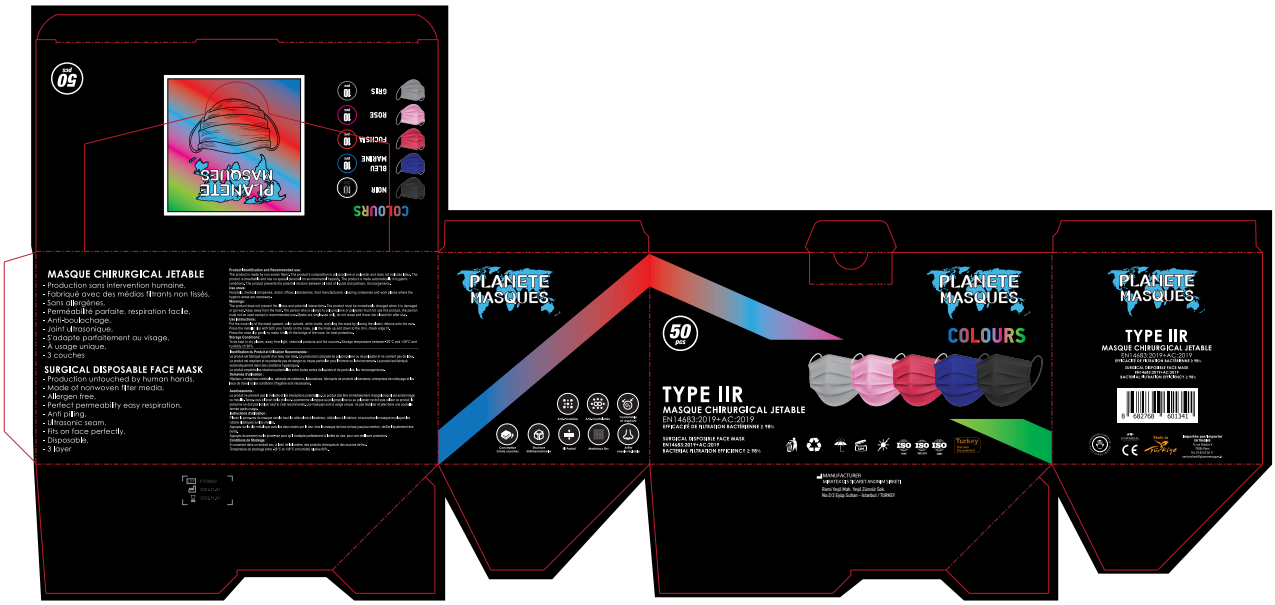
MASQUE MÉDICAL ADULTE TYPE IIR NORME EN14683 CERTIFIÉ CE MULTI COULEUR

NOIR / BLEU FONCE / FUSHIA / ROSE et GRIS

NORME EN14683 : 2019

CERTIFIÉ CE

PHOTO


50 pcs
COLOURS
NOIR
BLEU MARINE
FUCHSIA
ROSE
GRIS
PLANETE MASQUES
MASQUE CHIRURGICAL JETABLE
• Production sans intervention humaine.
• Fabriqué avec des médias filtrants non tissés.
• Sans allergènes.
• Perméabilité parfaite, respiration facile.
• Anti-éclaboussure.
• Joint ultrasonique.
• S'adapte parfaitement au visage.
• A usage unique.
• 3 couches
SURGICAL DISPOSABLE FACE MASK
• Production untouched by human hands.
• Made of nonwoven filter media.
• Allergen free.
• Perfect permeability easy respiration.
• Anti splash.
• Ultrasonic seam.
• Fits on face perfectly.
• Disposable.
• 3 layer
TYPE IIR
MASQUE CHIRURGICAL JETABLE
EN14683:2019+AC:2019
EFFICACITÉ DE FILTRATION BACTÉRIENNE ≥ 98%
SURGICAL DISPOSABLE FACE MASK
EN14683:2019+AC:2019
BACTERIAL FILTRATION EFFICIENCY ≥ 98%
ISO
Turkey

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BACTERIAL FILTRATION EFFICIENCY ≥ 98%
ISO
Turkey

DESCRIPTIF

- Masque médical non tissé (70%) et tissu fondu (30%)
- 3 couches de protection
- Taille 17,5cm x 9,5cm
- Fixation par boucles élastiquées
- Efficacité de filtration bactérienne >98 %
- Couleur NOIR / BLEU FONCE / FUSHIA / ROSE et GRIS

