



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

TEST REPORT
DENEY RAPORU



AB-0583-T
20026561- ing
08-20

Customer name: BİLGİN TEKS. ELEKTRONİK SAN. TİC. LTD. ŞTİ.
Address: İDOSB KAZLI ÇEŞME CD. NO:9 J 1 ÖZEL PARSEL ORHANLI TUZLA
Buyer name: -
Contact Person: BİLGEHAN BİLGİN
Order No: -
Article No: WELLCARE ,PROCARE ANTIVIRAL PROTECTIVE FACE MASK
Name and identity of test item: Blue cloth mask. (Claimed to be; Procure full protection /Comfort) (Blue)
The date of receipt of test item: 29.07.2020
Re-submitted/re-confirmation date: -
Date of test: 29.07.2020-12.08.2020
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. 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.



Date
12.08.2020

Customer Representative
Zahide TAPAN

Head of Testing Laboratory
Sevim A. RAZAK
12.08.2020

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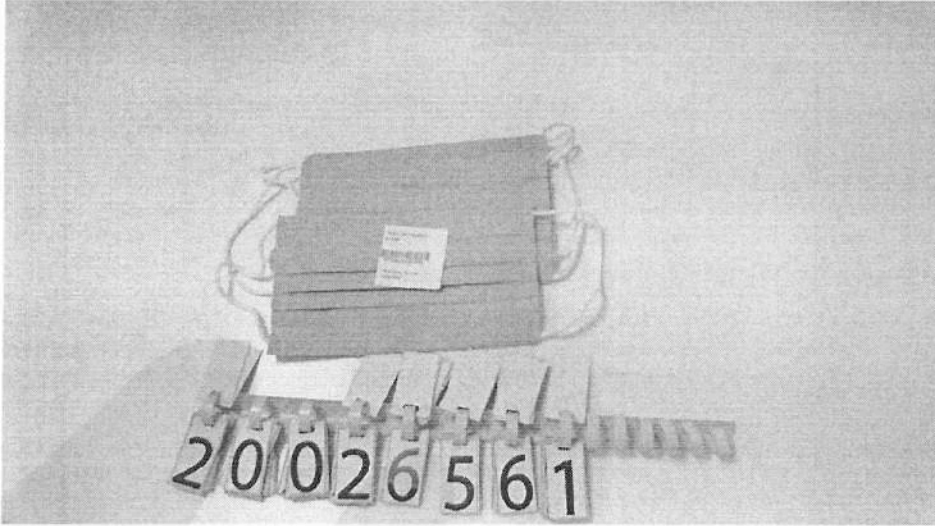
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REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency / Original	P	
Bacterial Filtration Efficiency / After 50 Washes	P	
Microbial Cleanliness(Bioburden) / Original	P	
Microbial Cleanliness(Bioburden) / After 50 Washes	P	
P: Pass F: Fail R: Refer to retailer technologist. Test results were evaluated according to TSE K 599; 2020 limit values ⁽¹⁾ No requirement was given		

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.



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TEST RESULTS

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	5 pieces mask
Test Condition	(21 ± 5) °C and (85 ± 5) % relative humidity, 4 hours
Test Microorganism	<i>Staphylococcus aureus</i> 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)	2.3x10 ³ cfu/ ml
Mean particle size (MPS)	3.0 µm

ORIGINAL

RESULTS			
Number of Test Sample	Test Sample (T) Number of Bacteria (cfu)	Bacterial Filtration Efficiency (% B)	Requirement BFE (%)
1	95	%95.9	≥90
2	103	%95.5	
3	112	%95.1	
4	106	%95.4	
5	114	%95.0	

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 Flow Rate	28,3 L/min
Total Test Flow Time	2 minute
Sample Sizes	5 pieces mask
Test Condition	(21 ± 5) °C and (85 ± 5) % relative humidity, 4 hours
Test Microorganism	<i>Staphylococcus aureus</i> ATCC 6538
Number of washing	50
Washing method	6N@60°C, Line Dry; TS EN 6330:2012 50 washes
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)	2.3x10 ³ cfu/ ml
Mean particle size (MPS)	3.0 µm

AFTER WASH

RESULTS			
Number of Test Sample	Test Sample (T) Number of Bacteria (cfu)	Bacterial Filtration Efficiency (% B)	Requirement BFE (%)
1	175	%92.4	≥90
2	163	%92.9	
3	180	%92.2	
4	183	%92.0	
5	196	%91.5	

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 RESULTS

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 microorganisms counts are calculated.

ORIGINAL		
	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	11 cfu/g	≤ 30 cfu/g Type I and Type II mask

*cfu= Colony forming unit.

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 microorganisms counts are calculated.

AFTER WASH		
After 5 washes, 6N@60°C Line Dry) / TS EN ISO 6330:2012		
	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	3 cfu/g	≤ 30 cfu/g Type I and Type II mask