7
As received 3	0,5	1,7
After temperature conditioning 1	0,5	1,7
After temperature conditioning 2	0,6	1,8
After temperature conditioning 3	0,6	1,8
After the simulated wearing treatment 1	0,6	1,7
After the simulated wearing treatment 2	0,5	1,7
After the simulated wearing treatment 3	0,5	1,7
After the flow conditioning 1	-	-



Report Nu. : M-2022-0345	Date: 2022-05-26 13:11:41	Page : 3 / 5		Rev:
After the flow conditioning 2	-		-	
After the flow conditioning 3	-		-	

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	2,9	2,9	2,8	2,8	2,8
As received 2	2,8	2,8	2,8	2,8	2,9
As received 3	2,9	2,9	2,9	2,9	2,9
After temperature conditioning 1	2,9	2,8	2,9	2,8	2,8
After temperature conditioning 2	2,8	2,8	2,8	2,8	2,8
After temperature conditioning 3	2,9	2,9	2,9	2,9	2,9
After the simulated wearing treatment 1	2,8	2,8	2,8	2,8	2,8
After the simulated wearing treatment 2	2,9	2,9	2,9	2,9	2,9
After the simulated wearing treatment 3	2,8	2,8	2,8	2,8	2,8
After the flow conditioning 1	-	-	-	-	-
After the flow conditioning 2	-	-	-	-	-
After the flow conditioning 3	-	-	-	-	-

# **Total Inward Leakage**

Т	ests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Total Inw	ard 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

Report Nu. : M-2022-0345 Date : 2022-05-26 13:11:41 Page : 4 / 5 Rev:

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



Report Nu.: M-2022-0345 Date: 2022-05-26 13:11:41 Page: 5 / 5 Rev:

Operating as a test laboratory, MNA Laboratories is accredited by TÜRKAK according to AB-1183-T and TS\_EN\_ISO/IEC\_17025:2017 standards has been done. A multilateral agreement with the European Accreditation Association (EA) on the recognition of the Turkish Accreditation Agency (TÜRKAK) test reports and It has signed a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC).

\*The analysis is within the scope of accreditation.

#### Note:

- 1. No part of this analysis report may be used alone or separately and may be partially copied or reproduced without the written permission of the laboratory. It cannot be reproduced, used by third parties or as a means of advertising.
- 2. Analysis results are valid for the sample sent and analyzed by the company/institution/individual to MNA Laboratories. represent the whole may not.
- 3. Unsigned and Unsealed reports are invalid.
- 4. This analysis report cannot be used in judicial-administrative proceedings and for advertising purposes.
- 5. Results are valid for the sample received.
- 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
- 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 pa ges, 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  $\pm$  2  $^{\circ}$  C temperature and 50  $\pm$  4% relative humidity) are applied for ambient conditions.

Selin Gergin

Numune Kabul ve Raporlama Sorumlusu

2022-05-26 10:59:56

Erhan Üstünel

Laboratuvar Sorumlusu

2022-05-26 10:54:02

**VOLKAN AKIN** 

Laboratuvar Müdürü

2022-05-26 10:35:02





AB-1183-T

M-2022-0346

05-22

Report Nu. : M-2022-0346 Date : 2022-05-26 13:11:53 Page : 1 / 3 Rev:

Purpose of Analysis : Special request

Sample Send Org. : Sega Grup Tekstil Sanayi ve Ticaret Limited Şirketi

Address : Çakmaklı mah. Hadımköy Yolu Cad. No: 137/1 Büyükçekmece İstanbul

Sample Acceptance Date : 2022-04-07 11:43:46

Analysis Date : 2022-04-07 14:33:40

Sample Quantity : 80 Pieces
Sample Description : SEGA-P2

Other informations :

## **Banned Azo Dyes \***

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Banned Azo Dyes	Check the table for results.	< 30 mg/kg	EN ISO 14362-1 / EN ISO 17234-1	PASS	-