Conditionnement

- Carton de 2 400 masques
- 48 boites de 50 masques (5 sachets de 10 masques)
- Poids par carton 8,65 kg
- Dimension :
  Hauteur : 380 mm
  Largeur : 420 mm
  Longueur : 600 mm

Palette de 16 cartons (38 400 masques)
hauteur 165 cm

Palette de 20 cartons (48 000 masques)
Hauteur 202 cm

Palette de 24 cartons (57 600 masques)
Hauteur 240 cm

Certificat de conformité

CERTIFICATE

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici/ Manufacturer
MİRATEX DIŞ TİCARET A.Ş.
Adres /Adress
TOPÇULAR MH. FERHATPAŞA CD. ÜRETMEN İŞ MERKEZİ C BLOK K:2 NO:301 EYÜPSULTAN / İSTANBUL/ TÜRKİYE
Telefon / Phone
+90 212 674 88 39
E-mail
info@lobamedical.com

Ürün İsmi / Product Name
KİŞİSEL KORUYUCU YÜZ MASKESİ / PERSONAL PROTECTIVE FACE MASK

Ürün Tipi / Types of Product
FFP1-FFP2-FFP3
VENTİLLİ MASKE / VENTİLSİZ MASKE / MASK WITHOUT VALVE / MASK WITH VALVE
KN95 MASK

Beyan/Statement
Burada, AB tarafından sınıflandırılan Üretici, Dağıtıcı / Temsilci olarak kendi sorumluluğumuz altında, yukarıda ismi ve modeli geçen ürünlerin, (EU)2016/425 Kişisel Koruyucu Ekipmanlar Direktifi EK-1 Temel Gereklere uygun olarak üretildiğini beyan ederiz.
Here, we declare that the products listed above are manufactured under our own responsibility as a Manufacturer, Distributor / Representative by the EU, in accordance with the (EU) 2016/425 Personal Protective Equipment Directive and regulations.

Direktif ve Yönetmelikler / Directives and Regulations
(EU) 2016/425 Kişisel Koruyucu Ekipmanlar Direktifi / Personal Protective Equipment Directive

Ürün Ticari Markası / Product Commercial Brand
MIRATEX lobamedical

Harmonize Standartlar / Harmonized Standards
93/42/EEC- Tıbbi Cihaz Yönetmeliği /SINIF I (Steril Olmayan) Medical Devices Regulation / Class I (Non Sterile)
TS EN 14683+AC Tıbbi yüz maskeleri – Gereklilikler ve deney yöntemleri-Tip II- Medical face masks - Requirements and test methods-Type II
ISO 9001:2015 Kalite Yönetim Sistemi-Quality Management System
ISO 13485:2016 Tıbbi Cihazlar İçin Kalite Yönetim Sistemi / Quality Management System for Medical Devices

Sertifika No/ Certificate No: 2021-13326
Sertifika Tarihi /Certificate Date: 02.08.2021
Sertifika Bitiş Tarihi /Certificate Expiration Date: 02.08.2022

Certification Officer Approval

CE

This certificate was issued electronicaly and remains the property of IFC Global Certification Inspection & Training Services GmbH and is bound by the conditions of contract.Printed copy can be validated on request.To verify the outhenticity send on e-mail to info@ifcglobal.de

IFC Global Certification Inspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
info@ifcglobal.de

CERTIFICATE OF CONFORMITY

WQM CERTIFICATION

MİRATEX DIŞ TİCARET ANONİM ŞİRKETİ

MEHMET NESİH ÖZMEN MAH. ÇINAR SK. NO: 14/16
GÜNGÖREN/İSTANBUL/TURKEY

PRODUCT: TYPE IIR DISPOSABLE 3 PLY SURGICAL FACE MASK

TRADEMARK : MİRATEX

Related Standards / Directives / Regulations

EN 14683:2019+AC Medical Face Masks-Requirements and Test Methods

Certification Ground

Technical File No:MİRATEX-CE-001

Technical file provided by the manufacturer and mentioned above complies with the requirements of "93/42/EEC Medical Device Directive/Annex VII - Class 1" and "Regulation (EU) 2017/745 of the European Parliament and of the Council/Annex II,III,IV - Class1"
Certification work related to the product:
-Preparation of EC Declaration of Comformity
-CE Marking On The Product

