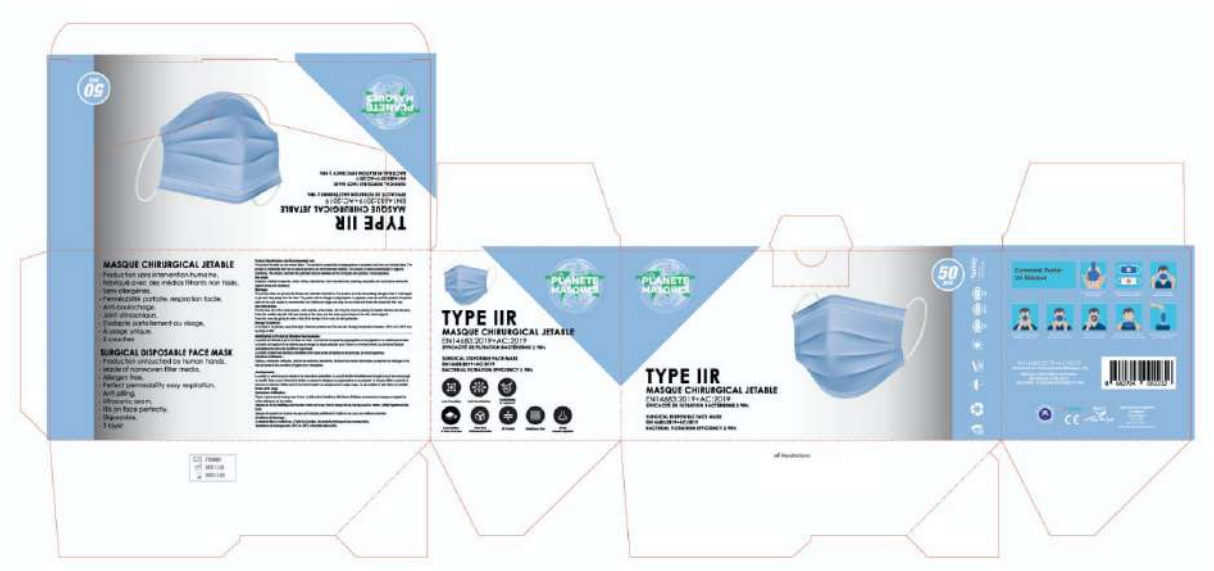
MASQUE MÉDICAL ADULTE TYPE IIR NORME EN14683 CERTIFIÉ CE COULEUR BLEU

NORME EN14683 : 2019

CERTIFIÉ CE

PHOTO


TYPE IIR
MASQUE CHIRURGICAL JETABLE
EN14683:2019+AC:2019
MASQUE CHIRURGICAL JETABLE
SURGICAL DISPOSABLE FACE MASK
TYPE IIR
MASQUE CHIRURGICAL JETABLE
EN14683:2019+AC:2019
TYPE IIR
MASQUE CHIRURGICAL JETABLE
50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MASQUE CHIRURGICAL JETABLE
EN14683:2019+AC:2019
TYPE IIR
MASQUE CHIRURGICAL JETABLE
EN14683:2019+AC:2019
SURGICAL DISPOSABLE FACE MASK
50

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 BLEU

Conditionnement

- Carton de 3 000 masques
- 60 boites de 50 masques
- Poids par carton 10,80 kg
- Dimension :
  Hauteur : 460 mm
  Largeur : 410 mm
  Longueur : 600 mm

Palette de 16 cartons (48 000 masques)
hauteur 192 cm

Palette de 20 cartons (60 000 masques)
Hauteur 242 cm

Code EAN : 0764460743005

Commande au camion (3 à 4 semaines de délais)
33 palettes de 60 000 masques > 1 980 000 masques

Notice d’utilisation dans les boites

NOTICE ET CONSIGNES D’UTILISATION

MASQUE TYPE IIR

EN14683 : 2019 + AC : 2019

AVERTISSEMENT

POUR PROTÉGER VOTRE SANTÉ ET CELLE DES AUTRES, IL EST IMPORTANT DE RESPECTER CES CONSIGNES D’UTILISATION.