CAS No	Substances
92-67-1	4-aminobiphenyl
92-87-5	Benzidine
95-69-2	4-chloro-o-toluidine
91-59-8	2-naphthylamine
97-56-3	o-aminoazotoluene
99-55-8	5-nitro-o-toluidine
106-47-8	4-chloroaniline
615-05-4	2,4-diaminoanisole
101-77-9	4,4-methylenedianiline
91-94-1	3,3-dichlorobenzidine
119-90-4	3,3-dimethoxybenzidine
119-93-7	3,3-dimethylbenzidine
838-88-0	4,4-methylenediotoluidine
120-71-8	p-cresidine
101-14-4	2,2-dichloro-4,4-methylene-dianiline
101-80-4	4,4-oxydianiline
139-65-1	4,4-thiodianiline
95-53-4	o-toluidine
95-80-7	2,4-diaminotoluene





AB-1183-T

M-2022-0346

05-22

Report Nu. : M-2022-0346 Date : 2022-05-26 13:11:53		Page: 2 / 3 Rev:		
137-17-7		2,4,5-trimethylaniline		
90-04-0		o-anisidine		
60-09-3		4-aminoazobenzene		

Part of Sample	Results(mg/kg)
Color1	<5
	-





TS EN ISO/IEC 17025 AB-1183-T

AB-1183-T

M-2022-0346

05-22

Report Nu. : M-2022-0346	Date: 2022-05-26 13:11:53	Page : 3 / 3	Rev:
--------------------------	---------------------------	--------------	------

Operating as a test laboratory, MNA Laboratories is accredited by TÜRKAK according to AB-1183-T and TS\_EN\_ISO/IEC\_17025:2017 standards has been done. A multilateral agreement with the European Accreditation Association (EA) on the recognition of the Turkish Accreditation Agency (TÜRKAK) test reports and It has signed a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC).

\*The analysis is within the scope of accreditation.

#### Note:

- 1. No part of this analysis report may be used alone or separately and may be partially copied or reproduced without the written permission of the laboratory. It cannot be reproduced, used by third parties or as a means of advertising.
- 2. Analysis results are valid for the sample sent and analyzed by the company/institution/individual to MNA Laboratories. represent the whole may not.
- 3. Unsigned and Unsealed reports are invalid.
- 4. This analysis report cannot be used in judicial-administrative proceedings and for advertising purposes.
- 5. Results are valid for the sample received.
- 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 pa ges, 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
- 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 ± 4% relative humidity) are applied for ambient conditions.

Selin Gergin

Numune Kabul ve Raporlama Sorumlusu

2022-05-26 11:00:13

Erhan Üstünel

Laboratuvar Sorumlusu 2022-05-26 10:54:22

VOLKAN AKIN

Laboratuvar Müdürü

2022-05-26 10:35:30

Sull



# AB Tip İnceleme Sertifikası **EU Type-Examination Certificate**

Belge No / Certificate No

Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /

Certification Date / Certificate Validity Date

Belge Gecerlilik Tarihi / Document Validity Period : 5 yıl / 5 years

Firma Unvanı ve Adresi /

Company Name and Address

Ürün Adı /Modeller / Product Name / Models

Direktifi / Directive

Modülü/Kategori / Module / Category

Teknik Değerlendirme Rapor No/ Technical Evaluation Report No

: 220-21-01-R02

: 18.11.2021-14.04.2026

: SEGA GRUP TEKSTIL SAN. TIC. LTD. STI. Çakmaklı Mah. Hadımköy yolu cad. No:137/1 Büyükcekmece-İSTANBUL

: SEGA-P2

: 2016/425 REGULATION

: B MODÜLÜ/ KATEGORİ III MODULE B / CATEGORY III

: 220-21-01-R02

Ürün Tipi / Product Type:

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

Ürünün Malzeme Bilgisi / Product Material Information: SEGA-P2 model ürünleri kumaş, elastik kayış, burun klipsi, filtre katmanı kullanılarak imal edilmiştir./: SEGA-P2 products are manufactured using fabric, elastic strap, nose clip, filter layer.