Certificate Number: **PS-24004**
Certificate Issue Date: **28 July 2021**
Certificate Validity Date: **27 July 2022**

CERTIFICATION DIRECTOR

WQM CERTIFICATION

CE

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63-66, Hatton Garden Fifth Floor, Suite 23 London UK +44 7441 429196

TR ENG

AT PERFORMANS BEYANI
EC DECLARATION OF CONFORMITY

AT PERFORMANS BEYANI

Üretici Firma Bilgileri *Manifactured Details*	**MİRATEX DIŞ TİCARET ANONİM ŞİRKETİ ŞİRKETİ TOPÇULAR MAH. FERHATPAŞA CAD. NO:6/301 EYÜPSULTAN İSTANBUL Tel : 0541 781 24 65 / ismailbeyazkilinc@miratex.com.tr**

Aşağıda tanımlanmış olan ürünler için Avrupa Topluluğu (EU) 2017/745 Tüzüğünde uygulanabilen gerekliliklerin yerine getirildiğini ve sorumluluğun alınmış olduğunu beyan ederiz.

We hereby declare that the requirements applicable to the European Community (EU) 2017/745 Regulation for the products described below have been met and responsibility has been taken.

Ürün *Product*	**ÜÇ KATLI CERRAHİ YÜZ MASKESİ**
Ürün Sınıfı Class of Product	**Sınıf 1 Diğer (steril ve ölçme fonksiyonu olmayan)**
Uygunluk Beyanı Ek Bilgisi	**Ek-4 Uygunluk Beyanı (Ek 2 & 3)**
Temel UDI-DI Basic UDI-DI	86827549238596164 6B
Uygulanan Standartlar *Applied Standarts*	**EN 14683:2019+AC Tıbbi yüz maskeleri-Gereklilikler ve deney yöntemleri EN ISO 14971 Tıbbi cihazlar-Tıbbi cihazlara risk yöneliminin uygulanması EN ISO 10993-1 Tıbbi cihazların biyolojik değerlendirilmesi- Bölüm 1:Bir risk yönetim sürecinde değerlendirme ve deney (ISO 10993-1:2009) EN ISO 10993-10 Tıbbi cihazların biyolojik değerlendirilmesi-Bölüm 10:Tahriş ve cilt duyarlılığı için deneyler (ISO 10993-10:2010) EN 1041+A1 Tıbbi cihaz imalatçıları tarafından sağlanan bilgi EN 980 Tıbbi cihazların etiketlenmesinde kullanılan semboller EN 13688 Koruyucu giyecekler-Genel özellikler TSE EN 13795-1 Cerrahi Giysiler ve Örtüler**
Sertifika No *Certificate Number*	**MRX - UB - 002**
Sertifika Tarihi *Date of Certificate*	**5 Temmuz 2021**
Yetkili Kişi / Görevi / Belge Yeri *Location, Name and position of authorized person*	**İsmail BEYAZKILINÇ (İmza Yetkilisi) - İSTANBUL**
Yetkili Kişi İmzası *Signature of authorized person*	MİRATEX DIŞ TİC. A.Ş. Topçular Mh. Ferhatpaşa Cd. No:6/301 Eyüpsultan / İST. * Tel: 0212 674 88 39 Merter V.D. 621 052 5682

Certificat ISO 9001 : 2015 Usine

CERTIFICATE

WQM CERTIFICATION

MİRATEX DIŞ TİCARET ANONİM ŞİRKETİ

MEHMET NESİH ÖZMEN MAH. ÇINAR SK. NO: 14/16
GÜNGÖREN/İSTANBUL/TURKEY

It is evaluated independently and determined that it complies with the requirements of the standard written below:

ISO 9001:2015

QUALITY MANAGEMENT SYSTEM

This certificate is given within the scope of the below:

MANUFACTURING AND SALES SERVICES OF MASK, SUIT, GOWN, BONE, SHOE COVER, POWDER-FREE NITRILE EXAMINATION GOWNS, FACE PROTECTIVE VISORS AND OTHER TEXTILE PRODUCTS USED IN HOSPITALS

Certificate Number: **MS-24002**
Certificate Initial Issue Date: **28 July 2021**
Certificate Issue Date: **28 July 2021**
Certificate Validity Date: **27 July 2022**