- Portez ce masque quand vous êtes en contact avec d’autres personnes et respectez les règles de distanciation sociale.
- Vérifiez toujours que le masque est bien ajusté et couvre votre bouche et votre nez.
- Ce masque ne remplace pas les gestes barrières (lavage régulier des mains, distanciation physique, réduction des contacts avec d’autres personnes). Il ajoute une barrière physique, à utiliser notamment lorsque vous êtes en contact avec d’autres personnes.

COMMENT METTRE ET UTILISER UN MASQUE CHIRURGICAL ?

1) Lavez-vous soigneusement les mains avant de toucher le masque et ne touchez pas l’intérieur du masque
2) Tirez le masque avec deux mains en positionnant le coté coloré vers l’extérieur.
3) Mettez les élastiques derrière vos oreilles et assurez-vous que le pince nez soit vers le haut.
4) Appuyez sur le pince nez pour l’adapter à la forme du nez. Tirez le masque vers le bas pour recouvrir l’ensemble du nez et de la bouche. Ne pas toucher l’intérieur du masque.
5) Ne pas toucher le masque avec les mains lorsque vous le portez et lavez-vous les mainsaprès avoir retiré le masque

PRÉCAUTIONS D’USAGE

1) Masques à couches de TYPE IIR, remplacez toutes les 4 heures.
2) Gardez les masques dans un endroit sec et à l’abri de l’humidité.
3) Utilisez avec prudence en cas de problème cardiopulmonaire et d’allergie aux tissus non-tissés.
4) Jeter le masque dans une poubelle fermée après usage. Si vous êtes malade, jetez le masque dans un sac fermé et conservez-le 48h avant élimination.
5) Changer de masque s’il est mouillé

MISE EN GARDE

1) Masque à usage unique pour une durée de 4h maximum.
En cas de réutilisation, le masque n’apporte plus de protection.
2) Mettre le masque usagé dans une poubelle pourvue à cet effet ou à défaut dans un sac fermé contenant uniquement le masque en question.
3) En cas d’incident grave survenu en lien avec le dispositif, ce dernier doit faire l’objet d’une notification au fabricant et à l’autorité compétente de l’État membre dans lequel l’utilisateur est établi.
4) En cas d’allergies ou effets secondaires tel que acné, toux, rougeurs, prenez rendez-vous avec votre médecin traitant.

CARACTÉRISTIQUES PERFORMANCES

Efficacité de filtration bactérienne (EFB) ≥ 98%
Respirabilité (pression différentielle) < 60Pa/cm²
Résistance aux projections ≥ 16,0 kPa

FABRICANT

KUZEY SKY TEKSTIL MED TUR ITH IHR SAN VE TIC.TTD STL
MERIC MAH 5746/8 SOKAK NO :6 BORNOVA / IZMIR

Le masque répond à la nouvelle règlementation du 26 avril 2021
Destination et description des indications et contre-indications
n°2017/745)

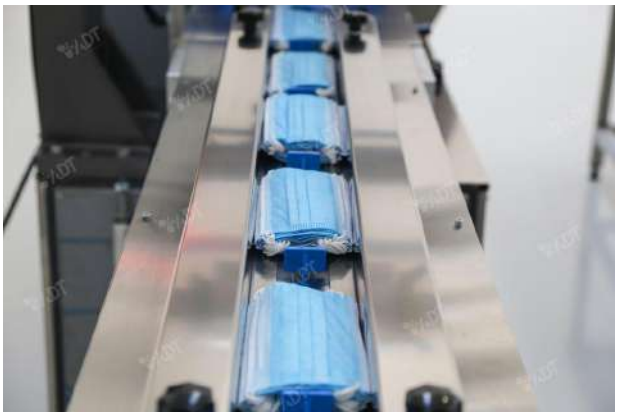
DISTRIBUTEUR EH TRADING

EH TRADING
14 rue Charles V
75004 PARIS
serviceclient@planetemasques.fr

Made in Europe

Notice du 24/11/2021 version 1.0

Photo de la chaine de production stérile



Certificat de conformité

NVA
QUALITY CERTIFICATION

Attestation of Conformity

This Certificate of Compliance states the below mentioned MANUFACTURER'S
Bu Uyumluluk Sertifikası aşağıda adı geçen ÜRETİCİ'nin

