YBM BELGELENDİRME

SERTİFİKA
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 Managament 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

UNITED ACCREDITATION FOUNDATION
UAF
CB–MDQMS–1605

F-126 (0)

Zühtü Özdemir
GENEL MÜDÜR
General Manager

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.
Telsiz Mah. Gül Sok. No.:1-3 Kat: 1 D.4 Zeytinburnu / İstanbul
Tel: 0212 547 31 00 Faks: 0212 547 76 00 info@ybm.com.tr **www.ybm.com.tr**

CERTIFICATE

EC DECLARATION OF CONFORMITY

MediGuard
be.safe

CE

EC DECLARATION OF CONFORMITY

AT UYGUNLUK BEYANI

AFG

Beyan ederiz ki;

Aşağıda tanımlanmış olan ürün için 2017/745/AT Tıbbi Cihaz Güvenliği Direktifi temel gerekliliklerini yerine getirildiğini ve sorumluluğun alınmış olunduğunu beyan ederiz. Aşağıda tanımlanan ürünün iç üretimi AFG TEKSTİL MEDİKAL TEKNOLOJİLER VE KİMYA SAN. TİC. LTD. ŞTİ. tarafından kontrol edilmektedir.

Ürün Adı

Medikal Yüz Maskesi

Tip-Model - Sınıf

MG501 - Sınıf 1
(Steril ve Ölçme Fonksiyonu Olmayan)

Marka

MediGuard

CE İşaretinin Vurulduğu Yılın Son İki Hanesi

21

Uygulanan AB Yönetmelikleri

AB TIBBİ CİHAZ GÜVENLİĞİ DİREKTİFİ 2017/745/AT

Uygulanan Standartlar

TS EN ISO 14971: 2019 Tıbbî Cihazlar – Tıbbî Cihazlara Risk Yönetiminin Uygulanması Genel Kurallar

EN 14683:2019 Medikal Yüz Maskesi Standardı

EN 1041: 2008+A1:2013 Tıbbi Cihazlarla Birlikte İmalatçı Tarafından Sağlanan Bilgiler

We herewith declare;

The undersigned Company declares under its sole responsibility that the item of product specified below satisfies the essential requirements of the Medical Device Regulation 2017/745/EC which are apply to it. The item of product identified below has been subject to internal manufacturing checks assessment by AFG TEKSTİL MEDİKAL TEKNOLOJİLER VE KİMYA SAN. TİC. LTD. ŞTİ.

Product Name

Medical Face Mask

Type-Models

MG501- Class 1
(No Sterile and Measuring Function)

Brand Name

MediGuard

Last Two Digit Year of CE marking affixing

21

Applicable EU Directives

MEDICAL DEVICE REGULATION 2017/745/EC

Applicable Standards

TS EN ISO 14971: 2019 Medical Devices - Application of Risk Management to Medical Devices General Rules

EN 14683: 2019 Medical Face Mask Standard

EN 1041: 2008+A1:2013 Information Provided by the Manufacturer with Medical Devices

Üretici Firma / Manufacturer Company and Address

AFG TEKSTİL MEDİKAL TEKNOLOJİLER VE KİMYA SAN. TİC. LTD. ŞTİ.
Merkez Mh. 709. Sk. No. 11/21 Bağcılar / İstanbul - Türkiye
T. +90 212 436 6956 • E-mail: info@mediguard.com.tr

Şirket Müdürü / Director
GÜLAY GÜNLER

AFG TEKSTİL VE KORUYUCU DONA... SAN. TİC. LTD. ŞTİ.
Merkez Mh. 709 Sk. No. 11/21 Bağcılar / İstanbul - TR
Esenler V.D. 009 1419 989 Mersis 0009141998900001

İstanbul / Türkiye 01.08.2021_R:0

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

AB-0583-T
20029421-ing
08-20

TEST REPORT
DENEY RAPORU

Customer name:	MEDIGUARD (AFG TEKSTİLVE 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.

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
	28.08.2020	Tuğba AKTAŞ	Sevim ARAZAK 28.08.2020

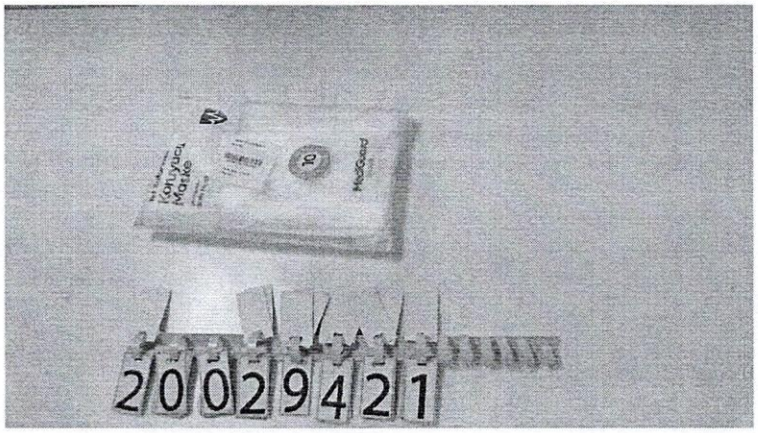
Gen.f136-2/03

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20029421-ing
08-20

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.



AB-0583-T
20029421-ing
08-20

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	*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)	**$2.64x10^3$ 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 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

AB-0583-T
20029421-ing
08-20

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.

	RESULTS	REQUIREMENT
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

	SPLASH RESISTANCE PRESSURE (kPa)	RESULTS	REQUIREMENT
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**	

AB-0583-T
20029421-ing
08-20

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/cm²	< 40 Pa/cm²
2	39.9 Pa/cm2	
3	38.2 Pa/cm2	
4	37.4 Pa/cm2	
5	39.5 Pa/cm2	
Average Result	38.6 Pa/cm2	