



**EKOTEKS LABORATUVAR ve GÖZETİM  
HİZMETLERİ A.Ş.**  
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar  
İstanbul/ TÜRKİYE



**TEST REPORT**  
*DENEY RAPORU*

AB-0583-T
22024896 -ing-Add- RER
10-22

**Customer name:** MUSK MEDİKAL TEKS. PLS. SAN. VE Tİ.C LTD. ŞTİ.  
**Address:** Başpınar OSB 1. Bölgede 83105 Nolu Cad. No:24 Şehitkamil/GAZİANTEP  
**Buyer name:** -  
**Contact Person:** -  
**Lot No / Party No :** WKGFF01  
**Article No:** MUSK021  
**Name and identity of test item:** White non-woven mask.(Claimed to be; White/ 100 Pieces)  
**The date of receipt of test item:** 09.09.2022  
**Re-submitted/re-confirmation date:**  
**Date of test:** 09.09.2022-11.10.2022  
**Remarks:** -  
**Sampling:** The results given in this report belong to the received sample by vendor.  
**End-Use:** Mask  
**Care Label:** Not Specified  
**Number of pages of the report:** 9

*The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports. Deney laboratuvarı olarak faaliyet gösteren EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. TÜRKAK'tan AB-0583-T akreditasyon dosya numarası ile ISO 17025:2017 standardına göre akredite edilmiştir.*

*The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.*



**Date**  
11.10.2022

**Customer Representative**  
Yeşim SAHİN

**Head of Testing Laboratory**  
Sevim A. RAZAK  
11.10.2022

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REQUIRED TESTS	EVALUATION	COMMENTS
<b>PHYSICAL PROPERTIES TESTS</b>		
Breathability (Differential Pressure)	P	Type IIR
Blood Splash Resistance	P	
<b>MICROBIOLOGICAL TEST</b>		
Bacterial Filtration Efficiency (BFE) <sup>(1)</sup>	P	
Microbial Cleanliness (Bioburden)	P	

P: Pass

F: Fail

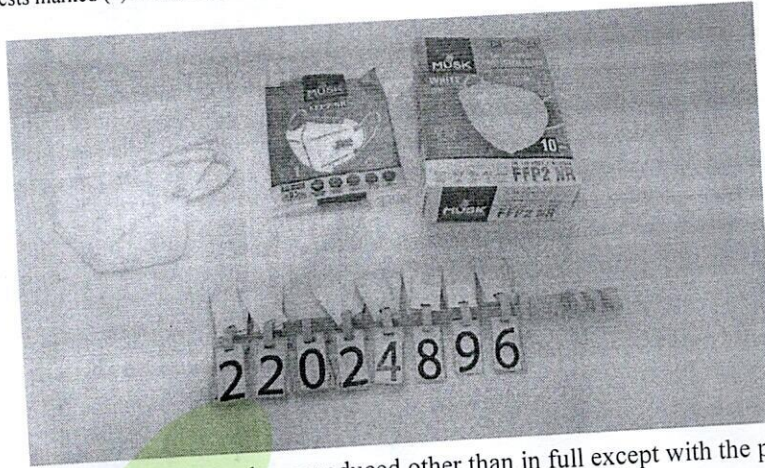
R: Refer to retailer technologist.

Test results were evaluated according to EN 14683:2019+AC:2019 Table 1 "Performance requirements for medical face masks" limit values .

(1) This report was reissued to add this test result

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified. If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values. The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. Tests marked (\*) in this report are not included in the accreditation schedule.

Gen.FI36-2/04



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Note: The report issued on 10.10.2022 with the report number 22024896 was withdrawn and replaced with the report 22024896-RER issued on 11.10.2022 as the vendor required to cancel Differential Pressure test result on new sample sent on 11.10.2022 dates (Report number:22027460)

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## TEST DETAILS AND RESULTS

**Test:** Bacterial Filtration Efficiency (BFE)

**Test Method:** EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) Medical face masks - Requirements and test methods, Annex-B (\*)

**Test Principle:** A sample of the mask material is clamped between an impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol. The test is repeated with five samples of the same mask material.

