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
20030702-ing
09-20

Customer name:	RED APPLE MEDİKAL A.Ş
Address:	YUKARI DUDULLU SERİFALİ CAD. NO:69 UMRANİYE /İSTANBUL
Buyer name:	-
Contact Person:	CENGİZ ŞENSİVAR
Order No:	-
Article No:	-
Name and identity of test item:	Blue,white non-woven mask. (Claimed to be; Colour , Blue ,white)
The date of receipt of test item:	26.08.2020
Re-submitted/re-confirmation date:	-
Date of test:	26.08.2020-03.09.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	Not Specified
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.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.

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
TESTED BY EKOTEKS TESTED	03.09.2020	Ahmet ÇİRKİN	Sevim A. RAZAK 03.09.2020

Gen.f136-2/03

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

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

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

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 %. Tests marked (*) in this report are not included in the accreditation schedule.

Gen.f 136-2/03

TEST RESULT

BREATHABILITY (Differential Pressure)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) EK-C

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	14.7 Pa/cm^2	< 60 Pa/cm^2 Type I and Type II mask
2	16.3 Pa/cm^2	
3	16.3 Pa/cm^2	
4	17.4 Pa/cm^2	
5	15.3 Pa/cm^2	
Average Result	16.0 Pa/cm^2	

TEST RESULT

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) EK-B

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	20x20 cm^2
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)	$3x10^3$ 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	53	**%98.0**	**Type I ≥95** **Type II ≥98**
2	41	**%98.4**	
3	49	**%98.1**	
4	50	**%98.1**	
5	37	**%98.6**	

cfu: Colony-forming unit

B= (C-T) / C x 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

TEST RESULT

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) EK-D
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)	10 cfu/g	≤30 cfu/g Type I and Type II mask

***cfu= Colony forming unit.**

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
6 different sample was 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**	
Average Result	>21.3 kPa	**PASS**	