Kuzey Sky Tekstil Medikal Turizm İthalat İhracat Sanayi ve Ticaret Limited Şirketi

Adress: MERİÇ MAH. 5746/8 SK. NO:6 İÇ KAPI NO: B1 BORNOVA/İZMİR/TURKEY

listed products's / listeli ürünleri için

Medical Face Masks
Brand Name: SKY
Model: N/A
Type IIR

are tested according to the following initial type tests by the manufacturer / üretici tarafından aşağıdaki ilk tip testlerine göre test edilir,

EN 14683:2019+AC:2019

are in conformance with following regulations is defined / aşağıdaki mevzuatla uyumluluğu tanımlanmıştır.

MEDICAL DEVICES DIRECTIVE 93/42/EEC / *TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC*

Has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components(if exists) and product technical drawing of the medical face masks manufactured and designed for use during the medical operations or similar medical situations with same requirements which require restriction of infectious materials to be spreed to patients. / Tıbbi operasyonlar veya benzeri tıbbi durumlar sırasında kullanılmak üzere üretilen ve tasarlanan tıbbi yüz maskelerinin üretimini, tasarımını, kullanım amacını, güvenlik amacına göre risk değerlendirmesini, Ürünün kendisini ve (varsa) ek bileşenlerini ve ürün teknik resimlerini değerlendirmiştir. Hastalara yayılmak üzere bulaşıcı malzemelerin kısıtlanmasını gerektiren aynı gereklilikler.

With this certificate, it is approved that the product fulfils all essential reqirements and yje related rules of 93/42/eec Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, 13, of the Medical Devices Directive (93/42/EEC) or Annex 1, 23, of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in Table I) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this cerificate with publishing an EU Declaration of Conformity. / Bu sertifika ile ürünün tüm temel gereksinimleri karşıladığı onaylanmakta ve 93/42/eec Tıbbi Cihazlar Direktifi (MDD) Sınıf I'in ilgili kurallarının uygulanması sağlanmaktadır. Yukarıda listelenen ürünler için ambalaj bilgileri, Tıbbi Cihazlar Direktifi (93/42/EEC) Ek I, 13'te veya Tıbbi Cihaz Yönetmeliği (AB) 2017/745 Ek 1, 23'te belirtilen gerekli bilgileri kapsar. . Bu bilgiler; EN 14683 standardına, maske tipine (Tablo I'de belirtildiği gibi) ve EN ISO 15223-1:2016 ve EN 1041:2008+A1:2013'te verilen diğer ilgili bilgilere referans. AB Uygunluk Beyanı yayınlanarak bu sertifikada verilen bilgiler doğrultusunda ürünlerinize aşağıda görüldüğü gibi CE işareti iliştirilmesi uygun görülmektedir.

Sertifika Numarası / *Certificate Number*	**: NVA-EN-21122201**
İlk Yayın Tarihi / *Certificate Issue Date*	**: 20.12.2021**
Sertifika Geçerlilik Tarihi / *Certificate Validity Date*	**: 20.12.2022**
Sertifika Periyodu / *Certificate Period*	**: 1 Yıl / 1 Year**

Belgelendirme Müdürü
Certification Manager

NVA denetim yürütülmesinde gerekli itina ve yetkinlik göstermesine rağmen büyük ihtimallerde dahi sorumluluk kabul etmeyecektir. Bu belgenin mülkiyet hakkı NVA aittir ve istenildiğinde iade edilmelidir.

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Beylikdüzü OSB Mahallesi 3. Cadde HSS İnşaat Corner Office Apt. No: B/55 Beylikdüzü / İSTANBUL / TURKEY
Tel: +90 212 855 58 98 www.nvabelge.com info@nvabelge.com

Certificat ISO 9001 : 2015 Usine

NVA
QUALITY CERTIFICATION

SERTİFİKA / CERTIFICATE

KUZEY SKY TEKSTİL MEDİKAL TURİZM İTHALAT İHRACAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MERİÇ MAH. 5746/8 SK. NO:6 İÇ KAPI NO: B1 BORNOVA / İZMİR / TURKEY

Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

Has been assessed and found to Comply with the Requirements of:

