

ybm
BELGELENDİRME

S E R T İ F İ K A
CERTIFICATE

**AFG TEKSTİL MEDİKAL TEKNOLOJİLERİ VE
KİMYA SAN. TİC. LTD. ŞTİ.**

MERKEZ MAH. 709. SK. NO:11/21
BAĞCILAR / İSTANBUL

MEDİKAL YÜZ MASKESİ İMALATI VE SATIŞI

MEDICAL FACE MASK PRODUCTION AND SALES

kapsamında
with a scope of

ISO 13485:2016

Tıbbi Cihazlar Kalite Yönetim Sistemine uygun bir sistem kurmuştur.
has established that is in compliance with the Medical Devices Quality Management System Standard.

Sertifika No : MDD1029

Certificate No.

İlk Yayın Tarihi : 07.04.2020

Initial Date

Sertifika Yayın Tarihi / Rev No : 07.04.2021/01

Date of This Certificate / Rev.No.

Sertifika Geçerlilik Tarihi : 06.04.2022

Certificate Expiry Date

Yeniden Belgelendirme Tarihi : 06.04.2023

Date of Re-Certification

F-126 (0)



CB-MDQMS-1605

Zühtü Özdemir
GENEL MÜDÜR
General Manager

Özdemir



Bu belge YBM'nin belgelendirme kurallarına uyulması ve periyodik ara tetkiklerin başarıyla tamamlanması kaydıyla geçerlidir.
This certificate is effective if it is complied with the certification rules of YBM and periodic surveillance audits are completed successfully.



Yönetim Belgelendirme Merkezi Test ve Gözetim Hizmetleri Ltd. Şti.
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Tel: 0212 547 31 00 Faks: 0212 547 76 00 info@ybm.com.tr www.ybm.com.tr

TEST REPORT
DENEY RAPORU

AB-0583-T

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08-20

Customer name:

MEDIGUARD (AFG TEKSTİL VE KORUYUCU DONANIMLARI SAN.
VE TİC. LTD. ŞTİ.

Address:

Merkez Mah. 709. Sk. No:11/21 BAĞCILAR/ İSTANBUL

Buyer name:

-

Contact Person:

ALİM ARAS

Order No:

-

Article No:

-

Name and identity of test item:

White non-woven mask.

The date of receipt of test item:

19.08.2020

**Re-submitted/re-confirmation
date:**

-

Date of test:

19.08.2020-28.08.2020

Remarks:

-

Sampling:

The results given in this report belong to the received sample by vendor.

End-Use:

-

Care Label:

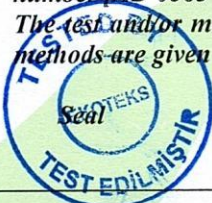
Not specified.

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
28.08.2020

Customer Representative
Tuğba AKTAŞ

Head of Testing Laboratory
Sevim ARAZAK
28.08.2020

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Testing reports without signature and seal are not valid.

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HİZMETLERİ A.Ş.**

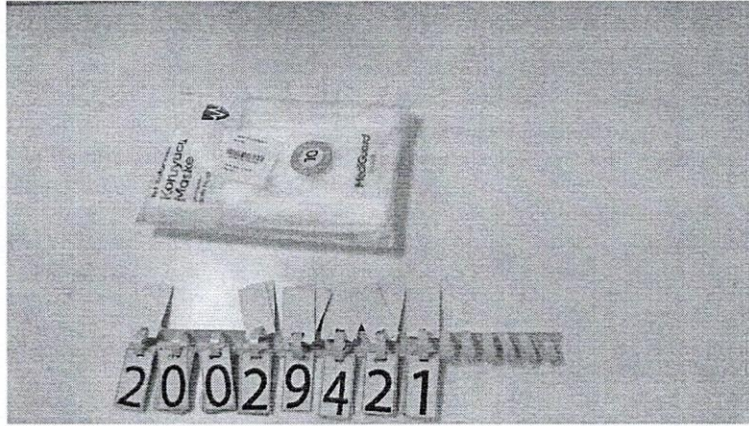
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REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	Type IIR
Microbial Cleanliness(Bioburden)	P	
Splash Resistance	P	
PHYSICAL PROPERTIES		
Breathability(Differential Pressure)	P	
P: Pass F: Fail R: Refer to retailer technologist. Tests results were evaluated according to EN 14683:2019+AC :2019 Tablo 1 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.



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TEST RESULTS

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metod: (Bacterial Filtration Efficiency Testing –BFE /Ref: EN 14683:2019+AC:2019 Medical Face Masks, Requirements and Test Methods

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
Test Flow Time	2 minute
Sample Sizes	5 pieces mask
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)	2.64x10 ³ cfu/ ml

RESULTS			
Number of Test Sample	Test Sample (T) Number of Bacteria (cfu/ml)	Bacterial Filtration Efficiency (% B)	Requirement BFE (%)
1	45	%98.3	Type I ≥95 Type II ≥98
2	40	%98.5	
3	33	%98.8	
4	54	%98.0	
5	51	%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 RESULTS

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN ISO 11737-1:2018

The sample is put in extraciton liquid after shaking well, inoculated on the agar.

After incubation at 30 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

	<u>RESULTS</u>	<u>REQUIREMENT</u>
Microbial cleanliness (cfu/g)	10 cfu/g	≤ 30 cfu/g Type I and Type II mask

*cfu= Colony forming unit.

SPLASH RESİSTANCE (ONLY FOR TYPE IIR)

Test Metod: EN 14683:2019+AC :2019 (Clause 5.2.4) the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1

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 samples were taken

	<u>SPLASH RESISTANCE PRESSURE (kPa)</u>	<u>RESULTS</u>	<u>REQUIREMENT</u>
1	>21.3 kPa	PASS	≥ 16 kPa
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	

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TEST SONUÇLARI

BREATHABILITY (Differential Pressure)

Test Method: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) Annex-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	37.8 Pa/cm ²	< 40 Pa/cm ²
2	39.9 Pa/cm ²	
3	38.2 Pa/cm ²	
4	37.4 Pa/cm ²	
5	39.5 Pa/cm ²	
Average Result	38.6 Pa/cm ²	