Test Details	
Test Flow Rate	28.3 L/min
Total Test Flow Time	2 min
Sample Dimensions	14.5x9.5 cm
Tested Area of Sample	49 cm <sup>2</sup>
Number of Tested Sample	5 Pieces
Tested Side of Sample	Inner
Sample Conditioning	4 h by exposure to a temperature of 21±5°C and a relative humidity of 85±5%
Test Conditions	Temperature: 20±5°C, relative humidity: 50±5%
Test Microorganism	<i>Staphylococcus aureus</i> ATCC 6538
Concentration of Test Microorganism	2.4x10 <sup>7</sup> CFU/mL
Mean of the Total Plate Count of the Positive Controls (C)	2.2x10 <sup>3</sup> CFU
Plate Count of the Negative Control	0 CFU
Mean Particle Size (MPS)	2,7 µm

Results			Requirement	
Sample	Total Plate Counts (CFU) for the Test Sample (T)	Bacterial Filtration Efficiency (%B)	Classification according to EN 14683	%B
1	12	%99,47	Type I	≥95
2	7	%99,65		
3	7	%99,69	Type II and Type IIR	≥98
4	11	%99,51		
5	9	%99,64		

For each test sample the Bacterial Filtration Efficiency (%B) was calculated using the following formula:  

$$\%B = (C - T) / C \times 100$$

CFU: Colony Forming Unit

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## TEST DETAILS AND RESULTS

**Test:** Breathability (Differential Pressure)

**Test Method:** EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) Medical face masks - Requirements and test methods, Annex-C

**Test Principle:** To measure the air exchange pressure of the medical face mask material, a device that measures the pressure difference required to draw air from a measured surface area at a constant air flow rate is used. The test is repeated with min five samples of the same mask material. If one specimen cannot provide 5 test areas of 25 mm diameter, the number of test areas retrieved should be representative for the entire mask.

Test Details	
Test Flow Rate	8 L/min
Sample Dimensions	19x17 cm
Sample Diameter & Tested Area of Sample	Diameter : 25 mm / Tested Area : 4,9 cm <sup>2</sup>
Number of Tested Sample	Min.5 masks / measure 5 test areas for each mask
Tested Side of Sample /airflow direction	From the inside of the mask to the outside of the mask
Sample Conditioning	4 h by exposure to a temperature of 21±5°C and a relative humidity of 85±5%
Test Conditions	Temperature: 20±2 °C, relative humidity: 65±4%

