

### **EC DECLERATION OF CONFORMITY**

The object of declaration described above is confirmed with the relevant community harmonization directives.

Company Name : CFU Uluslararası Dış Tic ve Serv Hiz. A.Ş.

Address : Ahi Evran Mah Ural Cad. No: 18/1 06935 Sincan/Ankara/Turkey

Regulation : EU 2016/425
Category : Category III

**Standards** : EN 149:2001+A1:2009

Product name & model: CF Umask FFP2 NR White, Black, Pink colour

Product brand : UMASK

Test Report Number : for "B" module : M-2021-00065

for "C2" module : M-2021-00485

We confirm that our company produce the given products as declared above. Quality standards were tested at MNA laboratories as given at EN 149:2001+A1:2009 with regulation given at 2016/425 regulations.

For "B" module: 146-21-01-R01 for "C2" module: 146-21-01-01-R01

Issued by:

MNA Labaratuvarları San Tic. Ltd. Şti. address; Küçükbakkalköy Mah. Yenidoğan Cad No:21, Ataşehir İstanbul, Turkey, Who has notified body number CE2841 had subjected into process out in "Module B and Module C2" of Regulation (EU) 2016/425 under the surveillance of MNA Lab.

#### **LABELLING**

Marketing, labelling and user information are prepared in accordance with regulation by EU 2016/425 PPE with EN 149:2001+A1:2009

This declaration of conformity is issued under the hole responsibility of the manufacturer.

**C** € 2841

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Date of issue

04/30th/2021

Sign and Stamp

ULUSLARAIN SEDIS TICARET VE SERVIS (IZALE ALIRI A.S. Ah Evran OSE Mat C0935 1 115 ( E.A. RE) Tel. (0312) 394 ( T. J. RE) ( 254 01 34

Sati Imre - Company Manager



# AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No

: 146-21-01-R01

Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /

Certification Date / Certificate Validity Date

: 30.04.2021-03.02.2026

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

Firma Unvanı ve Adresi / Company Name and Address

: CFU ULUSLARARASI DIŞ TİCARET VE

SERVİS HİZMETLERİ ANONİM ŞİRKETİ

Ahi Evran OSB Mah. Ural Cad. No: 18 İç kapı

no:1 Sincan/ ANKARA

Ürün Adı /Modeller / Product Name / Models

Direktifi / Directive

Modülü/Kategori / Module / Category

: UMASK

: 2016/425 REGULATION

: B MODÜLÜ/ KATEGORİ III MODULE B / CATEGORY III

: M-2021-00065, M-2021-00386

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

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

Revizyon nedeni/ Reason for revision: Farklı renkte ürünler eklenmiştir/ Different color products have been added.

Volkan AKIN 30.04.2021 Karar Verici / Approver

Okan AKEL 30.04.202 Şirket Müdi vi 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



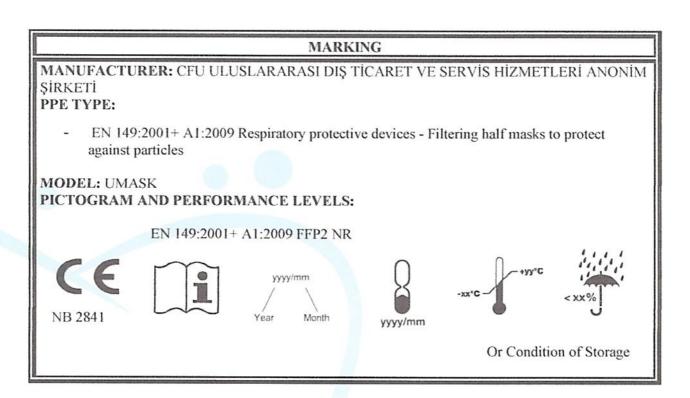
#### ATTACHMENTS (146-21-01-R01)

