PRİZMANET MEDİKAL SANAYİ TİCARET
İTHALAT İHRACAT LİMİTED ŞİRKETİ

OUR CERTIFICATES

CE
ISO 9001:2015
ISO 45001:2018
ISO 14001:2015
ISO 22716:2008:GMP
ISO 13485:2016

EN 14683:2019+AC:2019 TIP IIR
TEST REPORT

CE

prizmaNet

EU Declaration of Conformity

AB Uygunluk Beyanı

No. DoC-25052021-1

Ürün Adı / *Name of Product*	:	Tıbbi Yüz Maskesi (Tek Kullanımlık) (Üç Katmanlı) / Yetişkin / Çocuk *Medical Face Mask (Disposable) (Three-layer)* / Adult / Child
GMDN Kodu / *GMDN Code*	:	35177 (Surgical Face Mask, Single Use)
Branş Türü Kodu / *UMDNS Code*	:	1229 (Masks, Surgical)
Yasal Üretici (Adresi) / *Legal Manufacturer (Place of Issue)*	:	**PRİZMANET MEDİKAL SAN. TİC. İTH. İHR. LTD. ŞTİ.** Yahya Kemal Mah. Okul Cad. No:13/15, Kağıthane / İstanbul, Turkey
Marka / Trademark	:	**Medizer – Mora Mask**
Deney Raporu / *Test Report*		**Ekoteks Laboratuvar ve Gözetim Hiz. A.Ş.**
Deney Rapor No / *Test Report No*	:	**AB-0583-T 21005288 02-21**
Ürün Standartları / *Product Standards*	:	EN 14683:2019+AC:2019

Özellikler / *Parameters* :

EU Standard Class	:	**Type IIR**
Bacterial Filtration Efficiency (BFE) (%)	:	98,7
Breathing Resistance (Pa)	:	47,1
Splash Resistance Pressure (kPa)	:	>21,3
Microbial Cleanliness (cfu/g)	:	9

Ürün Sınıflandırması, Kurallar / *Device Classification, Rules*	:	**Sınıf I,** steril olmayan, ölçme fonksiyonu olmayan ve invaziv olmayan, Ek VIII uyarınca Kural 1 **(93/42/AT – Ek VII)** **Class I**, non-sterile, non-measuring and non-invasive, Rule 1 per Annex VIII **(Ex 93/42/EEC – Annex VII)**
Belge No / *CE Certificate Number*	:	N/A

Bu AB Uygunluk Beyanı yalnızca üretici sorumluluğunda düzenlenmiştir. Aşağıda imzası bulunan ben, işbu belgeyle, belirtilen tıbbi cihazların 5 Nisan 2017 tarihli Tıbbi cihazlarla ilgili Konsey ve Avrupa Parlamentosu (AB) 2017/745 (Eski 93/42/AT) sayılı tüzüğünün ilgili hükümlerini karşıladığını beyan ederim. Yukarıda belirtilen Direktife uygunluğu gösteren tüm destekleyici belgeler "PRİZMANET MEDİKAL SAN. TİC. İTH. İHR. LTD. ŞTİ." firması tarafından korunmaktadır. Bu beyan, imza tarihinden sonraki tüm cihazlar için geçerlidir.

This EU declaration of conformity is issued only under the responsibility of the manufacturer. I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of Regulation (EU) 2017/745 (Ex 93/42/EEC) of the European Parliament and of the Council of 5 April 2017 on medical devices. All supporting documentation that contains proof of compliance to the aforementioned Directive(s) is retained under the premises of "PRİZMANET MEDİKAL SAN. TİC. İTH. İHR. LTD. ŞTİ. This declaration applies to all devices from the signature date forward.

CE İşaretleme Tarihi / AB Uygunluk Beyanı Tarihi
Start of CE / EU Declaration of Conformity Date

25.05.2021

Yetkili İmzası, Authorized Signature

PRİZMANET MEDİKAL SAN. TİC. İTH. İHR. LTD. ŞTİ.

AHMET BİLAL ERBEK, Manager

İstanbul, 25-May-2021

CERTIFICATE

IQR CERTIFICATION

PRİZMANET MEDİKAL SANAYİ TİCARET İTHALAT İHRACAT LİMİTED ŞİRKETİ

YAHYA KEMAL MAH. OKUL CAD. NO:13/15
KAĞITHANE / İSTANBUL / TÜRKİYE

Has been assessed and found to Comply with the Requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 9001:2015

The Quality Management System is applicable to:
Kalite Yönetim Sistemi:

