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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-817

Respiratory protective devices, filtering half masks to protect against particles manufactured by

„Redacted for public use"

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: SKY SCREEN **Model:** 9902
Filtering half mask
Classification: FFP3 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **24/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
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Director

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NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE–817/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

„Redacted for public use"

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No.	Date	Issuing NB No.
SKY SCREEN / 9902	FFP3	2163-PPE-817	24.06.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **24/06/2020** and will be valid for one year, until **23/06/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
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UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO.
Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY

TEST REPORT

Report Date: 12.05.2020
Report Number: 05-2020-T-0082

CLIENT and SAMPLE INFORMATION

TEST OWNER				
ADDRESS				
SAMPLE DESCRIPTION	Cup shape with valve (See end of test report for sample photo)			
BRAND NAME – MODEL	SKY SCREEN model:9902			
TESTING STANDARD	EN 149+A1:2009			
CASE NUMBER	CE-PPE-1990			
SAMPLE RECEIVE DATE	24.04.2020	TESTING START DATE	28.04.2020	
DISINFECTION INSTRUCTION *If applicable*	Not given, single use only			
NUMBER OF SAMPLES	50	SAMPLE IDs:	1 – 46	
AS RECEIVED SAMPLE NO	26-46			
CONDITIONING SAMPLE NO	Simulated wearing treatment	1-2-3-4-5-6-7-8-9 (As Received)		
	Temperature conditioning	10-11-12-13-14-15 (Sample after test of Mechanical Strength)		
		16-17-18-19-20-21-22-23-24-25 (As Received)		
	Mechanical strength	10-11-12-13-14-15 (As Received)		

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Yukarı Dudullu-Ümraniye/İSTANBUL
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Suat KAÇMAZ
Director

1. *REPORT SUMMARY*

TEST STANDARD	*TEST NAME*	*RESULT*	*EVALUATION*
EN 149:2001 + A1:2009 clause 8.5 EN 13274-1:2001	Total Inward Leakage Testing	**Pass**	**FFP3**
EN 149:2001 + A1:2009 clause 8.11 EN 13274-7:2019	Penetration of Filter Material	**Pass**	**FFP3**
EN 149:2001 + A1:2009 clause 8.6 EN 13274-4:2001	Flammability Testing	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.7 EN 13274-6:2001	Carbon Dioxide Content of The Inhalation Air Testing	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Breathing Inhalation Resistance-30 l/min	**Pass**	**See results**
	Breathing Inhalation Resistance-95 l/min	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Exhalation Resistance, flow rate 160 l/min	**Pass**	**See results**

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2. *TEST RESULTS and EVALUATION*

7.4 PACKAGING (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Clause 8.2-Visual inspection

REQUIREMENT	RESULTS	COMMENT
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Pass	The masks were packaged in sealed plastic bags, in larger plastic bags inside a large cardboard box that gave some protection against mechanical damage or contamination before use

Lab A

7.5 MATERIAL (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)

Test Method: Clause 8.2-Visual inspection

Clause 8.3.1-Simulated wearing treatment

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask was mounted on a Sheffield dummy head.

For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head.

The air has been saturated at (37 ± 2) °C at the mouth of the dummy head

Clause 8.3.2-Temperature conditioning

The ambient temperature for testing has been between 16 °C and 32 °C and the temperature limits has been subject to an accuracy of ±1 °C.

a) for 24 h to a dry atmosphere of (70 ± 3) °C;

b) for 24 h to a temperature of (-30 ± 3) °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning has been carried out in a manner which ensures that no thermal shock occurs.

REQUIREMENT	RESULTS	COMMENT
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Pass	The materials used were able to withstand handling and wear during the limited laboratory testing carried out.
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass	It was not constitute a hazard or nuisance for the wearer.
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Pass	None of the specimens conditioned suffered mechanical failure.
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass	None of the specimens had not collapse after conditioning.

Lab B

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7.6 CLEANING AND DISINFECTING (EN 149:2001 + A1:2009 clause 8.4, 8.5, 8.11)

Test Method: Described in Clause 8.4, 8.5 and 8.11

REQUIREMENT	RESULTS	COMMENT
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	N/A	This article is not applicable for tested protective mask which is single use disposable mask.

7.7 PRACTICAL PERFORMANCE (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

REQUIREMENT	RESULTS	COMMENT
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that can not be determined by the tests described elsewhere in this standard. Two as received mask samples are used by two subject for the walking (10 mins walking with a speed of 6km/h) and work simulation (bended walking, crawling and basket filling excercises) tests.	No imperfections	Detail refer to Annex I

Annex I-Test Result:

Number of sample: 29 (A.R), 30 (A.R)

Assessed elements	Positive Assessment	Negative Assessment	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
The face piece fitting Head harness comfort Security of fastenings Field of vision	2 2 2 2	0 0 0 0	Filtering half masks should not have imperfections related to wearer's acceptance	Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.7 No imperfections

The subjects (MEG and MA) were able to complete the exercises and did not report any nuisance or problem with the mask.