ISO 9001:2015

KALİTE YÖNETİM SİSTEMİ

Quality Management System

Kuruluşunun "Dış Giyim Eşyası İmalatı, Dokuma, Örme(Trikotaj) Ve Tığ İşi (Kroşe) Kumaştan Olanlar (Kaban, Palto, Ceket, Pantolon, Takım Elbise, Döpiyes, Anorak, Yağmurluk, Gece Kıyafetleri) (Terzilerin Faaliyetleri Hariç) Her Türlü Tıbbi Ve Cerrahi Alet Ve Malzemelerini Medikal Malzemelerini (Korse, Koruyucu Yüz Maskesi Ve Cerrahi Maske ,Koruyucu Tulum, Bone, Bandana, Hasta Yatağı, Yastık, Minder, Çarşaf, Nevresim, Sedye Örtüsü, Uyku Bandı, Önlük, Galoş) Toptan Ve Perakende Alım Satımı Ve İmalatını Yapmak İthali Ve İhracatı" **Kapsamı İçin**

For scope "*Outerwear Manufacturing, Weaving, Knitting (Knitting) and Crochet (Crochet) Fabric (Coats, Coats, Jackets, Pants, Suits, Doubles, Anorak, Raincoats, Nightwear) (Excluding the Activities of the Tailors) All Kinds of Medical and Surgical Instruments and Materials, Medical Materials) (Corset, Protective Face Mask and Surgical Mask, Protective Jumpsuit, Bone, Bandana, Bed, Pillow, Cushion, Bed Sheet, Duvet Cover, Stretcher Cover, Sleeping Band, Apron, Shoe Covers) Import And Export Of Wholesale And Retail Buying And Selling*"

Sertifika Numarası / *Certificate Number*	**: NVA-QM-21122201**
İlk Yayın Tarihi / *Certificate Issue Date*	**: 22.12.2021**
Sertifika Geçerlilik Tarihi / *Certificate Validity Date*	**: 22.12.2022**
Sertifika Periyodu / *Certificate Period*	**: 1 Yıl / *1 Year***

Belgelendirme Müdürü
Certification Manager

NVA

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Tel: +90 212 855 58 98 www.nvabelge.com info@nvabelge.com

Certificat ISO 13485 : 2016 Usine

NVA
QUALITY CERTIFICATION

SERTİFİKA / CERTIFICATE

KUZEY SKY TEKSTİL MEDİKAL TURİZM İTHALAT İHRACAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MERİÇ MAH. 5746/8 SK. NO:6 İÇ KAPI NO: B1 BORNOVA / İZMİR / TURKEY

Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

Has been assessed and found to Comply with the Requirements of:

ISO 13485:2016

TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ

Medical Devices Quality Management System

Kuruluşunun "Dış Giyim Eşyası İmalatı, Dokuma, Örme(Trikotaj) Ve Tığ İşi (Kroşe) Kumaştan Olanlar (Kaban, Palto, Ceket, Pantolon, Takım Elbise, Döpiyes, Anorak, Yağmurluk, Gece Kıyafetleri) (Terzilerin Faaliyetleri Hariç) Her Türlü Tıbbi Ve Cerrahi Alet Ve Malzemelerini Medikal Malzemelerini (Korse, Koruyucu Yüz Maskesi Ve Cerrahi Maske ,Koruyucu Tulum, Bone, Bandana, Hasta Yatağı, Yastık, Minder, Çarşaf, Nevresim, Sedye Örtüsü, Uyku Bandı, Önlük, Galoş) Toptan Ve Perakende Alım Satımı Ve İmalatını Yapmak İthali Ve İhracatı" **Kapsamı için**

For scope "*Outerwear Manufacturing, Weaving, Knitting (Knitting) and Crochet (Crochet) Fabric (Coats, Coats, Jackets, Pants, Suits, Doubles, Anorak, Raincoats, Nightwear) (Excluding the Activities of the Tailors) All Kinds of Medical and Surgical Instruments and Materials, Medical Materials) (Corset, Protective Face Mask and Surgical Mask, Protective Jumpsuit, Bone, Bandana, Bed, Pillow, Cushion, Bed Sheet, Duvet Cover, Stretcher Cover, Sleeping Band, Apron, Shoe Covers) Import And Export Of Wholesale And Retail Buying And Selling*"