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: UMASK

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

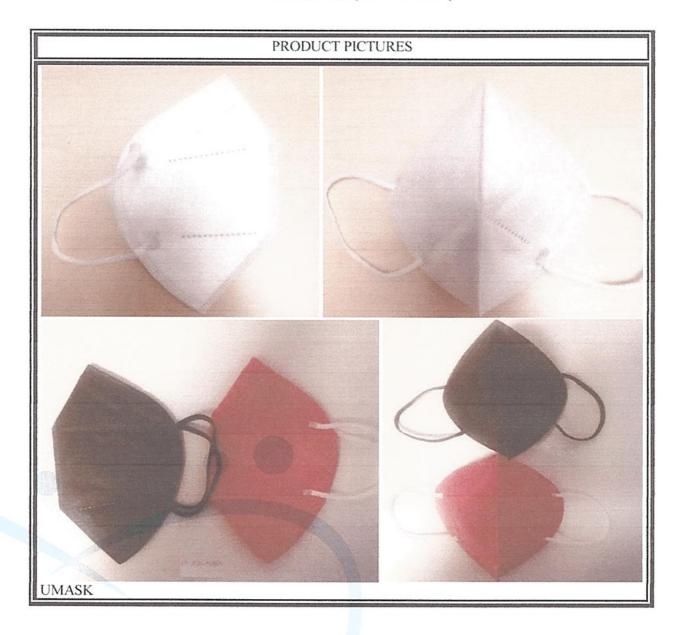
PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:



MNA LABORATORIES SAN. TIC. LTD. \$TI 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 (146-21-01-R01)



#### DOCUMENTS IN THE TECHNICAL FILE

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



#### TECHNICAL EVALUATION REPORT (146-21-01-R01)

Report No

: 146-21-01-R01

Report Date

: 30.04.2021

Application No

: 146-21-01-R01

#### 1. COMPANY INFORMATION:

CFU ULUSLARARASI DIŞ TİCARET VE SERVİS HİZMETLERİ ANONİM ŞİRKETİ Ahi Evran OSB Mah. Ural Cad. No: 18 İç kapı no:1 Sincan/ ANKARA

Tel: 0312 394 01 32

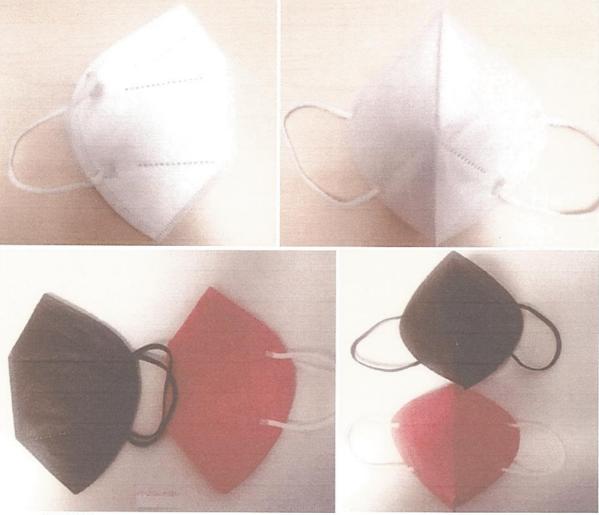
#### 2. PPE INFORMATION:

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



**UMASK** 

# © mna

#### MNA LABORATUVARLARI

#### TECHNICAL EVALUATION REPORT (146-21-01-R01)

#### 5. PPE DIMENSIONS:

UMASK 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 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 AND EVALUATIONS:

#### EN 149:2001 +A1:2009

TESTS	PARAMETER	PARAMETER PERFORMANCE LEVELS			RESULTS	PERFORMANC E LEVELS	EVALUATIO N
		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	for sale packaged in	filtering half mask shall be offered packaged in such a way that they tected against mechanical damage tamination before use			Appropriate	-	PASS
Part 7.5 Material		When conditioned in accordance 8.3.1 & .3.2 the particle filter half mask shall not collarse			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.			sfy the	Not applicable	-	Not applicable
Part 7.7 Practical performance		egative comments should be made by est subject regarding any of the criteria ated.			Appropriate	•	PASS
Part 7.8 Finish of parts		f the device likely to come into with the wearer shall have no sharp burrs.			Appropriate	-	PASS



