

GRUPPO GDA

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Produttore: **MMS MEDİKAL ÜRÜNLERİ A. Ş.**
Halkali Dereboyu Cad. No: 8/B
Kucukcekmece / ISTANBUL

Maschera FFP2-MODELLO "ASEL01"

Importatore e distributore: **GDA S.R.L.**

MODELLO GDA: "ASEL01"

DESCRIZIONE PRODOTTO

Maschera protettiva facciale filtrante modello FFP2 , morbida e confortevole ,inodore , con nasello interno regolabile e elastici auricolari che garantiscono il corretto posizionamento.

Dispositivo utilizzabile per proteggere la salute pubblica, fornisce una protezione minima del 95% contro particelle inferiori a 0,3 micron grazie alla struttura a 5 strati.

Mascherina **certificata CE** da ente notificato EUROPEO "MNA", con **Certificato CE no.227-21-01-R01 (modulo B) e no. 227-21-01-01 (modulo C2).**

E' quindi conforme al Regolamento EU 2016/425 (ex Direttiva 89/686/CEE e Decreto Lg.vo nr. 475/1992) SUI DISPOSITIVI DI PROTEZIONE PERSONALE E ALLA NORMA EN 149:2001+A1:2009 SUI DISPOSITIVI DI PROTEZIONE DELLE VIE RESPIRATORIE, IN BASE ALLA QUALE È CLASSIFICATO COME DPI di III categoria.

COMPOSIZIONE:

No.	materiali	specifiche
1	Primo strato esterno : Spunbond	50 gr/m2
2	Secondo strato interno: Meltblown	25 gr/m2
3	Terzo strato interno: Spunbond	30 gr/m2
4	Quarto strato: Meltblown	25 gr/m2
5	Quinto strato interno(a contatto con il viso): Spunbond	30 gr/m2
6	Elastici auricolari	
7	Nasello regolabile	

GDA srl

S.P. 362 km 15,700 - Galatina - (LE) - 73013 - Italy
Tel : 0836 562531 - 0836 569443
Fax: 0836 631418
decorartex.com - info@decorartex.com
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IMBALLAGGIO:

confezionate in bustine singole da 1 pezzo.

ISTRUZIONI D'USO:

1. Aprire la mascherina su entrambe le mani (appoggiandole sul lato esterno della mascherina)
2. Appoggiare la mascherina sul viso facendo aderire lo stringinaso
3. Fissare i laccetti elastici dietro alle orecchie e controllare che sia ben ferma
4. Adattare lo stringinaso al naso
5. Verificare che la mascherina aderisca bene al viso su tutti i lati :
 - per verificare l'aderenza, appoggiare entrambe le mani sulla mascherina e inspirare energicamente; si dovrà percepire una pressione negativa
 - se si sente entrare aria dai margini della mascherina dalla zona intorno al naso, verificare eventuali non aderenze e sistemare lo stringinaso
 - se l'aria entra da altri margini della mascherina, verificare l'aderenza, sistemare ogni lato e fissare meglio i laccetti
6. Cambiare mascherina immediatamente se non si riesce a respirare o se la mascherina si danneggia
7. Cambiare la mascherina se non aderisce in modo corretto
8. È importante osservare le istruzioni qui riportate per garantire un uso corretto e sicuro della mascherina

CONDIZIONI E METODI DI CONSERVAZIONE:

1. Le maschere inutilizzate devono essere conservate in un ambiente ben ventilato, asciutto e al riparo dalla luce. Tenere lontano da fuoco, sostanze inquinanti e potenziale fonte di inquinamento.
2. Temperatura di stoccaggio: da -20 °C a 25 °C e umidità relativa inferiore all'80%.
3. Conservare le maschere nelle confezioni originali durante il trasporto al riparo da danni meccanici e contaminazioni.
4. Vita utile del prodotto 5 anni.

