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

Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

AB-0583-T
21033693 -ing
11-21

Customer name:	PRİZMA NET MEDİKAL SAN. TİC. İHR. İTH. LTD. ŞTİ.
Address:	YAHYA KEMAL MAH. OKUL CAD. NO:13/15 KAĞITHANE/İST.
Buyer name:	
Contact Person:	-
Order No:	-
Article No:	DMB01 (DMB01-DMB115)
Name and identity of test item:	Designed white non woven mask (Claimed to be;50 PIECES Color:DESIGNED)
The date of receipt of test item:	10.11.2021
Re-submitted/re-confirmation date:	-
Date of test:	10.11.2021-15.11.2021
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	-
Number of pages of the report:	5

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.
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.
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.

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
	15.11.2021	Servin YURTSEVEN	Sevim A. RAZAK 15.11.2021

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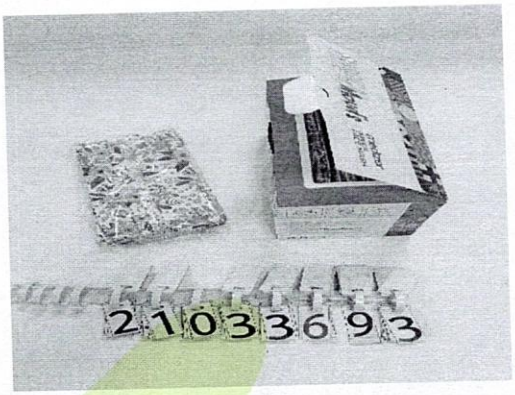
REQUIRED TESTS	EVALUATION	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	**TYPE IIR**
Microbial Cleanliness(Bioburden)	P	
PHYSICAL PROPERTIES		
Breathability(Differential Pressure)	P	
Blood Splash Resistance	P	

P: Pass
F: Fail
R: Refer to retailer technologist

Test results evaluated according to EN 14683:2019+AC:2019 limit values

Gen.f136-2/03

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.



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TEST RESULTS

Medical face masks - Requirements and test methods EN 14683:2019+AC:2019 (TS EN 14683+AC:2019)

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019)
A specimen of the mask material is clamped between a 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.

Test Flow Rate	28,3 L/min
Total Test Flow Time	2 minute
Sample Sizes	5 pieces mask
Test Alanı	4.9 cm² (5 replicas)
Test Condition	(21 ± 5) °C and (85 ± 5) % relative humidity, 4 hours
Test Microorganism	*Staphylococcus aureus* ATCC 6538
Bacterial concentration (cfu/ ml)	$5x10^5$ cfu/ ml
incubation conditions	24 hour, 35°C ± 2°C
Positive control sample average of number of Bacteria (C)	$3 x10^3$ cfu/ ml
Mean particle size (MPS)	3.0 µm

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	58	**%98.1**	**Type I ≥95**
2	55	**%98.2**	**Type II ≥98**
3	52	**%98.3**	
4	54	**%98.2**	
5	57	**%98.1**	

cfu: Colony-forming unit

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

%B: Bacterial Filtration Efficiency
C: is the mean of the total plate counts for the two positive control runs
T: is the total plate count for the test specimen

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TEST RESULT

BREATHABILITY (Differential Pressure)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019)

Test Condition (21 ± 5) °C ve (85 ± 5) % relative humidity, 4 hrs
Test area is 25 mm in diameter , 5 different sample was taken
Adjusted airflow is 8 l/min.The differential pressure is read directly using a differential pressure manometer .

SAMPLE	DIFFERENTIAL PRESSURE RESULT	REQUIREMENT
1	46.0 Pa/cm²	< 60 Pa/cm²
2	47.3 Pa/cm2	
3	46.5 Pa/cm2	
4	49.9 Pa/cm2	
5	49.3 Pa/cm2	
Average Result	47.8 Pa/cm2	

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MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019)
EN ISO 11737-1:2018 /TS EN ISO 11737-1 :2018

5 sample were taken.The sample is weighted and put in extraction liquid after shaking well (250 rpm,5 min), inoculated on the suitable agar.
The plates are incubated for 3 days at 30 ± 1 ° C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively.Total microoragnisms counts are calculated.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	4cfu/g	≤30 cfu/g

***cfu= Colony forming unit.**

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TEST RESULT

BLOOD SPLASH RESİSTANCE

Test Metod: EN 14683:2019+AC :2019 (Clause 5.2.4) the resistance of the medical face mask to penetration
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 Condition (21 ± 5) °C ve (85 ± 5) % relative humidity, 4 hrs
32 different samples were taken

	SPLASH RESISTANCE PRESSURE (kPa)	RESULTS	REQUIREMENT
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	