# TECHNICAL EVALUATION REPORT (146-21-01-R01)

TESTS PARAI	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	7.5	5.7	7.0	7.1	6.8					
Subject 2 (As recieved)	8.4	7.4	6.6	8.6	6.9	7.6					
Subject 3 (As recieved)	8.1	5.7	6.2	6.9	6.8	6.7					
Subject 4 (As recieved)	7.8	8.9	6.3	8.6	8.7	8.1					
Subject 5 (As recieved)	7.7	8.4	8.2	8.7	8.8	8.4					
Subject 6 (After temperature conditioning)	7.5	8.7	8.1	5.8	7.6	7.5					
Subject 7 (After temperature conditioning)	7.8	8.1	6.3	6.9	9.1	7.6					
Subject 8 (After temperature conditioning)	7.8	8.0	7.7	6.7	7.6	7.6					
Subject 9 (After temperature conditioning)	7.9	9.1	7.5	7.6	7.8	8.0					
Subject 10 (After temperature conditioning)	6.5	8.8	9.0	8.6	9.2	8.4					

#### Subject facial dimensions

Subject	Subject Face Length (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		125	83	

TESTS P.	PARAMETER	PERFORMANCE LEVELS		RESULTS	PERFORMANCE 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



# TECHNICAL EVALUATION REPORT (146-21-01-R01)

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)	
As recieved	4.7	5.3	
As recieved	4.9	4.8	
As recieved	5.3	5.1	
After the simulated wearing treatment	4.4	5.5	
After the simulated wearing treatment	4.8	5.1	
After the simulated wearing treatment	5.1	5.8	
Mechanical strength and temperature conditioning	5.5	5.5	
Mechanical strength and temperature conditioning	5.3	5.9	
Mechanical strength and temperature conditioning	5.7	5.7	

TESTS	PARAMETER	PERFO	RMANO	CE LEVELS	RESULTS	PERFORMANCE	EVALUATION
		FFP1	FFP2	FFP3		LEVELS	
Part 7.10 Compatibility with skin	Materials shall not be cause irritation or an health			-	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	verage o	f % 1		0.75 0.78 0.72	-	PASS
Part 7.13 Head harness	It can be donned and	removed	deasily		Appropriate	-	PASS
Part 7.14 Field of vision	The field of vision sha performance test.	all accep	table in	practical	Appropriate	-	PASS
Part 7.15 Exhalation valve(s)	It shall withstand axia apply for 10 s. If fitted, shall continuafter a continuous L/min over a period of	ue to o exhalatio	perate	correctly	Not applicable	-	Not applicable

TESTS PARAMETER	PARAMETER	ARAMETER PERFORMANCE LEVE			RESULTS	PERFORMANCE	EVALUATION
	FFP1	FFP2	FFP3		LEVELS		
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	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



# TECHNICAL EVALUATION REPORT (146-21-01-R01)

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0,6	2,3
As recieved	0.6	2,4
As recieved	0.5	2,3
After temperature conditioning	0.5	2,3
After temperature conditioning	0.5	2,4
After temperature conditioning	0.6	2,3
After the simulated wearing treatment	0.6	2,4
After the simulated wearing treatment	0.5	2,3
After the simulated wearing treatment	0.6	2,3

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

TESTS	PARAMETER	PERFO LEVEL	RMANO S	CE	RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3		SECURIO PER PROPERTO	
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 No 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 par readily connected possible by hand.				Not applicable	-	Not applicable

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#### MNA LABORATUVARLARI

#### TECHNICAL EVALUATION REPORT (146-21-01-R01)

#### 9. DECISION

Analysis and examinations UMASK 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 products have been added.

