UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-285

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Commission directive 2007/47/EEC amending Medical Devices Directive dated 05 September 2007,

the products manufactured by

AREA TEKNOLOJİ SİSTEMLERİ DAĞITIM PAZARLAMA VE SANAYİ DIŞ TİC. LTD. ŞTİ

at the following address

Cevizlibağ Maltepe Mah. Londra Asfaltı Cad K.4 No:38 Zeytinburnu ISTANBUL / TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: WMATE
Model: MASKY3
Classification: Type IIR

are tested according to the following initial type tests by the manufacturer

Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

For the assessment of conformity, the following documents were also applied to:
Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Bacterial Filtration Efficiency, Microbial Cleanliness, Differential Pressure and Splash Resistance Pressure tests.

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings 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 spread to patients. With this certificate, it is approved that the product fulfils all essential requirements and the 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 I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in Table 1) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 20/10/2020 and valid until 19/10/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

ISTANBUL – 20/10/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
General Manager

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

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

TEST REPORT
DENEY RAPORU

AB-0583-T
20036059
10-20

Customer name:	AREA TEKNOLOJİ SİS. DAĞ. PAZ. VE SAN. DIŞ TİC. LTD. ŞTİ.
Address:	MALTEPE MAH. LOMDRA ASFALTI CAD. NO:38/4 İSTANBUL
Buyer name:	-
Contact Person:	-
Order No:	-
Article No:	-
Name and identity of test item:	White non woven mask
The date of receipt of test item:	30.09.2020
Re-submitted/re-confirmation date:	-
Date of test:	30.09.2020-05.10.2020
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*
	05.10.2020	SENANUR AĞIRBAŞ	Sevim A. RAZAK 05.10.2020

AB-0583-T
20036059
10-20

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

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to EN 14683:2019+AC :2019 Table/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 %. 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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20036059
10-20

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)	$2.84x10^3$ cfu/ ml
Mean particle size (MPS)	3.0µm

Gen.f136-2/03

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	50	%98.1	**Type I ≥95** **Type II ≥98**
2	40	%98.5	
3	35	%98.7	
4	48	%98.2	
5	36	%98.6	

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

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10-20

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 , 4different 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	48.4 Pa/cm^2	< 60 Pa/cm^2
2	47.2 Pa/cm2	
3	58.8 Pa/cm2	
4	62.1 Pa/cm2	
5	59.6 Pa/cm2	
Average Result	55.2 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)	16 cfu/g	≤30 cfu/g

*cfu= Colony forming unit.

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10-20

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
5 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	
Average Result	>21.3 kPa	PASS	

NVA QUALITY CERTIFICATION

NVA QUALITY CERTIFICATION

SERTİFİKA / CERTIFICATE

AREA TEKNOLOJİ SİST. DAĞ. PAZ. VE SAN. DIŞ TİC. LTD. ŞTİ.

MALTEPE MAH. LONDRA ASFALTI CAD. NO:38/4
ZEYTİNBURNU / İSTANBUL / TURKEY

Kuruluşunun "TEK KULLANIMLIK CERRAHİ MASKE, TEK KULLANIMLIK YÜZ MASKESİ, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK MEDİKAL ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK ELDİVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONE, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI "

Kapsamı için

For scope "SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GOWNS, SINGLE USE MEDICAL GOWNS, SINGLE USE SURGICAL DRAPE, SINGLE USE INSPECTION COVERS, SINGLE USE GLOVES, SINGLE USE OVERALLS, SINGLE USE BONNET, WAG, SILICON MASK, FILTERED SILICON MASK, PROTECTIVE GLASSES, SINGLE USE STRETCHER COVER, PRODUCTION AND SALES"

ISO 9001:2015
KALİTE YÖNETİM SİSTEMİ
Quality Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / ***Certificate Number***	**: 20042126**
Sertifika Kodu / ***Certificate Code***	**: AREA TEKNOLOJİ**
Sertifika Yayın Tarihi / ***Certificate Issue Date***	**: 21.04.2020**
Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 21.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

Certification Manager
Belgelendirme Müdürü

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NVA QUALITY CERTIFICATION

NVA QUALITY CERTIFICATION

CE

CE UYGUNLUK BEYANI

CE ATTESTATION OF CONFORMITY

AREA TEKNOLOJİ SİST. DAĞ. PAZ. VE SAN. DIŞ TİC. LTD. ŞTİ.

MALTEPE MAH. LONDRA ASFALTI CAD. NO:38/4
ZEYTİNBURNU / İSTANBUL / TURKEY

In our delivered version, we declare that the product described below complies with the essential safety and health requirements of the **Medical Devices Directive 93/42/EEC-General Product Safety Directive 2001/95/EEC** regulations as circulating by us. This declaration will cease to be valid if the product specified below is replaced.