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AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 227-21-01-R01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 05.05.2021-22.04.2026
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 years
Firma Unvanı ve Adresi /
Company Name and Address : MMS MEDİKAL ÜRÜNLERİ A.Ş.
Halkalı Dereboyu Cad. No: 8/B
Küçükçekmece/ İSTANBUL
Ürün Adı /Modeller / Product Name / Models : ASELO1
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : **B MODÜLÜ/ KATEGORİ III**
MODULE B / CATEGORY III
Test Rapor No/ları / Test Report No : MNA M-2021-00636
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: ASELO1 model ürünleri kumaş, elastik kayış, burun klipsi, filtre katmanı kullanılarak imal edilmiştir./ ASELO1 model products are manufactured using fabric, elastic strap, nose clip, filter layer.

Revizyon nedeni / Reason for revision: Farklı renkte ürün eklenmiştir./ Different color product has been added.

Volkan AKIN
05.05.2021
Karar Verici / Approver



Okan AKEL
05.05.2021
Şirket Müdürü / General manager



Report No : 227-21-01-R01

Report Date : 05.05.2021

Application No : 227-21-01

1. COMPANY INFORMATION:

MMS MEDİKAL ÜRÜNLERİ A.Ş.

Halkalı Dereboyu Cad. No: 8/B Küçükçekmece/ İSTANBUL

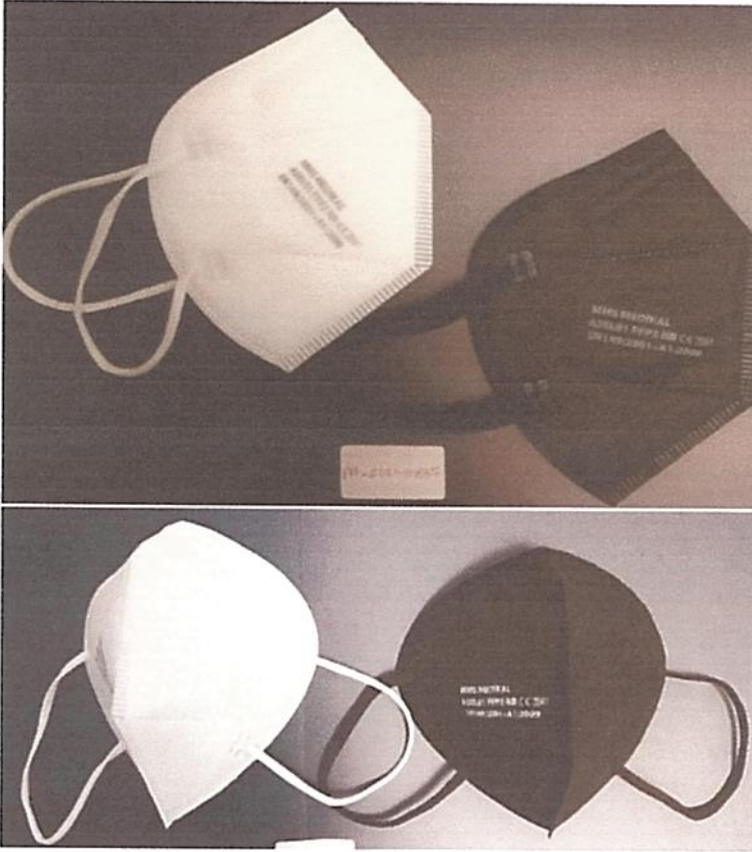
2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection filter 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



ASEL01

5. PPE DIMENSIONS:

ASEL01 model has been found to be produced using standart sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of elastic strap, nonwoven fabric on the outer and inner layers and filter 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 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 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)	6.3	6.1	8.6	7.7	7.8	7.3
Subject 2 (As recieved)	6.2	6.9	6.0	7.2	6.6	6.6
Subject 3 (As recieved)	6.9	8.4	8.7	7.6	6.1	7.5
Subject 4 (As recieved)	6.6	5.7	8.4	7.7	7.7	7.2