Sertifika Numarası / *Certificate Number*	: **NVA-MD-21122201**
İlk Yayın Tarihi / *Certificate Issue Date*	: **22.12.2021**
Sertifika Geçerlilik Tarihi / *Certificate Validity Date*	: **22.12.2022**
Sertifika Periyodu / *Certificate Period*	: **1 Yıl / *1 Year***

Belgelendirme Müdürü
Certification Manager

NVA

NVA KALİTE TEST ÖLÇÜM HİZMETLERİ EĞİTİM VE BELGELENDİRME TİC. LTD. ŞTİ.
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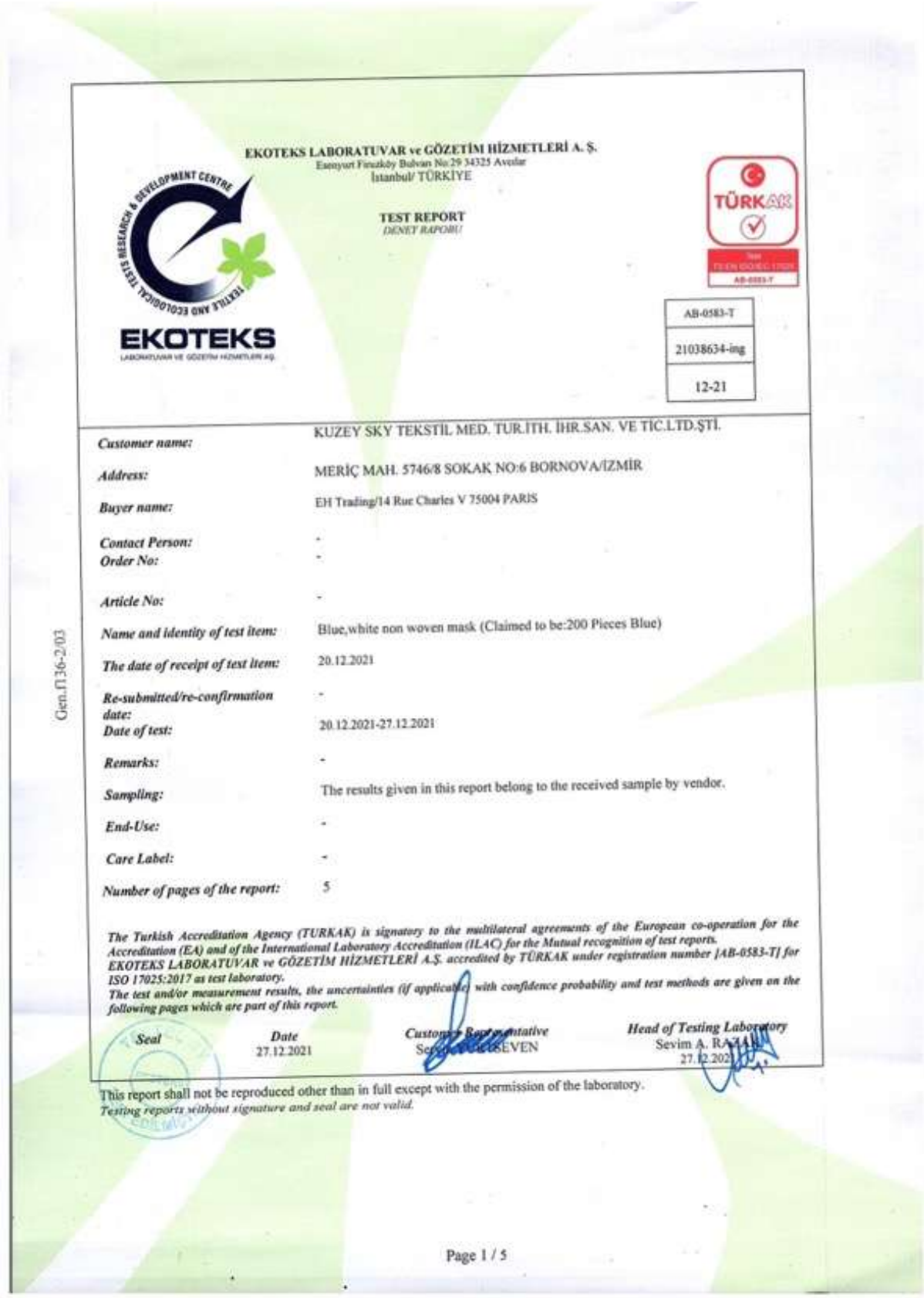
Rapport de Test