*Teslim edilen versiyonumuzda aşağıda açıklanan ürünün, tarafımızda dolaşıma sokulduğu şekliyle **Tıbbi Cihazlar Direktifi 93/42/EEC-Genel Ürün Güvenliği Direktifi 2001/95/EEC** yönetmeliklerinin temel güvenlik ve sağlık gerekliliklerine uygun olduğunu beyan ederiz. Aşağıda bilgileri belirtilen ürünün değiştirilmesi halinde bu beyan geçerliliğini yitirecektir.*

Description Of The Product *Ürünün Tanımı*	: **NONWOVEN DISPOSABLE MEDICAL MASK** **NONWOVEN *TEK KULLANIMLIK MEDİKAL MASKE***
Product Type / *Ürün Tipi*	: **3 LAYER MASK / 3 KATLI MASKE**
Product Commercial Brand / *Marka*	: **WMATE MASK 3**
Applicable EC Directives *Geçerli AT Direktifleri*	: **GENERAL PRODUCT SAFETY DİRECTİVE 2001/95/EEC** **MEDİCAL DEVİCES DİRECTİVE 93/42/EEC** ***GENEL ÜRÜN GÜVENLİĞİ DİREKTİFİ 2001/95/EEC*** ***TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC***
Applicable Harmonised Standards *Geçerli Uyumlaştırılmış Standartlar*	: **TS EN 14683+AC, EN 1041+A1, EN ISO 13485, EN ISO 14971, EN ISO 10993-1, EN ISO 10993-10, EN ISO 15223-1**

Applicable National Technical Standards and Specifications
Uygulanabilir Ulusal Teknik Standartlar ve Özellikler

Classifications / *Sınıflandırma*	: **CLASS-I, NONSTERIL**
Certificate Number / *Sertifika Numarası*	: **20042131**
Certificate Code */ Sertifika Kodu*	: **AREA TEKNOLOJİ**
Certificate Issue Date / *Sertifika Yayın Tarihi*	: **21.04.2020**
Certificate Validity Date / *Sertifikanın Geçerlilik Tarihi*	: **21.04.2021**

EU Representative / *AB Temsilcisi*
(Authorized Signature and Title) / *(Yetkili İmza ve Ünvan)*

Certification Manager
Belgelendirme Müdürü

AREA TEKNOLOJİ SİST. DAĞ. PAZ. VE SAN. DIŞ TİC. LTD. ŞTİ. declares that the Medical Devices Directive 93/42/EEC-General Product Safety Directive 2001/95/EEC has fulfilled the applicable requirements and responsibility has been taken for the above-described product groups.The product groups described above have been controlled depending on internal production controls.

***AREA TEKNOLOJİ SİST. DAĞ. PAZ. VE SAN. DIŞ TİC. LTD. ŞTİ.** olarak yukarıda tanımlanmış olan ürün grupları için Tıbbi Cihazlar Direktifi 93/42/EEC-Genel Ürün Güvenliği Direktifi 2001/95/EEC' nin uygulanabilen gerekliliklerini yerine getirdiğini ve sorumluluğun alınmış olunduğunu beyan etmektedir. Yukarıda tanımlanan ürün grupları, iç üretim kontrollerine bağlı olarak kontrol edilmiştir.*

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NVA QUALITY CERTIFICATION

ZEYTİNBURNU
BELEDİYESİ

T.C.
ZEYTİNBURNU BELEDİYE BAŞKANLIĞI

İşyeri Açma ve Çalışma Ruhsatı

Veriliş Tarihi : 27-04-2020
Ruhsat No : 2020/RS-209

İŞYERİ SAHİBİNİN

Adı Soyadı / Ünvanı : AREA TEKNOLOJİ SİST. DAĞ. PAZ. VE SAN DIŞ TİC. LTD

Ticaret Ünvanı :
Faaliyet Konusu : BURO
İşyeri Adresi : MALTEPE MAH. LONDRA ASFALTI Cad. No:38/ 4

Bağımsız Birim Kütük No : 114333
Kullanılan toplam motor adedi/gücü(hp) :
İşyerinin harca esas olan kullanım alanı : 100 M2
İşyerinin ilgili yönetmenliğe göre sınıfı :

Sıhhi Müesseseler
2020/S-247(018890)

Gayri Sıhhi Müesseseler

Açılış / Kapanış Saati : 08:00 - 20:00
Lüzumlu İzahat : 11/03/2020 TARİH ve 4N9UV86S SAYILI YAPI KAYIT BELGESİNE İSTİNADEN DÜZENLENMİŞTİR.