Subject 5 (As recieved)	6.3	6.1	8.6	9.0	7.7	7.5
Subject 6 (After temperature conditioning)	6.2	6.9	6.7	6.2	7.7	6.7
Subject 7 (After temperature conditioning)	6.0	7.2	6.6	7.5	10.1	7.5
Subject 8 (After temperature conditioning)	8.7	7.6	6.6	5.7	7.6	7.2
Subject 9 (After temperature conditioning)	6.3	6.5	6.3	6.1	6.1	6.3
Subject 10 (After temperature conditioning)	6.4	7.5	7.7	7.5	6.3	7.1

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 recieved	4.4	4.2
As recieved	4.2	4.3
As recieved	3.7	4.6
After the simulated wearing treatment	4.1	5.0
After the simulated wearing treatment	3.8	4.6
After the simulated wearing treatment	4.7	4.8
Mechanical strength and temperature conditioning	5.0	5.7
Mechanical strength and temperature conditioning	5.3	5.4
Mechanical strength and temperature conditioning	4.9	5.7

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 Carbondioxide content of the inhalation air	Shall not exceed an average of % 1				0,88 0,82 0,85	-	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

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	1,8
As recieved		0.5	1,8
As recieved		0.5	1,7
After temperature conditioning		0.6	1,7
After temperature conditioning		0.5	1,7
After temperature conditioning		0.5	1,7
After the simulated wearing treatment		0.5	1,7
After the simulated wearing treatment		0.6	1,8
After the simulated wearing treatment		0.5	1,8
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	2,7	2,8	2,7	2,7
As recieved	2,8	2,7	2,8	2,7	2,7
As recieved	2,7	2,8	2,7	2,7	2,7
After temperature conditioning	2,7	2,8	2,7	2,8	2,7
After temperature conditioning	2,7	2,7	2,7	2,8	2,7
After temperature conditioning	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	2,8	2,7	2,7	2,7	2,8
After the simulated wearing treatment	2,7	2,7	2,7	2,7	2,8
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	-	-	-

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

9. DECISION

Analysis and examinations ASEL01 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

Reason for revision : Different color product has been added.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 05.05.2021



**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 : 227-21-01-01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 05.05.2021-05.05.2022
Belge Geçerlilik Tarihi / Document Validity Period: 1 yıl / 1 year
Firma Unvanı ve Adresi /
Company Name and Address : MMS MEDİKAL ÜRÜNLERİ A.Ş.
Halkalı Dereboyu Cad. No: 8/B Küçükçekmece/
İSTANBUL

Ürün Adı /Modeller / Product Name / Models : ASEL01
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : C2 MODÜLÜ/ KATEGORİ III
MODULE C2 / CATEGORY III
Test Rapor No/ları / Test Report No : M-2021-00885

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: ASEL01 model ürünleri kumaş, elastik kayış,
burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ ASEL01 model products are manufactured using
fabric, elastic strap, nose clip, filter layer.

Volkan AKIN
05.05.2021
Karar Verici / Approver



Okan AKEL
05.05.2021
Şirket Müdürü / General manager



Report No : 227-21-01-01

Report Date : 05.05.2021

Application No : 227-21-01-01

1. COMPANY INFORMATION:

MMS MEDİKAL ÜRÜNLERİ A.Ş.

Halkalı Dereboyu Cad. No: 8/B Küçükçekmece/ İSTANBUL

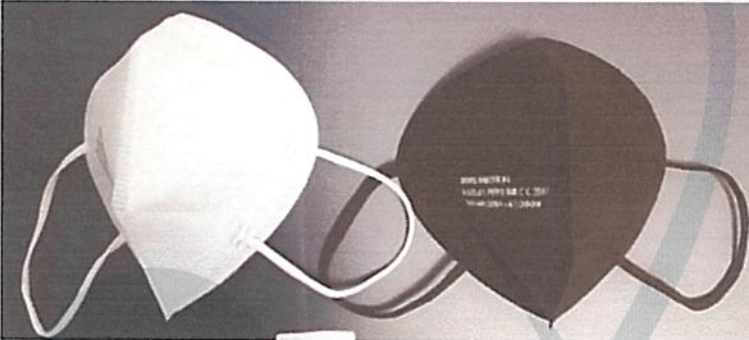
2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection filter 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