Lab B

7.8 FINISH OF PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Pass	None of the specimens used in laboratory testing showed evidence of sharp edges or burrs while visual inspection and performance tests.

Lab A

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7.9.1 TOTAL INWARD LEAKAGE (EN 149:2001 + A1:2009 clause 8.5)

Test Method: Described in Clause 8.5

REQUIREMENT	RESULTS	COMMENT
The total inward leakage consists of three components: face seal leakage, exhalation value leakage (if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual results shall be not greater than: 25 % for FFP1, 11 % for FFP2, 5 % for FFP3 and in addition at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than: 22 % for FFP1, 8 % for FFP2, 2 % for FFP3	Pass	Classified as FFP3 Detail refer to Annex II

Annex II-Test Result:

The test results obtained are given in the tables as follows

Test Subject	No of sample	Cond.	1. Walk (%)	Head side/ side (%)	Head up/down (%)	Talk (%)	2. Walk (%)	Average (%)
1	31	A.R.	1,61	1,78	1,96	1,56	1,97	1,78
2	32	A.R.	1,56	1,73	1,79	1,58	1,56	1,64
3	33	A.R.	1,54	1,80	1,91	1,38	1,68	1,66
4	34	A.R.	1,65	1,99	1,83	1,69	1,57	1,75
5	35	A.R.	1,52	1,78	1,88	1,48	1,57	1,65
6	16	T.C.	1,77	1,81	1,85	1,96	1,88	1,85
7	17	T.C.	1,67	1,90	1,93	1,55	1,69	1,75
8	18	T.C.	1,81	1,97	1,99	2,14	2,18	2,02
9	19	T.C.	1,72	1,94	1,96	1,98	2,10	1,94
10	20	T.C.	1,75	1,88	1,90	1,97	1,86	1,87
All 50 individual exercise results were not greater than 5 %. At least 9 of 10 individual wearer arithmetic means were not greater than 2 %.								Pass (FFP3)

Test Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	117	155	130	60
2	113	148	128	62
3	112	160	134	59
4	115	148	125	61
5	120	158	132	57
6	118	150	134	59
7	115	152	130	57
8	117	155	134	59
9	114	149	128	57
10	110	150	131	55

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Lab B

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7.9.2 PENETRATION OF FILTER MATERIAL (EN 149:2001 + A1:2009 clause 8.11)

Test Method: Described in Clause 8.11

REQUIREMENT	RESULTS	COMMENT
<table><tr><th rowspan="2">Classification</th><th colspan="2">Max penetration of test aerosol</th></tr><tr><th>NaCl test 95 l/min %max</th><th>Paraffin oil test 95 l/min %max</th></tr><tr><td>FFP1</td><td>20</td><td>20</td></tr><tr><td>FFP2</td><td>6</td><td>6</td></tr><tr><td>FFP3</td><td>1</td><td>1</td></tr></table>	Pass	Detail refer to Annex IIIA and IIIB

Annex IIIA-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Sodium Chloride in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
36	As received	0,78	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first, second and third protection class (FFP1, FFP2, FFP3)
37		0,76		
38		0,72		
1	Simulated wearing treatment	0,81		
2		0,79		
3		0,83		
10	Mechanical strength + Temperature conditioned	0,85		
11		0,82		
12		0,89		

Annex IIIB-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
39	As received	0,51	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first, second and third protection class (FFP1, FFP2, FFP3
40		0,55		
41		0,57		
4	Simulated wearing treatment	0,62		
5		0,65		
6		0,68		
13	Mechanical strength + Temperature conditioned	0,76		
14		0,75		
15		0,79		

Lab A + B

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7.10 COMPATIBILITY WITH SKIN (EN 149:2001 + A1:2009 clause 8.4, 8.5)

Test Method: Described in Clause 8.4 and 8.5.

REQUIREMENT	RESULTS	COMMENT
Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Pass	No irritation or any other adverse effect to health or sensitivity reported by the subjects during the practical performance and TIL tests.