PRODUCTION AND SALES OF WORKING CLOTHES AND SHOES AND MEDICAL MATERIALS

İŞ ELBİSELERİ VE AYAKKABILARI VE MEDİKAL MALZEMELERİN ÜRETİMİ VE SATIŞI

Certificate Number: QMS-11646/01
Belge Numarası: QMS-11646/01

Initial Certification Date: 03.11.2020
İlk Belgelendirme Tarihi: 03.11.2020

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 02.11.2021
Belge Geçerlilik Tarihi: 02.11.2021

IQR Sertifikasyon Onayı

IAS ACCREDITED
Management Systems Certification Body
MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.
Beşevler Mah. Kocayunus Sk. Arslan Han İş Merkezi K:2 Nilüfer / BURSA
Tel: +90 224 266 00 16 Faks: +90 224 249 41 13 www.iqrcert.com e-posta:info@iqrcert.com

CERTIFICATE

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PRİZMANET MEDİKAL SANAYİ TİCARET İTHALAT İHRACAT LİMİTED ŞİRKETİ

YAHYA KEMAL MAH. OKUL CAD. NO:13/15
KAĞITHANE / İSTANBUL / TÜRKİYE

Has been assessed and found to Comply with the Requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 45001:2018

The Occupational Health and Safety Management System is applicable to:
İş Sağlığı Ve Güvenliği Yönetim Sistemi:

PURCHASE, SALES, IMPORT, EXPORT OF WORK CLOTHES, SHOES AND MEDICAL SUPPLIES, FACE SHIELDS, FFP2 MASKS, DISPOSABLE MASKS, SABOT SLIPPERS, CHILD MASKS, HEALTHCARE PERSONNEL OUTFITS, SURGICAL CAPS AND SURGICAL GLOVES

İŞ ELBİSELERİ, AYAKKABILARI VE MEDİKAL MALZEMELERİN, YÜZ SİPERLİĞİ, FFP2 MASKE, TEK KULLANIMLIK MASKE, SABO TERLİK, ÇOCUK MASKESİ, SAĞLIK PERSONELİ KIYAFETİ, CERRAHİ BONE VE CERRAHİ ELDİVEN ALIMI, SATIMI, İTHALATI, İHRACATI

Certificate Number: ISO-05044
Belge Numarası: ISO-05044

Initial Certification Date: 15.02.2021
İlk Belgelendirme Tarihi: 15.02.2021

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 14.02.2022
Belge Geçerlilik Tarihi: 14.02.2022

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ. IQR

IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.
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CERTIFICATE

IQR CERTIFICATION

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PRİZMANET MEDİKAL SANAYİ TİCARET İTHALAT İHRACAT LİMİTED ŞİRKETİ

YAHYA KEMAL MAH. OKUL CAD. NO:13/15
KAĞITHANE / İSTANBUL / TÜRKİYE

Has been assessed and found to Comply with the Requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 14001:2015

The Environmental Management System is applicable to
Çevre Yönetim Sistemi:

PURCHASE, SALES, IMPORT, EXPORT OF WORK CLOTHES, SHOES AND MEDICAL SUPPLIES, FACE SHIELDS, FFP2 MASKS, DISPOSABLE MASKS, SABOT SLIPPERS, CHILD MASKS, HEALTHCARE PERSONNEL OUTFITS, SURGICAL CAPS AND SURGICAL GLOVES

İŞ ELBİSELERİ, AYAKKABILARI VE MEDİKAL MALZEMELERİN, YÜZ SİPERLİĞİ, FFP2 MASKE, TEK KULLANIMLIK MASKE, SABO TERLİK, ÇOCUK MASKESİ, SAĞLIK PERSONELİ KIYAFETİ, CERRAHİ BONE VE CERRAHİ ELDİVEN ALIMI, SATIMI, İTHALATI, İHRACATI

Certificate Number: EMS-12879
Belge Numarası: EMS-12879

Initial Certification Date: 15.02.2021
İlk Belgelendirme Tarihi: 15.02.2021

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 14.02.2022
Belge Geçerlilik Tarihi: 14.02.2022

IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

IAS ACCREDITED
Management Systems Certification Body
MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.
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Certificate

PRİZMANET MEDİKAL SANAYİ TİCARET İTHALAT İHRACAT LİMİTED ŞİRKETİ

YAHYA KEMAL MAH. OKUL CAD. NO:13/15
KAĞITHANE / İSTANBUL / TÜRKİYE

Has been assessed and found to Comply with the Requirements of:
Denetlenmiş ve aşağıdaki standartın gerekliliklerine uygunluğu görülmüştür:

ISO 22716:2008:GMP

GOOD MANUFACTURING PRACTICES

The GMP System is applicable to:
İyi Üretim Uygulamaları:

PURCHASE, SALES, IMPORT, EXPORT OF WORK CLOTHES, SHOES AND MEDICAL SUPPLIES, FACE SHIELDS, FFP2 MASKS, DISPOSABLE MASKS, SABOT SLIPPERS, CHILD MASKS, HEALTHCARE PERSONNEL OUTFITS, SURGICAL CAPS AND SURGICAL GLOVES