ASEL01

5. PPE DIMENSIONS:

ASEL01 model has been found to be produced using standard sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

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

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (227-21-01-01)**

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 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
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 7.9.2 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 recieved	4.4	4.2
As recieved	4.3	4.3
As recieved	4.0	4.4

**CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (227-21-01-01)**

After the simulated wearing treatment	4.1	5.0
After the simulated wearing treatment	4.1	4.6
After the simulated wearing treatment	4.7	4.6
Mechanical strength and temperature conditioning	5.2	5.6
Mechanical strength and temperature conditioning	5.3	5.4
Mechanical strength and temperature conditioning	4.9	5.7

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 7.13 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	2,1
As recieved	0.5	2,1
As recieved	0.5	2,2
After temperature conditioning	0.6	2,1
After temperature conditioning	0.5	2,2
After temperature conditioning	0.6	2,1
After the simulated wearing treatment	0.5	2,2
After the simulated wearing treatment	0.5	2,1
After the simulated wearing treatment	0.6	2,2

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	2,6	2,6	2,7	2,6	2,6
As recieved	2,7	2,7	2,6	2,7	2,7
As recieved	2,6	2,6	2,7	2,7	2,6

**CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (227-21-01-01)**

After temperature conditioning	2,7	2,6	2,6	2,6	2,6
After temperature conditioning	2,6	2,7	2,7	2,7	2,7
After temperature conditioning	2,6	2,6	2,6	2,7	2,7
After the simulated wearing treatment	2,7	2,7	2,6	2,6	2,7
After the simulated wearing treatment	2,6	2,6	2,7	2,7	2,7
After the simulated wearing treatment	2,7	2,6	2,7	2,6	2,6

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

9. DECISION

Analysis and examinations ASEL01 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-2021-00885)
- User Instruction

CONTROLLER : VOLKAN AKIN

SING :

DATE : 05.05.2021



07.02.2021

Dear Customer,

We declare that, that ref. 'ASEL 01' FFP2 NR(EN 149:2001+ A1:2009) masks do not contain any Latex in it.

Ayhan CANLIOGLU
General Manager



EC DECLARATION OF CONFORMITY AT UYGUNLUK BEYANI



İMALATÇI/MANUFACTURER

MMS MEDİKAL ÜRÜNLERİ A.Ş.

Halkalı Mahallesi Dereboyu Caddesi No: 8 B Küçükçekmece / İSTANBUL / TURKEY

İLGİLİ DİREKTİF/Related Directive

EN 149:2001+A1:2009

ÜRÜN ADI/Product Name-GMDN KODU/GMDN Code

MARKA/Trade Mark

MMS MASK⁺

SERTİFİKA NO/Certificate Number **227-21-01**

Model: ASEL 01

ONAYLAYICI KURULUŞ/Notified Body

MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.

İLGİLİ STANDARTLAR/Standarts Applied

EN 149:2001+A1:2009

Ürünlerimizin uyumlaştırılmış standartlara göre üretildiğini ve 2016/425/AT Kişisel Koruyucu Donanım Yönetmeliği hükümlerine uygun olduğunu beyan ederiz. Destekleyici tüm belgeler firmamızda bulunmaktadır.
We declare that our products are manufactured according to harmonized standards and comply with the provisions of the 2016/425/EU Personal Protective Equipment Directive. All supporting documents are available in our company.