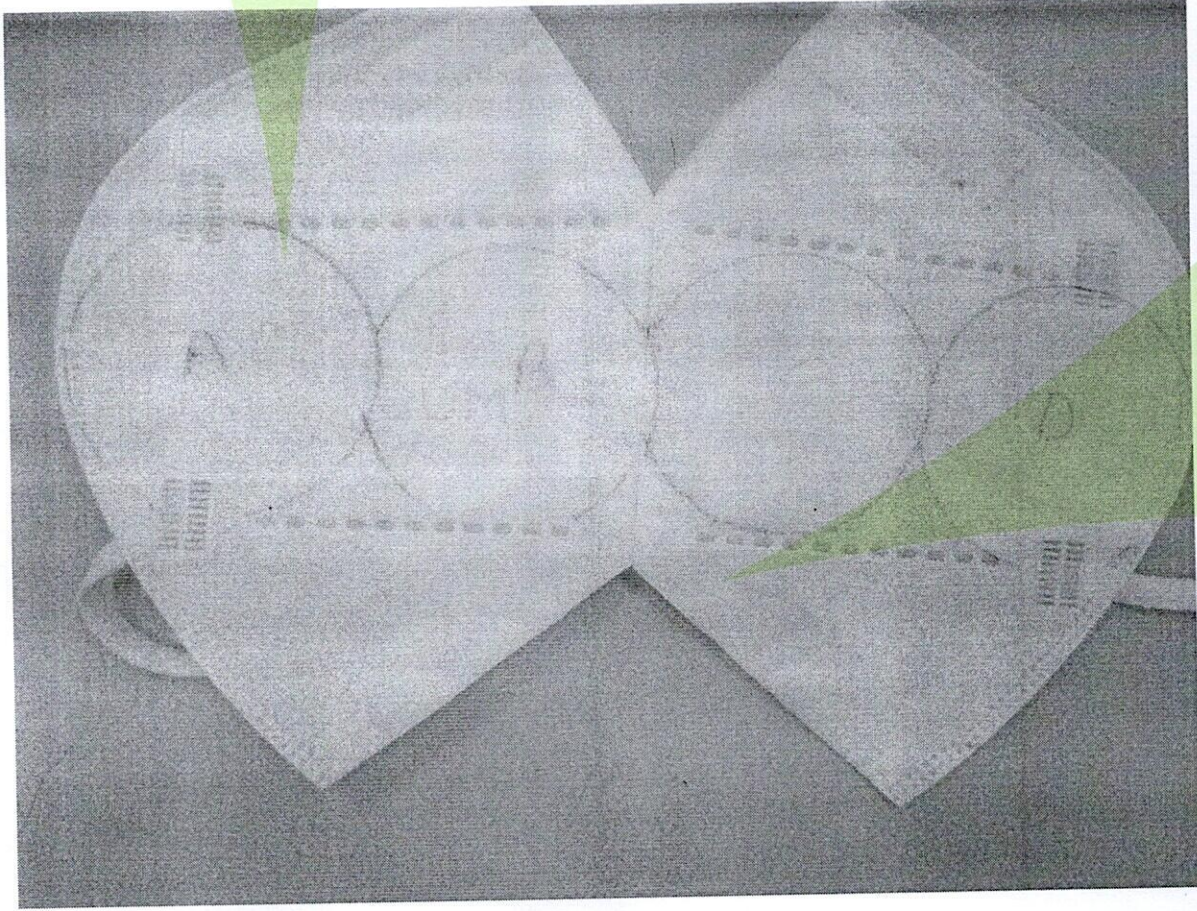
Results						
Differential Pressure (Pa/cm <sup>2</sup> )						
Test Location	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Requirement
A	48.5	43.1	48.1	39.3	40.9	< 60 Pa/cm <sup>2</sup> Type IIR mask
B	41.8	41.4	33.0	33.6	35.2	
C	32.4	31.5	30.0	37.0	30.7	
D	45.3	48.5	44.0	45.7	39.5	
E	-	-	-	-	-	
Average Result Delta P (Pa/cm <sup>2</sup> )	42.0	41.1	38.7	38.9	36.5	

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Test location of sample

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## TEST DETAILS AND RESULTS

**Test:** Microbial Cleanliness (Bioburden)

**Test Method:** EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) Medical face masks - Requirements and test methods, Annex-D  
EN ISO 11737-1:2018/Amd 1:2021 / TS EN ISO 11737-1 :2018/Amd 1:2021-05 Sterilization of health care products- Microbiological Methods-Part 1 : Determination of population of microorganisms on products Amendment 1

**Test Principle:** This method is applied to check the absence of live microorganism populations on the medical face mask material. Mask samples to be used for the test should be supplied as presented to the end user in their original packaging. When selecting 5 samples, the top and bottom 3 samples are randomly selected. If the mask contains a visor or similar accessories, it should be tested in this way..