İŞ ELBİSELERİ, AYAKKABILARI VE MEDİKAL MALZEMELERİN, YÜZ SİPERLİĞİ, FFP2 MASKE, TEK KULLANIMLIK MASKE, SABO TERLİK, ÇOCUK MASKESİ, SAĞLIK PERSONELİ KIYAFETİ, CERRAHİ BONE VE CERRAHİ ELDİVEN ALIMI, SATIMI, İTHALATI, İHRACATI

Certificate No: ISO/23181
Sertifika Numarası: ISO/23181

Date of Certification Audit: 08.02.2021
Denetim Tarihi: 08.02.2021

Date of Issue: 15.02.2021
Yayınlanma Tarihi: 15.02.2021

Date of Expiry: 14.02.2022
Son Geçerlilik Tarihi: 14.02.2022

1st Surveillance Audit : February 2022
1. Gözetim Denetim Tarihi : Şubat 2022
2nd Surveillance Audit : February 2023
2. Gözetim Denetim Tarihi : Şubat 2023

Qcs International Certifications Services Pvt. Ltd
Certificate of validity information E-mail: info@qcscert.com
mail to confirm

◆ CERTIFICAT ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ CERTIFICATE ◆ ZERTIFIKAT

CERTIFICATE
OF REGISTRATION

This is to Certify that the

Medical Devices - Quality Management System

of

PRİZMANET MEDİKAL SANAYİ TİCARET İTHALAT İHRACAT LİMİTED ŞİRKETİ

YAHYA KEMAL MAH. OKUL CAD. NO:13/15 KAĞITHANE / İSTANBUL / TÜRKİYE

has been independently assessed and is compliant with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

PRODUCTION AND SALE OF MEDICAL MASK FOR ADULT, MEDICAL MASK FOR CHILDREN, BONNET, VISOR AND OVERALLS

YETİŞKİN TIBBİ MASKESİ, ÇOCUK TIBBİ MASKESİ, BONE, SİPERLİK, TULUM ÜRETİMİ VE SATIŞI

Certificate No.: TR53320H

Date of initial registration	08 October 2020
Date of this Certificate	08 October 2020
Surveillance audit on or before	07 October 2021
Recertification Due / Certificate expiry	07 October 2023

This Certificate is remains valid subject to satisfactory surveillance audits.

Emmanuel ADEMOSU
Director

For verification and updated information concerning the present certificate visit to http://staunchlyservices.com/search_certified_client.php

STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED
Labrynth Business Centre, 43 Middle Hill Gate, Stockport,
Great Manchester, England-SK1 3DG
Web :- www.staunchlyservices.com
E-mail :- info@staunchlyservices.com
Phone :- +44 345 680 0199
Company Registered in England and Wales with Company Number 11488683

IAS ACCREDITED Management Systems Certification Body MSCB125

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

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

AB-0583-T
21005288 -ing
02-21

Customer name:	PRİZMA NET MEDİKAL SAN. TİC. İHR. İTH. LTD. ŞTİ.
Address:	YAHYA KEMAL MAH. OKUL CAD. NO:13/15 K.HANE/İST.
Buyer name:	
Contact Person:	-
Order No:	-
Article No:	MEDIZER MB001
Name and identity of test item:	Blue non woven mask (Claimed to be;70PIECES-WHITE)
The date of receipt of test item:	10.02.2021
Re-submitted/re-confirmation date:	-
Date of test:	10.02.2021-15.02.2021
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	-
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***
TESTED BY EKOTEKS TEST EDİLMİŞTİR	15.02.2021	Servin YURTSEVEN	Sevim A. RAZAK 15.02.2021

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

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

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

Gen.f136-2/03

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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02-21

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)
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 Alanı	4.9 cm² (5 replicas)
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)	$3 x10^3$ 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	39	**%98.7**	**Type I ≥95** **Type II ≥98**
2	42	**%98.6**	
3	45	**%98.5**	
4	46	**%98.5**	
5	47	**%98.4**	

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

Gen.f136-2/03

AB-0583-T
21005288 -ing
02-21

TEST RESULT

BREATHABILITY (Differential Pressure)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019)

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	39.7 Pa/cm²	< 60 Pa/cm²
2	47.3 Pa/cm2	
3	46.3 Pa/cm2	
4	49.0 Pa/cm2	
5	53.3 Pa/cm2	
Average Result	47.1 Pa/cm2	

Gen.f136-2/03

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019)
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)	9 cfu/g	≤30 cfu/g

*cfu= Colony forming unit.

AB-0583-T
21005288 -ing
02-21

TEST RESULT

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
32 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	
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	