Date: 29.11.2021

Place: Istanbul / Turkey
General Manager
MMS MEDİKAL ÜRÜNLERİ A.Ş.
HALKALI MAHALLESİ DEREBOYU CAD.
NO: 8 B KÜÇÜKÇEKMECE / İSTANBUL
HALKALI V.D. 623 044 7823



mna
LABORATUVARLARI

Notified Body Number: 2841

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No	: 63-20-12-R01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / Certification Date / Certificate Validity Date	: 05.04.2021-05.01.2026
Belge Geçerlilik Tarihi / Document Validity Period	: 5 yıl/ 5 years
Firma Unvanı ve Adresi / Company Name and Address	: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130 Ümraniye 34775 İstanbul / Türkiye
Ürün Adı /Modeller / Product Name / Models SV-135 - SV-136 - SV-137 - SV-138 - SV-139	: SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 -
Direktifi / Directive	: 2016/425 REGULATION
Modülü/Kategori / Module / Category	: B MODÜLÜ/ KATEGORİ III MODULE B / CATEGORY III
Test Rapor No/ları / Test Report No	: MNA M-2020-00707
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: SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139 model ürünleri kumaş, kulak kayışı, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139 Mask model products are manufactured using fabric, ear loop, nose clip, filter layer.

Revizyon nedeni/ Reason for revision: Firma unvanı ve model adı revize edilmiştir./ Company name and model name has been revised.

Volkan AKIN
05.04.2021

Karar Verici / Approver

Okan AKEL
05.04.2021

Şirket Müdürü / General manager



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 www.mnalab.com



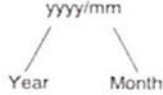

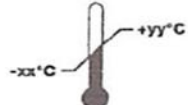

ATTACHMENTS (63-20-12-R01)

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 : SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139

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:

MARKING	
MANUFACTURER: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.	
PPE TYPE :	
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles	
MODEL: SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139	
PICTOGRAM AND PERFORMANCE LEVELS:	
EN 149:2001+ A1:2009 FFP2 NR	
 NB 2841	
	
	
	
Or Condition of Storage	

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 (63-20-12-R01)

PRODUCT PICTURES



SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139

DOCUMENTS IN THE TECHNICAL FILE

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

Report No :63-20-12-R01

Report Date :05.04.2021

Application No :63-20-12

1. COMPANY INFORMATION:

PODİMA MEDİKAL VE TEKSTİL SAN. TIC. LTD. ŐTİ.

Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130 Ümraniye 34775 İstanbul / Türkiye

Tel: +905333221100

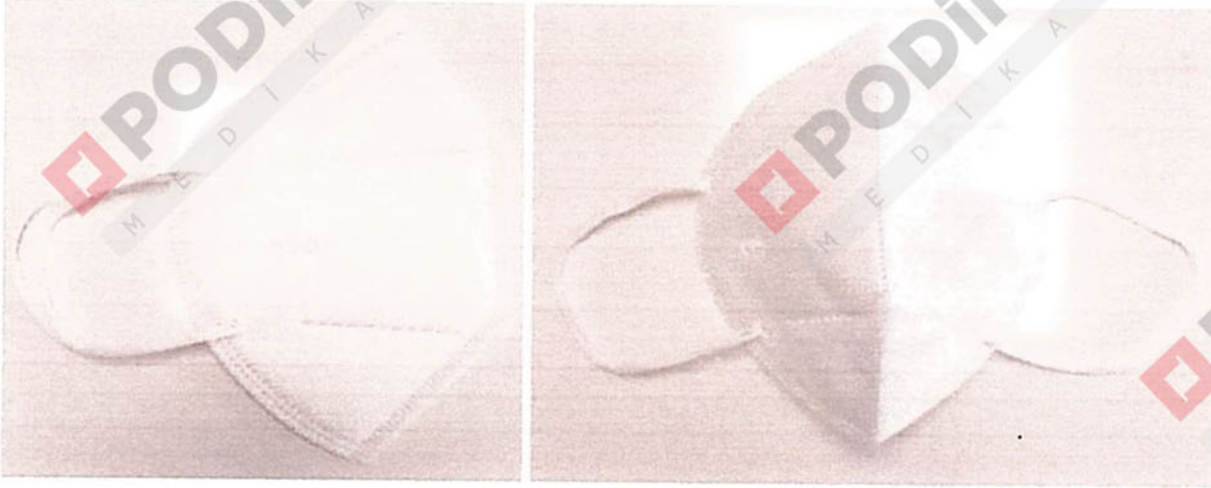
2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection filter 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