CERTIFICATION DIRECTOR

WQM CERTIFICATION EQRAS ACCREDITATION NUMBER 3412-MS

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Certificat ISO 13485 : 2016 Usine

CERTIFICATE

WQM CERTIFICATION

MİRATEX DIŞ TİCARET ANONİM ŞİRKETİ

MEHMET NESİH ÖZMEN MAH. ÇINAR SK. NO: 14/16
GÜNGÖREN/İSTANBUL/TURKEY

It is evaluated independently and determined that it complies with the requirements of the standard written below:

ISO 13485:2016

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM

This certificate is given within the scope of the below:

MANUFACTURING AND SALES SERVICES OF MASK, SUIT, GOWN, BONE, SHOE COVER, POWDER-FREE NITRILE EXAMINATION GOWNS, FACE PROTECTIVE VISORS AND OTHER TEXTILE PRODUCTS USED IN HOSPITALS

Certificate Number: **MS-24003**
Certificate Initial Issue Date: **28 July 2021**
Certificate Issue Date: **28 July 2021**
Certificate Validity Date: **27 July 2022**

CERTIFICATION DIRECTOR

WQM CERTIFICATION

EQRAS

ACCREDITATION NUMBER 3412-MS

This certificate belongs to World Quality Management Certification Limited Company. The certificate maintains its validity with regular audits and compliance of the company to certification rules. The validity of the document can be inquired at www.wqmcertification.com
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Rapport de Test

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

TEST REPORT
DENEY RAPORU

AB-0583-T
20046720-ing-Add
04-21

Customer name:	MIRATEX DIŞ TİCARET A.Ş.
Address:	MEHMET NESİH ÖZMEN MAH. ÇINAR SOK. NO:14/16 GÜNGÖREN/ İSTANBUL
Buyer name:	-
Contact Person:	TUĞRUL DUMAN/ YAĞMUR BAKIR
Order No:	-
Article No:	-
Name and identity of test item:	White non-woven medical mask. (Claimed to be; White)
The date of receipt of test item:	10.12.2020
Re-submitted/re-confirmation date:	13.04.2021
Date of test:	13.04.2021-21.04.2021
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:	6

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*
TESTED BY EKOTEKS TEST EDİLMİŞTİR	21.04.2021	Tuğba AKTAŞ	Sevim A. RAZAK 21.04.2021

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Testing reports without signature and seal are not valid.

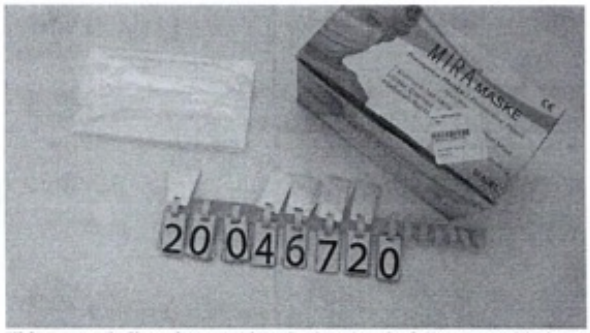
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20046720-ing-Add
04-21

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES		
Splash Resistance	P	
Breathability(Differential Pressure) (1)	P	
MICROBIOLOGICAL TESTS (1)		
Bacterial Filtration Efficiency-BFE	P	Type IIR
Microbial Cleanliness(Bioburden)	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.
(1) This report was reissued to add this test result

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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20046720-ing-Add
04-21

TEST RESULTS

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

32 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	
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**	

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	38,6 Pa/cm²	< 40 Pa/cm²
2	37,1 Pa/cm²	
3	36,3 Pa/cm²	
4	35,8 Pa/cm²	
5	40,4 Pa/cm²	
Average Result	37,6 Pa/cm²	

AB-0583-T
20046720-ing-Add
04-21

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)	**$3x10^3$ cfu/ ml**

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu/ml)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	60	**%98,0**	**Type I ≥95** **Type II ≥98**
2	52	**%98,3**	
3	53	**%98,2**	
4	54	**%98,2**	
5	59	**%98,0**	

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

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20046720-ing-Add
04-21

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)	7 cfu/g	≤30 cfu/g Type I and Type II mask

***cfu= Colony forming unit.**

Gen.I136-2/03