CONTROLLER : VOLKAN AKIN

SING :

DATE :30.04.202



#### 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 DENETIMLI MUAYENESINE DAYALI TIPE UYGUNLUK

Belge No / Certificate No

: 146-21-01-01-R01

Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /

Certification Date / Certificate Validity Date

: 30.04.2021-16.04.2022

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

Firma Unvanı ve Adresi /

Company Name and Address

: CFU ULUSLARARASI DIŞ TİCARET VE

SERVIS HIZMETLERI ANONIM SIRKETI

Ahi Evran OSB Mah. Ural Cad. No: 18 İç kapı

no:1 Sincan/ ANKARA

Ürün Adı /Modeller / Product Name / Models

Direktifi / Directive

Modülü/Kategori / Module / Category

: UMASK

: 2016/425 REGULATION

: C2 MODÜLÜ/ KATEGORİ III

MODULE C2 / CATEGORY III : M-2021-00485, M-2021-00386

Test Rapor No/lari / 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

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

Revizyon nedeni/ Reason for revision: Farklı renkte ürünler eklenmiştir/ Different color products have been added.

Volkan AKIN 30.04.2021

Karar Verici / Approver

Okan AKEL



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



#### CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS Notified Body Number: 2841

(MODULE C2, ANNEX VII) (146-21-01-01-R01)

: 146-21-01-01-R01 Report No

Report Date : 30.04.2021

**Application No** : 146-21-01-01

#### 1. COMPANY INFORMATION:

CFU ULUSLARARASI DIŞ TİCARET VE SERVİS HİZMETLERİ ANONİM ŞİRKETİ

Ahi Evran OSB Mah. Ural Cad. No: 18 İç kapı no:1 Sincan/ ANKARA

Tel: 0312 394 01 32

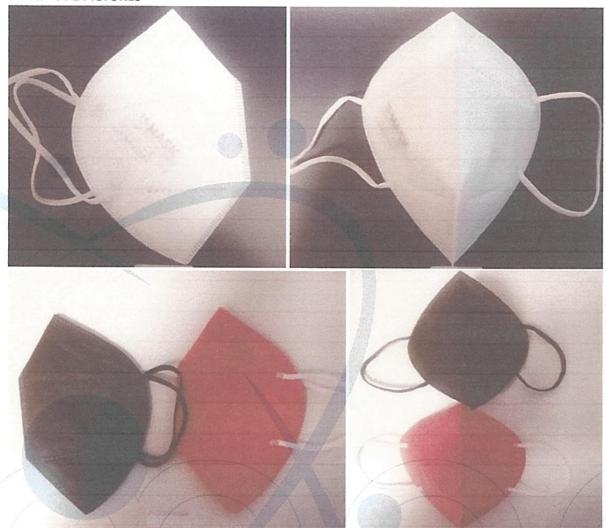
#### 2. PPE INFORMATION:

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



**UMASK** 



## CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (146-21-01-01-R01)

#### 5. PPE DIMENSIONS:

UMASK 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 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 AND EVALUATIONS:

#### EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFO LEVELS		Œ	RESULTS	PERFORMANCE LEVELS	EVALUATION	
		FFP1	FFP2	FFP3				
Banned Azo Dyes	< 30 mg/kg				< 5mg/kg	-	PASS	
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.			sfy the	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	



# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT

Notified Body Number: 2841

**CHECK AT RANDOM INTERVALS** (MODULE C2, ANNEX VII) (146-21-01-01-R01)

TESTS	PARAMETER	ER 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)	7.3	8.5	7.9	8.4	6.7	7.8					
Subject 2 (As recieved)	7.9	5.5	6.0	6.7	6.6	6.5					
Subject 3 (As recieved)	7.6	8.8	7.3	8.5	7.9	8.0					
Subject 4 (As recieved)	7.5	8.2	8.0	8.5	8.8	8.2					
Subject 5 (As recieved)	7.3	8.5	7.9	5.6	7.4	7.3					
Subject 6 (After temperature conditioning)	7.6	7.9	6.1	6.7	8.9	7.4					
Subject 7 (After temperature conditioning)	7.3	7.3	8.5	7.9	7.4	7.7					
Subject 8 (After temperature conditioning)	7.3	8.5	7.9	7.9	7.6	7.8					
Subject 9 (After temperature conditioning)	8.5	7.9	6.1	8.4	7.9	7.8					
Subject 10 (After temperature conditioning)	6.1	8.4	5.6	7.4	8.4	7.2					