Revizyon nedeni/ Reason for revision: Ürün adı revize edildi. / Product name has been revised.

Volkan AKIN 18.11.2021 Karar Verici / Approver

Okan AKEL 18.11.2021 Şirket Müdürü / General manager



MNA Laboratuvarları San. Tic.Ltd .Sti

Tel: 0216 574 07 08 Faks: 0216 575 13 31 www.mnalab.com

Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul





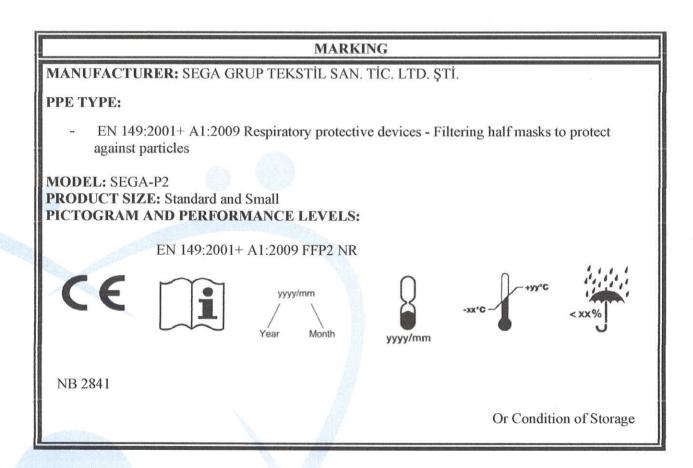
### ATTACHMENTS (220-21-01-R01)

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

Model: SEGA-P2

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
Reusable / Single Shift Use	NR

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

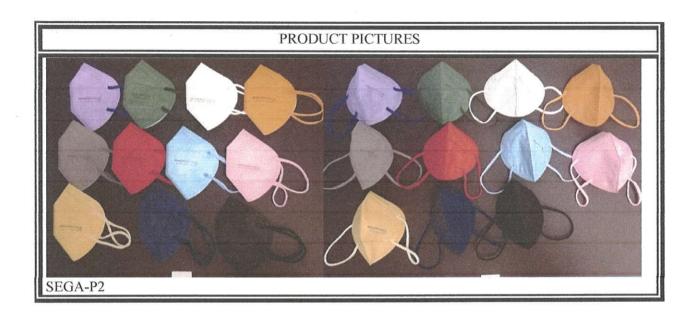


MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

MNA Laboratuvarları San. Tic.Ltd .Şti Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul Tel: 0216 574 07 08 Faks: 0216 575 13 31 <u>www.mnalab.com</u>



### ATTACHMENTS (220-21-01-R01)



# DOCUMENTS IN THE TECHNICAL FILE

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Technical Report



### **TECHNICAL EVALUATION REPORT (220-21-01-R02)**

Report No

: 220-21-01-R02

Report Date

: 18.11.2021

**Application No** 

: 220-21-01-R02

### 1. COMPANY INFORMATION:

SEGA GRUP TEKSTIL SAN. TIC. LTD. ŞTİ.

Çakmaklı Mah. Hadımköy yolu cad. No:137/1 Büyükçekmece-İSTANBUL

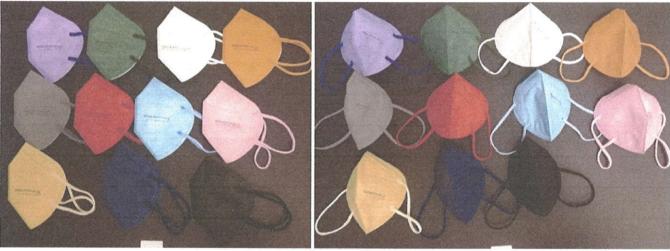
#### 2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection fitler material.