Lab B

7.11 FLAMMABILITY (EN 149:2001 + A1:2009 clause 8.6)

Test Method: Described in Clause 8.6

REQUIREMENT	RESULTS	COMMENT
The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn 5s after removal from the flame.	Pass	Detail refer to Annex IV

Annex IV-Test Result: The test results obtained are given in the tables as follows:

No. of Sample	Condition	Visual inspection	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
45	As received	1,3	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.11
46		1,1		
21	Temperature conditioned	1,2		
22		1,2		

Lab B

7.12 CARBON DIOXIDE CONTENT OF THE INHALATION AIR (EN 149:2001 + A1:2009 clause 8.7)

Test Method: Described in Clause 8.7

REQUIREMENT	RESULTS	COMMENT
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Pass	Detail refer to Annex V

Annex V-Test Result: The test results obtained are given in the tables as follows:

No. of Sample	Condition	CO_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air [%] by volume	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
26	As received	0,68	0,65	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.12
27		0,63			
28		0,65			

Lab B

7.13 HEAD HARNESS (EN 149:2001 + A1:2009 clause 8.4, 8.5)

Test Method: Described in Clause 8.4, 8.5

REQUIREMENT	RESULTS	COMMENT
The head harness shall be designed so that the particle filtering half-mask can be donned and removed easily.	Pass	No problem with the head harness reported by the wearers during the practical performance test.
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and capable of maintaining total inward leakage requirements for the device.	Pass	No problem with the head harness reported by the wearers during the practical performance test.

Lab B

7.14 FIELD OF VISION (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

REQUIREMENT	RESULTS	COMMENT
The field of vision is acceptable if determined so in practical performance tests.	Pass	There were no adverse comments following practical performance tests.

Lab B

7.15 EXHALATION VALVE (EN 149:2001 + A1:2009 clause 8.2, 8.3.4, 8.8, 8.9.1)

Test Method: Clause 8.2, 8.3.4, 8.8, 8.9.1

REQUIREMENT	RESULTS	COMMENT
A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Pass	The valve on the mask was functioning tested during the visual inspection. Total 12 valved sample (3 as received, 3 after temperature conditioning and 3 after the test for simulated wearing and 3 after the flow conditioning) tested and the results are valid for FFP3 protection class. See results on 7.16
If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9	Pass	The samples tested in accordance to 7.9 were functional those subjected to temperature, mechanical and flow conditioned processes..
Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s.	Pass	No problem with the functionality of the valves noted while subjected to 300 L/min flow for 30 seconds.
When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10s.	Pass	The valve tested withstand to a 10 N force applied to the valve horizontally.

Lab -A

7.16 BREATHING RESISTANCE (EN 149:2001 + A1:2009 clause 8.9)

Test Method: Described in Clause 8.9

REQUIREMENT	RESULTS	COMMENT
See table below	Pass	Classified as FFP3 Detail refer to Annex VIA-VIB

Classification	Max permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Annex VIA-Test Result:

The test results obtained are given in the tables as follows;

Inhalation Resistance

No. of Sample	Condition	Inhalation Resistance (mbar)				
		Flow rate 30 l/min	Requirements in accordance with EN 149:2001+A1:2009	Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
42	As received	0,78	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	2,24	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	The results are valid for third protection class, FFP3. Passed
43		0,76		2,25		
44		0,71		2,28		
7	Simulated wearing treatment	0,80		2,36		
8		0,83		2,42		
9		0,81		2,40		
23	Temperature conditioned	0,85		2,24		
24		0,89		2,25		
25		0,92		2,28		
13	Flow conditioned	0,84		2,32		
14		0,93		2,30		
15		0,89		2,26		

Exhalation Resistance

No. of Sample	Condition	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001 +A1:2009	Assessment of Test Result Conformity / Nonconformity
		Flow Rate 160 L/min						
42	As received	2,03	2,05	1,79	2,05	2,03	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	The results are valid for third protection class, FFP3. Passed
43		1,90	1,87	1,77	1,51	2,04		
44		1,83	1,89	1,84	1,88	2,02		
7	Simulated wearing treatment	2,13	1,95	1,78	2,01	1,83		
8		2,25	1,92	2,06	2,19	2,07		
9		2,08	2,02	1,77	1,88	2,01		
23	Temperature conditioned	1,83	1,85	1,69	1,86	1,80		
24		2,12	1,75	2,04	2,07	1,98		
25		1,84	1,89	2,15	2,17	2,23		
13	Flow conditioned	2,05	2,01	2,04	2,06	2,03		
14		1,88	2,19	1,96	1,94	1,80		
15		1,74	2,68	1,75	2,04	2,16		

Lab A

7.17 CLOGGING (EN 149:2001 + A1:2009 clause 8.9, 8.10)

Test Method: Described in Clause 8.8, 8.10

REQUIREMENT	RESULTS	COMMENT
Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:4mbar, FFP2:5mbar, FFP3:7mbar at 95L/min continuous flow. The exhalation resistance shall not exceed 3mbar at 160L/min continuous flow. Valveless particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:3mbar, FFP2:4mbar, FFP3:5mbar at 95L/min continuous flow	NAs	This is optional test and not desired by client.