#### 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	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE 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



# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT

CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (146-21-01-01-R01)

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As recieved	3.9	4.2
As recieved	4.2	4.5
As recieved	4.2	4.4
After the simulated wearing treatment	4.2	4.4
After the simulated wearing treatment	4.1	4.6
After the simulated wearing treatment	4.2	4.5
Mechanical strength and temperature conditioning	5.7	5.2
Mechanical strength and temperature conditioning	5.5	5.8
Mechanical strength and temperature conditioning	5.3	5.5

TESTS	PARAMETER	PARAMETER PERFORMANCE LEVELS				PERFORMANCE	EVALUATION
		FFP1	FFP2	FFP3		LEVELS	
Part 7.10 Compatibility with skin	Materials shall not be cause irritation or an 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 a	verage o	f % 1		0,88 0,84 0,83	-	PASS
Part 7.13 Head harness	It can be donned and	removed	deasily		Appropriate	-	PASS
Part 7.14 Field of vision	The field of vision sha performance test.	all accep	table in	practical	Appropriate	-	PASS
Part 7.15 Exhalation valve(s)	It shall withstand axia apply for 10 s. If fitted, shall continuafter a continuous L/min over a period o	ue to o	perate	correctly	Not applicable	-	Not applicable

TESTS PARAMETER		PERFORMANCE LEVELS			RESULTS	PERFORMANCE	EVALUATION
		FFP1	FFP2	FFP3		LEVELS	
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 FFP2 below	FFP2	PASS
Exhalation 160L	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar	See the table below	FFP2	PASS



# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT

**CHECK AT RANDOM INTERVALS** 

(MODULE C2, ANNEX VII) (146-21-01-01-R01)

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0,6	2,2
As recieved	0,6	2,2
As recieved	0,5	2,3
After temperature conditioning	0,5	2,3
After temperature conditioning	0,6	2,3
After temperature conditioning	0,5	2,2
After the simulated wearing treatment	0,5	2,3
After the simulated wearing treatment	0,6	2,3
After the simulated wearing treatment	0,6	2,3

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	2,8	2,8	2,8	2,7	2,8
As recieved	2,7	2,8	2,8	2,7	2,8
As recieved	2,7	2,8	2,8	2,7	2,8
After temperature conditioning	2,7	2,8	2,8	2,8	2,8
After temperature conditioning	2,8	2,8	2,8	2,8	2,8
After temperature conditioning	2,8	2,8	2,8	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,7	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,7	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,8	2,8	2,8

TESTS	PARAMETER	PERFO	RMANO S	CE	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 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.		1.5		Not applicable	-	Not applicable



## CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (146-21-01-01-R01)

#### 9. DECISION

Analysis and examinations UMASK 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-2021-00485, M-2021-00386)
- User Instruction

Reason for revision : Different color products have been added.

CONTROLLER : Volkan AKIN

SING

DATE : 30.04.2023



# COLOREBIANCO FFP2 NR



SEMIMASCHERA FILTRANTE
Conforme EN 149:2001+A1:2009

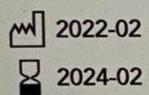
Regolamento (UE) 2016/425

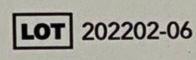
DPI CATEGORIA III | IMBUSTATA SINGOLARMENTE | PFE ≥ 94%

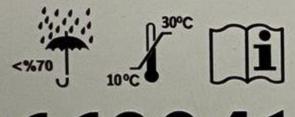
















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Importato da ESSECI Italia S.r.L. Via Provinciale Nocera Sarno, 157 84014 - Nocera Inferiore (SA) - Italia

Organismo Notificato MNA LABORATUVARLARI **SANAYI TICARET** LIMITED ŞIRKETI KüçükbakkalköyMah.