#### 3. PPE TYPE IDENTIFICATION

EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking

### 4. PPE PICTURES



SEGA-P2

### 5. PPE DIMENSIONS:

SEGA-P2 model has been found to be produced using standard and small size.

#### 6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of elastic strap, nonwoven fabric on the outer and inner layers and fitler material on the middle layer.

### 7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- A visual inspection was made according to EN 149:2001 +A1:2009 for ergonomics.
- · Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials were determined by visual inspection according to EN 149:2001 +A1:2009.



# TECHNICAL EVALUATION REPORT (220-21-01-R02)

# 8. ANALYSIS AND EVALUATIONS: EN 149:2001 +A1:2009

TESTS	PARAMETER PERFORMANCE LEVELS		RESULTS	PERFORMANCE LEVELS	EVALUATION		
		FFP1	FFP2	FFP3			
Part 7.3 Visual inspection	Shall also the marking and the information supplied by the manufacturer		Appropriate	-	PASS		
Banned Azo Dyes	< 30 mg/kg				< 5 mg/kg	-	PASS
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 contact with the wear edge or burrs.				Appropriate	-	PASS

TESTS PARAMETER	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)	6.6	6.8	6.6	6.4	7.0	6.7			
Subject 2 (As recieved)	7.8	6.7	7.0	6.4	6.8	6.9			
Subject 3 (As recieved)	6.8	6.9	6.6	7.4	7.1	7.0			
Subject 4 (As recieved)	6.8	7.0	7.8	7.1	6.6	7.1			
Subject 5 (As recieved)	7.6	6.6	6.8	6.4	6.9	6.9			
Subject 6 (After temperature conditioning)	7.5	7.9	7.3	6.8	6.8	7.3			
Subject 7 (After temperature conditioning)	7.0	6.8	6.5	6.9	6.8	6.8			



# TECHNICAL EVALUATION REPORT (220-21-01-R02)

Subject 8 (After temperature conditioning)	7.4	6.8	7.7	6.3	6.2	6.9
Subject 9 (After temperature conditioning)	7.8	6.9	7.2	6.4	6.9	7.0
Subject 10 (After temperature conditioning)	7.0	6.9	7.0	6.5	7.0	6.9

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

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As recieved	3.6	4.0
As recieved	3.5	4.1
As recieved	3.5	4.0
After the simulated wearing treatment	3.6	4.5
After the simulated wearing treatment	3.6	4.6
After the simulated wearing treatment	3.5	4.6
Mechanical strength and temperature conditioning	4.9	5.1
Mechanical strength and temperature conditioning	5.0	5.4
Mechanical strength and temperature conditioning	5.2	5.3

TESTS	PARAMETER	PERFO LEVELS	RMAN	CE	RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.10 Compatibility with skin	Materials shall not be cause irritation or any health			ALTERNATION CONTRACTOR ACTIONS	Appropriate	-	PASS
Part 7.11 Flammibility	Mask shall not burn of for more than 5 s	r not to	continu	e to burn	Flame not seen	-	PASS
Part 7.12 Carbondioxide content of the inhalation air	Shall not exceed an av	erage o	of % 1		0,76 0,79 0,78	-	PASS
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



# TECHNICAL EVALUATION REPORT (220-21-01-R02)

TESTS PARA	PARAMETER	PARAMETER PERFORMAI LEVELS				PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.16 Breathing	Inhalation 30L/min	0,6 mbar	0,7 mbar	1,0 mbar	See the table below	FFP2	PASS
Resistance	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	2,1
As recieved	0.5	2,0
As recieved	0.5	2,1
After temperature conditioning	0.5	2,0
After temperature conditioning	0.5	2,0
After temperature conditioning	0.5	2,1
After the simulated wearing treatment	0.5	2,0
After the simulated wearing treatment	0.6	2,1
After the simulated wearing treatment	0.6	2,1
After the flow conditioning	-	-
After the flow conditioning	-	-
After the flow conditioning	-	**

