

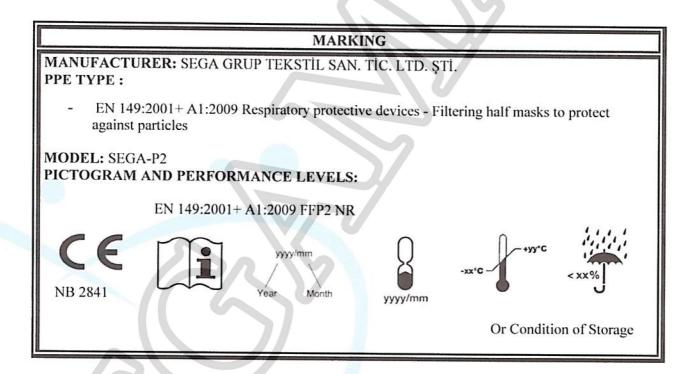
## **ATTACHMENTS (220-21-01)**

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

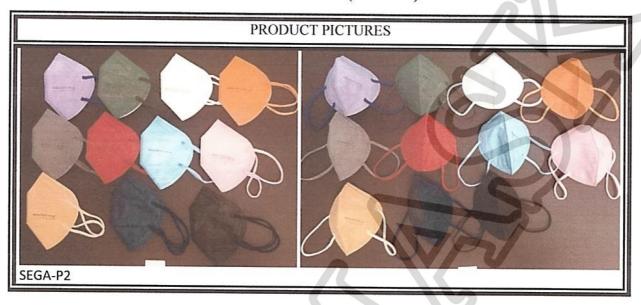
PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:



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.



## ATTACHMENTS (220-21-01)



## DOCUMENTS IN THE TECHNICAL FILE

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



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

Report No : 220-21-01

Report Date : 14.04.2021

Application No : 220-21-01

#### 1. COMPANY INFORMATION:

SEGA GRUP TEKSTIL SAN. TIC, LTD. ŞTİ.

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

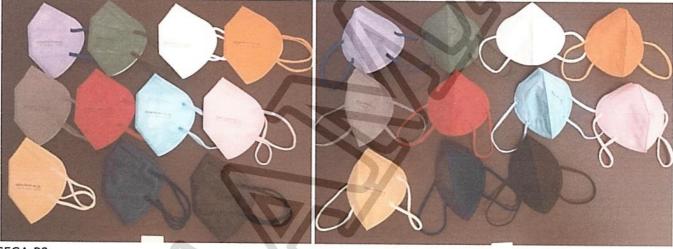
## 2. PPE INFORMATION:

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 sizes.

#### 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)**

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

TESTS	PARAMETER	PERFORMANCE LEVELS FFP1 FFP2 FFP3		RESULTS	PERFORMANCE LEVELS	EVALUATION
Part 7.3 Visual inspection	Shall also the marking supplied by the manuf		rmation	Appropriate		PASS
Banned Azo Dyes	< 30 mg/kg			< 5 mg/kg		PASS
Part 7.4 Packaging	Particle filtering half for sale packaged in are protected against and contamination be	such a way th t mechanical	at they	Appropriate	2)	PASS
Part 7.5 Material	When conditioned in 8.3.2 the particle filte collapse.			Appropriate	37	PASS
Part 7.6 Cleaning and disinfecting	After cleaning and disi particle filtering half penetration requirem class.	mask shall sat	isfy the	Not applicable	7	Not applicable
Part 7.7 Practical performance	No negative comment the test subject regard evaluated.			Appropriate	-	PASS
Part 7.8 Finish of parts	Parts of the device contact with the wear edge or burrs.			Appropriate	ā	PASS

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3	7		
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				
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				



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

TESTS PARAMETER	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	PARAMETER PERFORMANCI			CE LEVELS	RESULTS	PERFORMANCE	EVALUATION
	FFP1	FFP2	FFP3	NO	LEVELS		
Part 7.10 Compatibility with skin	Materials shall not cause irritation or ar health				Appropriate	-	PASS
Part 7.11 Flammibility	Mask shall not burn for more than 5 s	or not to	continu	e to burn	Flame not seen	-	PASS
Part 7.12 Carbondioxide content of the inhalation air	Shall not exceed an a	verage o	f%1		0,76 0,79 0,78	-	PASS
Part 7.13 Head harness	It can be donned and	remove	d easily		Appropriate	-	PASS
Part 7.14 Field of vision	The field of vision sh performance test.	all accep	table in	practical	Appropriate	-	PASS
Part 7.15 Exhalation valve(s)	It shall withstand axis apply for 10 s. If fitted, shall continuous after a continuous L/min over a period of	nue to c	perate	correctly	Not applicable	-	Not applicable



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

TESTS PARAMETER	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE	EVALUATION
	FFP1	FFP2	FFP3		LEVELS		
Breathing Resistance Inhalation	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	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	- 1	-
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	-	-	1-	-	-
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	1-	-	-



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TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Clogging i	After clogging the inhalation resistances shall not exceed. (valved)	4 mbar	5 mbar	7 mbar	Not applicable		Not applicable
	The exhalation resist 3 mbar at 160 L/ (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 par readily connected possible by hand.		2500		Not applicable	7	Not applicable

#### 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

CONTROLLER : VOLKAN AKIN

SING :

DATE : 14.94.2021



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

Belge No / Certificate No

Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /

Certification Date / Certificate Validity Date

: 14.04.2021-14.04.2026

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

Firma Unvanı ve Adresi /

Company Name and Address

: SEGA GRUP TEKSTIL SAN. TIC. LTD.

STİ.

: 220-21-01

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

Ürün Adı /Modeller / Product Name / Models : SEGA-P2

Direktifi / Directive

Modülü/Kategori / Module / Category

: 2016/425 REGULATION

B MODÜLÜ/ KATEGORİ III MODULE B / CATEGORY III

: MNA M-2021-00569

Test Rapor No/ları / Test Report No

Urün 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 model products are manufactured using fabric, elastic strap, nose clip, filter layer.

Volkan AKIN 14.04.2021

Karar Verici / Approver

Okan AKEL 14.04.2021

Şirket Müdürü / General manager









## 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 : 05.06.2021-05.06.2022

Belge Geçerlilik Tarihi / Document Validity Period: 1 yıl / 1 year

Firma Unvanı ve Adresi /

Company Name and Address : SEGA GRUP TEKSTİL SAN. TİC. LTD. ŞTİ.

Çakmaklı Mah. Hadımköy yolu cad. No:137/1

Büyükçekmece-İSTANBUL

Ürün Adı /Modeller / Product Name / Models

Direktifi / Directive

Modülü/Kategori / Module / Category

: 2016/425 REGULATION

: C2 MODÜLÜ/ KATEGORİ III MODULE C2 / CATEGORY III

: MNA M-2021-00948

: 220-21-01-01

: SEGA-P2

Test Rapor No/ları / Test Report No

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

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Erhan ÜSTÜNEL 05.06.2021 Karar Verki / Approver

Okan AKEL 05.06.2021 Şirket Müdürü / General manager