Yenidoğan Cad. No: 21 Ataşehir/İSTANBUL NB number: 2841



**CFU ULUSLARARASI DI**Ş TICARET HIZMETLERI A.Ş.

ASO 1. O.S.B Ural Caddesi No:18 Sincan-Ankara/TURKEY +903123940132 medikal@cfu.com.tr

Cod.: 40056

Cod. Fabbricante: UMask

**MADE IN TURKEY** 



# ISTRUZIONI PER L'USO









- Estrarre la semimaschera e aprirla afferrando gli elastici
- Mettere la semimaschera sul viso coprendo naso e bocca, con la barra nasale poggiata sul naso.
- Tendere e fissare gli elastici dietro le orecchie.
- Regolare la barra nasale premendola sul naso.

ATTENZIONE: Questa semimaschera è solo per uso singolo.

Deve essere sostituita quando viene deformata o bagnata. Dopo l'uso deve essere gettata nel rispetto delle norme igieniche vigenti nel comune di appartenenza. Conservare in un luogo asciutto.

# SOLO USO SINGOLO (NR)

Questa semimaschera filtrante non deve essere utilizzata per più di 8 ore.

# **AVVERTENZE:**

- · L'utilizzatore deve conoscere, selezionare e utilizzare correttamente la semimaschera filtrante in conformità con le normative vigenti in materia di salute e sicurezza.
- Non apportare modifiche alla semimaschera filtrante.
- Controllare la misura della semimaschera filtrante prima di ogni utilizzo.
- · L'uso di una semimaschera filtrante con i peli del viso che impediscono la perfetta tenuta al volto dei bordi della semimaschera, può impedire un buon adattamento ed è improbabile che i requisiti di sicurezza vengano raggiunti in questa circostanza.
- La semimaschera filtrante non fornisce ossigeno, si prega di utilizzare in ambiente con livello di ossigeno sufficiente e buona ventilazione.

Abbandonare l'area contaminata in caso di vertigini, irritazione o altro disagio.

- Gettare la semimaschera filtrante e sostituirla con una nuova se:
- a. si nota maggiore resistenza al respiro e conseguente difficoltà respiratoria.
- b. La semimaschera filtrante viene danneggiata o distorta.
- c. Non è possibile ottenere una corretta vestibilità facciale.

Sul sito www.setablu.it è disponibile la dichiarazione di conformità e la scheda informativa del prodotto.

# LIMITAZIONI D'USO

Non utilizzare la semimaschera di filtraggio delle particelle ed entrare o rimanere in ambiente contaminato se:

- L'utente presenta lesioni alle orecchie che impediscono il corretto indossamento della maschera.
- L'atmosfera contiene meno del 19,5% di ossigeno.
- L'utente odora o assapora il contaminante.
- L'ambiente contiene gas o vapori pericolosi.
- I contaminanti e le loro concentrazioni sono sconosciuti o immediatamente pericolosi alla vita o alla salute.
- Nelle operazioni di sabbiatura, verniciatura a spruzzo e ambiente con amianto.
- In atmosfere esplosive.
- Dopo la data di scadenza della semimaschera filtrante.
- I controlli prima dell'uso non sono stati eseguiti.
- Se la semimaschera risulta danneggiata o alterata in qualche sua parte.

# **CONSERVAZIONE**

Conservare il prodotto a una temperatura ambiente di 10 - +30°C e un'umidità massima del 70%. Prevenire l'estrusione meccanica, l'eccessiva temperatura e umidità, l'esposizione alla luce solare e il contatto con prodotti chimici. Conservare la semimaschera nella sua confezione originale al riparo dalla luce diretta del sole fino al suo utilizzo. Il prodotto non richiede manutenzione.

# FFP2 NR

SEMIMASCHERA FILTRANTE

Conforme EN 149:2001+A1:2009 Regolamento (UE) 2016/425 10 PEZZI