Test Details	
Sample Dimensions	15x15 cm
Number of Tested Sample	Min.5 masks / randomly selected
Shaker	5 min at 250rpm
Test Conditions	Temperature: 20±2 °C, relative humidity: 50±4%
Total viable aerobic microbial count	Temperature : 30±1°C Time: 72 hrs , PCA medium (Lot No: 807251)
Total fungi count	Sıcaklık: 20-25 °C Süre: 7 gün , SDA medium (Lot No: UK303787/061)
Used Test Solution	Sodium chloride peptone buffer

RESULT						REQUIREMENT
Number of Sample	Weight (g)	Aerobic cfu/100 ml	Fungal cfu/100 ml	Total Bioburden (cfu/sample)	Total Bioburden (cfu/g)	
1	5.04	40	0	120	23.8	≤30 cfu /g Type IIR mask
2	4.92	35	0	105	21.3	
3	5.02	43	0	129	25.6	
4	4.98	38	0	114	22.8	
5	4.99	41	0	123	24.6	

\*CFU: Colony forming unit

## TEST DETAILS AND RESULTS

**Test:** Splash Resistance

**Test Method:** EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) Medical face masks - Requirements and test methods, Clause 5.2.4  
ISO 22609 :2004 Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

**Test Principle:** The resistance of the medical face mask material to the penetration of synthetic blood should comply with the minimum value given for Type IIR in Table 1. Medical face masks are visually evaluated against pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa at three different rates, corresponding to human blood. The sample removed from the conditioning cabinet should be tested in 60 seconds, and  $(10 \pm 1)$  s after the synthetic blood is sprayed. must be visually inspected .

Test Details	
Air Pressure Source	$(700 \pm 25)$ kPa.
Sample Dimenisons	15x15 cm
Number of Tested Sample	32 pieces
Tested side of sample	Outer side
Sample Conditioning	4 h by exposure to a temperature of $21 \pm 5^\circ\text{C}$ and a relative humidity of $85 \pm 5\%$
Test Conditions	Temperature : $21 \pm 5^\circ\text{C}$ , Relative humidity : $85 \pm 5\%$
Surface Tension of Synthetic Blood (N/m)	$(0,042 \pm 0,002)$ N/m
Volume of Synthetic Blood Fluid (ml)	2 ml $(2,010 \pm 0,040)$ g
Pneumatic controlled valve at a distance (mm)	$(300 \pm 10)$ mm
Velocity (cm/s)	635 cm/s
Blood Pressure (kPa)	21,3 kPa
Pre-treatment	-

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**TEST DETAILS AND RESULTS**

	<u>SPLASH RESISTANCE PRESSURE (kPa)</u>	<u>RESULTS</u>	<u>REQUIREMENT</u>
1	>21.3 kPa	PASS	≥16 kPa Type IIR mask
2	>21.3 kPa	PASS	
3	>21.3 kPa	PASS	
4	>21.3 kPa	PASS	
5	>21.3 kPa	PASS	
6	>21.3 kPa	PASS	
7	>21.3 kPa	PASS	
8	>21.3 kPa	PASS	
9	>21.3 kPa	PASS	
10	>21.3 kPa	PASS	
11	>21.3 kPa	PASS	
12	>21.3 kPa	PASS	
13	>21.3 kPa	PASS	
14	>21.3 kPa	PASS	
15	>21.3 kPa	PASS	
16	>21.3 kPa	PASS	
17	>21.3 kPa	PASS	
18	>21.3 kPa	PASS	
19	>21.3 kPa	PASS	
20	>21.3 kPa	PASS	
21	>21.3 kPa	PASS	
22	>21.3 kPa	PASS	
23	>21.3 kPa	PASS	
24	>21.3 kPa	PASS	
25	>21.3 kPa	PASS	
26	>21.3 kPa	PASS	
27	>21.3 kPa	PASS	
28	>21.3 kPa	PASS	
29	>21.3 kPa	PASS	
30	>21.3 kPa	PASS	
31	>21.3 kPa	PASS	
32	>21.3 kPa	PASS	
Average result	>21.3 kPa	PASS	

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