SUVICOM SV-130-SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139

5. PPE DIMENSIONS:

SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139 model has been found to be produced using standart sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of elastic strap, nonwoven fabric on the outer and inner layers and filter 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 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
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)	3,2	3,4	3,2	3,0	3,9	3,3
Subject 2 (As recieved)	3,6	3,3	3,6	3,0	3,8	3,5
Subject 3 (As recieved)	3,4	3,5	3,2	3,2	3,7	3,4
Subject 4 (As recieved)	3,4	3,6	3,6	3,6	3,2	3,5
Subject 5 (As recieved)	3,5	3,2	3,4	3,4	3,6	3,4
Subject 6 (After temperature conditioning)	3,5	3,6	3,4	3,4	3,4	3,5
Subject 7 (After temperature conditioning)	4,0	3,4	3,5	3,5	3,4	3,6
Subject 8 (After temperature conditioning)	4,0	3,4	3,5	3,5	3,5	3,6
Subject 9 (After temperature conditioning)	4,1	3,5	3,8	3,0	3,5	3,6
Subject 10 (After temperature conditioning)	4,1	3,5	3,9	3,1	3,6	3,6

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	133	132	132	65
2	125	144	116	67
3	126	135	124	75
4	123	133	134	74
5	117	135	122	73
6	122	142	133	66
7	113	132	114	75
8	135	123	123	65
9	122	135	133	74
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 recieved	3,6	3,6
As recieved	3,6	3,6
As recieved	3,7	3,6
After the simulated wearing treatment	3,6	3,8
After the simulated wearing treatment	3,6	3,8
After the simulated wearing treatment	3,7	3,8
Mechanical strength and temperature conditioning	3,7	3,7
Mechanical strength and temperature conditioning	3,7	3,7
Mechanical strength and temperature conditioning	3,7	3,8

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 Carbondioxide content of the inhalation air	Shall not exceed an average of % 1				0,65 0,67 0,63	-	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

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	1.3
As recieved	0.4	1.4
As recieved	0.4	1.3
After temperature conditioning	0.5	1.3
After temperature conditioning	0.5	1.4
After temperature conditioning	0.4	1.4
After the simulated wearing treatment	0.4	1.3
After the simulated wearing treatment	0.5	1.3
After the simulated wearing treatment	0.4	1.3

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	1,2	1,2	1,3	1,3	1,2
As recieved	1,2	1,3	1,2	1,2	1,2
As recieved	1,3	1,3	1,2	1,2	1,2
After temperature conditioning	1,3	1,3	1,2	1,2	1,3
After temperature conditioning	1,3	1,3	1,2	1,3	1,2
After temperature conditioning	1,3	1,2	1,3	1,2	1,2
After the simulated wearing treatment	1,2	1,3	1,2	1,2	1,2
After the simulated wearing treatment	1,2	1,2	1,3	1,2	1,2
After the simulated wearing treatment	1,2	1,3	1,2	1,2	1,2

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

9. DECISION PROPOSAL

Analysis and examinations SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139 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
- Test Reports
- User Instruction

Reason for revision : Company name and model name has been revised.

CONTROLLER : VOLKAN AKIN

SIGN :

DATE : 05.04.2021

Notified Body Number: 2841

Report No : 63-20-12-01-R01

Report Date : 05.04.2021

Application No : 63-20-12-01

1. COMPANY INFORMATION:

PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130 Ümraniye 34775 İstanbul / Türkiye

Tel: +905333221100

2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection filter 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



SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139

5. PPE DIMENSIONS:

SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139 model has been found to be produced using standard sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

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

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTON CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (63-20-12-01-R01)**

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.
- Respiratory protective dimensions are evaluated according to EN 149:2001 +A1:2009.
- Conditioning EN 149:2001 +A1:2009 part 8.3, Penetration EN 149:2001 +A1:2009 part 8.11 (EN 13274-7), Application performance EN 149:2001 +A1:2009 part 8.4, Inward leakage EN 149:2001 +A1:2009 part 8.5, Flammability EN 149:2001 +A1:2009 part 8.6, The carbon dioxide content of the inhaled air EN 149:2001 +A1:2009 part 8.7, Inhalation resistance EN 149:2001 +A1:2009 part 8.9, Exhalation resistance EN 149:2001 +A1:2009 part 8.9 has been tested and evaluated.