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	2,7	2,6	2,7	2,7	2,6
As recieved	2,6	2,7	2,6	2,7	2,7
As recieved	2,6	2,7	2,7	2,7	2,6
After temperature conditioning	2,6	2,7	2,6	2,7	2,6
After temperature conditioning	2,7	2,7	2,7	2,7	2,7
After temperature conditioning	2,7	2,7	2,6	2,7	2,7
After the simulated wearing treatment	2,7	2,7	2,7	2,7	2,7
After the simulated wearing treatment	2,7	2,7	2,7	2,7	2,7
After the simulated wearing treatment	2,7	2,6	2,7	2,6	2,6
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	***	-	-
After the flow conditioning	-	-	-	-	-

## **TECHNICAL EVALUATION REPORT (220-21-01-R02)**

TESTS	PARAMETER	PERFO LEVEL	ORMAN S	CE	RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.17	After clogging the	4	5	7	Not applicable	-	Not applicable
Clogging	inhalation	mba	mba	mbar			
	resistances shall	r	r				
	not exceed.						
	(valved)						
	The exhalation resist	ance sh	all not	exceed	Not applicable	-	Not applicable
	3 mbar at 160 L/ i	min cor	ntinuou	s flow.			
	(valved)						
	After clogging the	3	4	5	Not applicable	-	Not applicable
	inhalation and	mba	mba	mbar	500000 43507		
	exhalation	r	r				
	resistances shall						
	not exceed.						
	(valveless)						
Part 7.18	All demountable par	rts (if fi	itted) sl	hall be	Not applicable	-	Not applicable
Demountable	readily connected	and s	ecured	were			
part	possible by hand.						

### 9. DECISION

Analysis and examinations SEGA-P2 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. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

#### 10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- User Instruction
- Test Reports (M-2021-00569)

Reason for Revision

: Product name has been revised.

CONTROLLER

: VOLKAN AKIN

**SIGNATURE** 

:

DATE

: 18.11.2021

# **EU DICHIARAZIONE DI CONFORMITÀ**

La presente Dichiarazione di Conformità è rilasciata sotto la responsabilità esclusiva del fabbricante: SEGA GRUP TEKSTIL SAN. TIC. LTD. STI.

PRODUTTORE: SEGA GRUP TEKSTIK SAN. TIC. LTD. STI.

Cakmakli Mah. Hadimköy yolu cad. No: 137/1 Büyükcekmece, İstanbul Turkey

IMPORTATORE: T-TEX SRL - Via Boggia 9,28013 Gattico (NO) - ITALY

MARCHIO: SEGA

CLASSIFICAZIONE: Semimaschera Filtrante, III Categoria, FFP2 NR

MODELLO: SEGA-P2

STANDARD ARMONIZZATI RISPETTATI: EN149:2001+A1:2009 Respiratory Protective Device

Filtering Half Masks to Protect against particles

Requirements, Testing, Marking

LEGISLAZIONE UE: Regolamento (EU) 2016/425

NUMERO DEL CERTIFICATO: 2841

ENTE NOTIFICATO: MNA LABORATUVARLARI SANAYI TICARET LIMITED SIRKETI

KüçükbakkalköyMah. Yenidoğan Cad. No: 21

Ataşehir/ISTANBUL Country: Turkey

Module B EU Type Examination Certification

Certificato N.:220-21-01-R02

Questo Certificato è valido dal 18/11/2021 fino al 14/04/2026

Module C2 Conformity to type based on Production Monitoring

Certificato N.:220-21-01-R02-02

Questo Certificato è valido dal 07/06/2022 fino al 07/06/2023

Questa Dichiarazione è valida fino al 02/11/2026

FIRMATA A NOME E PER CONTO DI:

LUOGO E DATA DI EMISSIONE: ISTANBUL, 02/11/2021

FIRMA: GOKCEN MUKAN

NOME E MANSIONE: DIRETTORE GENERALE

NOME DELL'AZIENDA: SEGA GRUP TEKSTIL SAN. TIC. LTD. STI.