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

TEST REPORT
DENEY RAPORU

AB-0583-T
21038634-ing
12-21

Customer name:	KUZEY SKY TEKSTİL MED. TUR.İTH. İHR.SAN. VE TİC.LTD.ŞTİ.
Address:	MERİÇ MAH. 5746/8 SOKAK NO:6 BORNOVA/İZMİR
Buyer name:	EH Trading/14 Rue Charles V 75004 PARIS
Contact Person:	-
Order No:	-
Article No:	-
Name and identity of test item:	Blue,white non woven mask (Claimed to be:200 Pieces Blue)
The date of receipt of test item:	20.12.2021
Re-submitted/re-confirmation date:	-
Date of test:	20.12.2021-27.12.2021
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*
	27.12.2021	Sc[illegible]SEVEN	Sevim A. RAZAK
			27.12.2021

This report shall not be reproduced other than in full except with the permission of the laboratory.
Testing reports without signature and seal are not valid.

Cien.Fl.36-2/03

Page 1 / 5

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
21038634-ing
12-21

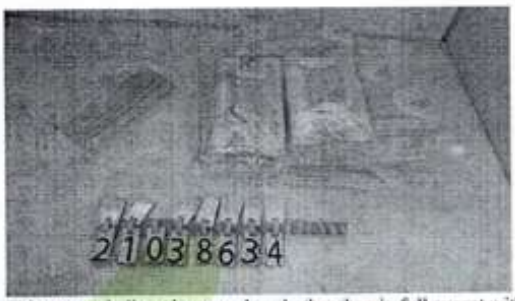
REQUIRED TESTS	EVALUATION	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	**TYPE IIR**
Microbial Cleanliness(Bioburden)	P	
PHYSICAL PROPERTIES		
Breathability(Differential Pressure)	P	
Blood Splash Resistance	P	

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.



EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.

AB-0583-T
21038634-ing
12-21

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.

Gen.f136-2/03

Test Flow Rate	28,3 L/min
Total Test Flow Time	2 minute
Sample Sizes	5 pieces mask
Test Alanı	4.9 cm^2 (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	40	**%98.0**	**Type I ≥95** **Type II ≥98**
2	39	**%98.1**	
3	33	**%98.4**	
4	34	**%98.3**	
5	38	**%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
Total uncertainty: 0.40 %

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HİZMETLERİ A.Ş.

AB-0583-T
21038634-ing
12-21

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	15.5 Pa/cm²	< 60 Pa/cm²
2	15.6 Pa/cm2	
3	12.3 Pa/cm2	
4	15.4 Pa/cm2	
5	16.8 Pa/cm2	
Average Result	15.1 Pa/cm2	

Total uncertainty: ±% 4.6

Gen.Ü36-2/03

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)	6 cfu/g	≤30 cfu/g

*cfu= Colony forming unit.

Total uncertainty: ± 0.36%

EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.

AB-0583-T
21038634-ing
12-21

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 were taken

	SPLASH RESISTANCE PRESSURE (kPa)	RESULTS	REQUIREMENT
1	>16.0 kPa	PASS	≥16 kPa Type IIR mask
2	>16.0 kPa	PASS	
3	>16.0 kPa	PASS	
4	>16.0 kPa	PASS	
5	>16.0 kPa	PASS	
6	>16.0 kPa	PASS	
7	>16.0 kPa	PASS	
8	>16.0 kPa	PASS	
9	>16.0 kPa	PASS	
10	>16.0 kPa	PASS	
11	>16.0 kPa	PASS	
12	>16.0 kPa	PASS	
13	>16.0 kPa	PASS	
14	>16.0 kPa	PASS	
15	>16.0 kPa	PASS	
16	>16.0 kPa	PASS	
17	>16.0 kPa	PASS	
18	>16.0 kPa	PASS	
19	>16.0 kPa	PASS	
20	>16.0 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	

Total uncertainty: ± %0.9

Gen.f136-2/03