8. ANALYSIS AND EVALUATIONS:

EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
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)	3.6	3.8	3.6	3.4	4.3	3.7
Subject 2 (As recieved)	4.0	3.7	4.0	3.4	4.2	3.9
Subject 3 (As recieved)	3.8	3.9	3.6	3.6	4.1	3.8
Subject 4 (As recieved)	3.8	4.0	4.0	4.0	3.6	3.9
Subject 5 (As recieved)	3.9	3.6	3.8	3.8	4.0	3.8
Subject 6 (After temperature conditioning)	3.9	4.0	3.8	3.8	3.8	3.9
Subject 7 (After temperature conditioning)	4.4	3.8	3.9	3.9	3.8	4.0
Subject 8 (After temperature conditioning)	4.4	3.8	3.9	3.9	3.9	4.0
Subject 9 (After temperature conditioning)	4.5	3.9	4.2	3.4	3.9	4.0
Subject 10 (After temperature conditioning)	4.5	3.9	4.3	3.5	4.0	4.0

**CONFORMITY TO TYPE BASED ON INTERNAL
 PRODUCT CONTROL PLUS SUPERVISED PRODUCT
 CHECK AT RANDOM INTERVALS
 (MODULE C2, ANNEX VII) (63-20-12-01-R01)**

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Flammibility	Mask shall not burn or not to continue to burn for more than 5 s				Flame not seen	-	PASS
Carbondioxide content of the inhalation air	Shall not exceed an average of % 1				0.70 0.77 0.75	-	PASS
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 recieved	3.8	3.0
As recieved	3.6	3.3
As recieved	3.3	3.1
After the simulated wearing treatment	3.7	3.5
After the simulated wearing treatment	3.8	3.2
After the simulated wearing treatment	3.5	3.3
Mechanical strength and temperature conditioning	3.5	3.5
Mechanical strength and temperature conditioning	3.6	3.5
Mechanical strength and temperature conditioning	3.8	3.2

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Compatibility with skin	Materials shall not be known to be likely to cause irritation or any other adverse effect to health				Appropriate	-	PASS
Head harness	It can be donned and removed easily				Appropriate	-	PASS
Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1 mbar	See the table below	FFP2	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3 mbar	See the table below	FFP2	PASS
	Exhalation 160L/min	3 mbar	3 mbar	3 mbar	See the table below	FFP2	PASS

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0.6	1.5
As recieved	0.6	1.5

As recieved	0.5	1.5
After temperature conditioning	0.6	1.4
After temperature conditioning	0.6	1.4
After temperature conditioning	0.5	1.5
After the simulated wearing treatment	0.6	1.4
After the simulated wearing treatment	0.6	1.5
After the simulated wearing treatment	0.5	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	1,3	1,3	1,2	1,2	1,2
As recieved	1,3	1,2	1,2	1,2	1,2
As recieved	1,2	1,3	1,3	1,2	1,2
After temperature conditioning	1,2	1,3	1,3	1,2	1,3
After temperature conditioning	1,2	1,3	1,2	1,2	1,2
After temperature conditioning	1,2	1,2	1,3	1,3	1,2
After the simulated wearing treatment	1,3	1,2	1,3	1,3	1,3
After the simulated wearing treatment	1,2	1,3	1,3	1,3	1,2
After the simulated wearing treatment	1,2	1,3	1,2	1,2	1,2

9. DECISION

Analysis and examinations SUVICOM SV-130- SV-131 - SV-132 - SV-133 - SV-134 - SV-135 - SV-136 - SV-137 - SV-138 - SV-139 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-2021-00018)
- User Instruction

Reason for revision : Company name and model name has been revised.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 05.04.2021