Lab -

7.18 DEMOUNTABLE PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	N/A	No demountable part.

Lab -

Pass	*Requirement satisfied.*
NCR	*Requirement not satisfied. Refer to the "Result details" section for more information.*
NAs	*Assessment not carried out.*
N/A	*Requirement not applicable.*

LABORATORY INFORMATION

Code	Laboratory Name	Competency Explanations
Lab A	UNIVERSAL SERTIFIKASYON VE GOZETIM HIZMETLERI TIC. LTD. STI.	Internal Laboratory Services of Notified Body
Lab B	GCNTR ULUSLARARASI BELGELENDIRME, GOZETIM, EGITIM VE DIS TICARET LIMITED SIRKETI KOCAELI DILOVA SUBESI	Laboratory holds an accreditation by Turkish Accreditation Agency with number AB-1252-T according to EN ISO/IEC 17025:2017.

- The laboratories are contracted bodies with UNIVERSAL CERTIFICATION and the technical competence of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based on the provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and services standard.
- Each test result given in this test report shown with the issuing laboratory code.

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Yukarı Dudullu-Ümraniye/İSTANBUL
Telefon: 0216 455 80 [illegible] Faks: 0216 455 80 08
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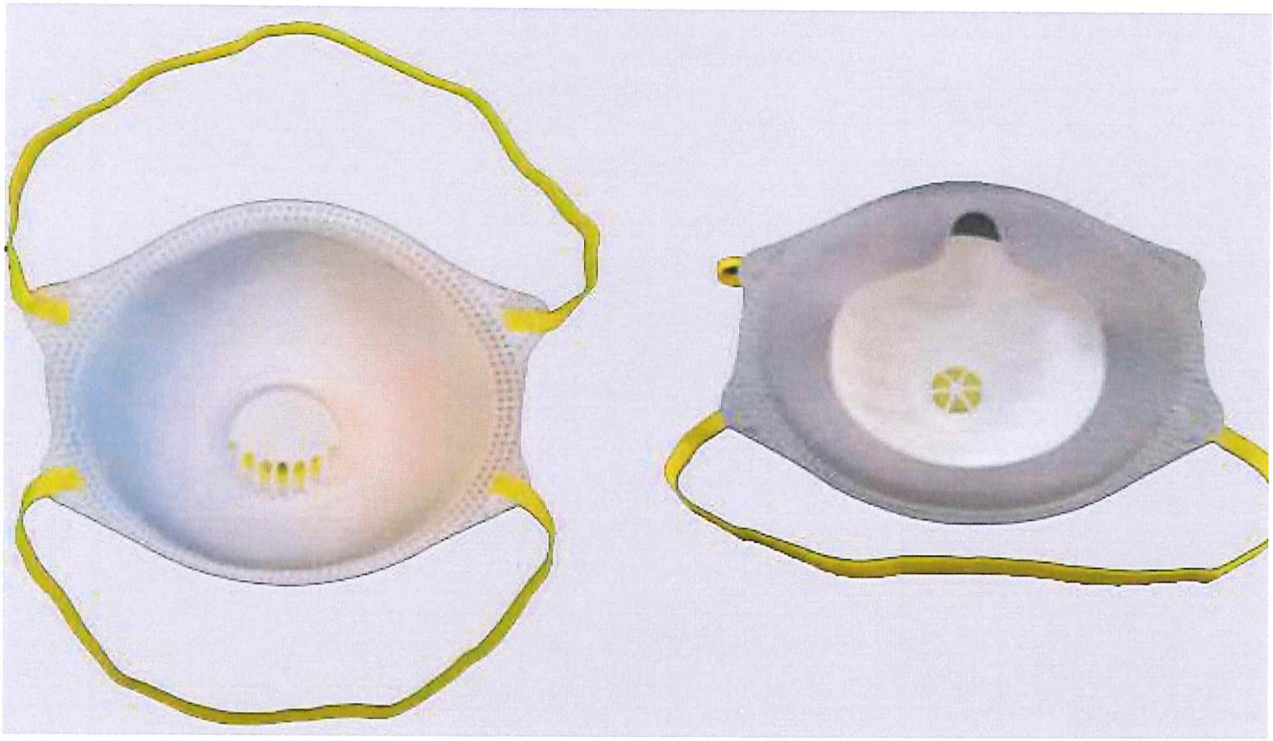
CERTIFICATION

Sample Photo of Mask



- End of Report -

UNIVERSAL
SERTİFİKASYON
VE GÖZETİM HİZM.
TİC. LTD. ŞTİ.
Necip Fazıl Bulvarı, Keyap Sitesi, E2 Blok, No:44/84
Yukarı Dudullu-Ümraniye/İSTANBUL
Telefon: 0216 455 80 80 Faks: 0216 455 80 08
Sarıgazi V.D. 892 025 8722