Diğer Faaliyet Alanları :

Basınçlı Kaplar :

Yukarıda Adı / Ünvanı ve adresi yazılı Sıhhi / Gayri Sıhhi Müessese mer'i mevzuat açısından tetkik edilerek çalışmasında mahsur görülmemiştir.

Av. Saffet ÖZ
Başkan a.
Başkan Yardımcısı

Ticaretin Küresel Dili

Başvurunuz Onaylanmıştır

GS1 Türkiye Sistem Üyelik başvurunuz onaylanmıştır.

Alabileceğiniz hizmetler ile tarafınıza tahsis edilen/edilecek numaraların takibini sistem üzerinden yapabilirsiniz.

Herhangi bir sorunuz olması halinde lütfen GS1 Türkiye ile temasa geçiniz.

Tescil Bilgileri

Firma Unvanı	AREA TEKNOLOJİ SİSTEMLERİ DAĞITIM PAZARLAMA VE SANAYİ DIŞ TİCARET LİMİTED ŞİRKETİ		
Basamak Sayısı	11 Basamaklı		
Tahsis Edilen Firma Önek Numarası/ları (GCP)	**GCP**	**GLN**	**Tescil Tarihi**
	ŞİRKET No 86827423704	BARKOT No 8682742370416	06/05/2020 14:34:23

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AREA TEKNOLOJİ SİST. DAĞ. PAZ. VE SAN. DIŞ TİC. LTD. ŞTİ.

MALTEPE MAH. LONDRA ASFALTI CAD. NO:38/4
ZEYTİNBURNU / İSTANBUL / TURKEY

Kuruluşunun "TEK KULLANIMLIK CERRAHİ MASKE, TEK KULLANIMLIK YÜZ MASKESİ, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK MEDİKAL ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK ELDİVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONE, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI"

Kapsamı için

For scope "SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GOWNS, SINGLE USE MEDICAL GOWNS, SINGLE USE SURGICAL DRAPE, SINGLE USE INSPECTION COVERS, SINGLE USE GLOVES, SINGLE USE OVERALLS, SINGLE USE BONNET, WAG, SILICON MASK, FILTERED SILICON MASK, PROTECTIVE GLASSES, SINGLE USE STRETCHER COVER, PRODUCTION AND SALES"

ISO 10002:2018

MÜŞTERİ MEMNUNİYETİ YÖNETİM SİSTEMİ
Customer Satisfaction Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / ***Certificate Number***	**: 20042128**
Sertifika Kodu / ***Certificate Code***	**: AREA TEKNOLOJİ**
Sertifika Yayın Tarihi / ***Certificate Issue Date***	**: 21.04.2020**
Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 21.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

Certification Manager
Belgelendirme Müdürü

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MALTEPE MAH. LONDRA ASFALTI CAD. NO:38/4
ZEYTİNBURNU / İSTANBUL / TURKEY

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Kapsamı için

For scope "SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GOWNS, SINGLE USE MEDICAL GOWNS, SINGLE USE SURGICAL DRAPE, SINGLE USE INSPECTION COVERS, SINGLE USE GLOVES, SINGLE USE OVERALLS, SINGLE USE BONNET, WAG, SILICON MASK, FILTERED SILICON MASK, PROTECTIVE GLASSES, SINGLE USE STRETCHER COVER, PRODUCTION AND SALES"

ISO 13485 : 2016

TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ

Medical Devices Quality Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / ***Certificate Number***	**: 20042237**
Sertifika Kodu / ***Certificate Code***	**: AREA TEKNOLOJİ**
Sertifika Yayın Tarihi / ***Certificate Issue Date***	**: 22.04.2020**
Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 22.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

Certification Manager
Belgelendirme Müdürü

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ZEYTİNBURNU / İSTANBUL / TURKEY

Kuruluşunun "TEK KULLANIMLIK CERRAHİ MASKE, TEK KULLANIMLIK YÜZ MASKESİ, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK MEDİKAL ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK ELDİVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONE, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI"

Kapsamı için

For scope "SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GOWNS, SINGLE USE MEDICAL GOWNS, SINGLE USE SURGICAL DRAPE, SINGLE USE INSPECTION COVERS, SINGLE USE GLOVES, SINGLE USE OVERALLS, SINGLE USE BONNET, WAG, SILICON MASK, FILTERED SILICON MASK, PROTECTIVE GLASSES, SINGLE USE STRETCHER COVER, PRODUCTION AND SALES"

ISO 14001:2015

ÇEVRE YÖNETİM SİSTEMİ

Environmental Management System

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Sertifika Numarası / ***Certificate Number***	**: 20042127**
Sertifika Kodu / ***Certificate Code***	**: AREA TEKNOLOJİ**
Sertifika Yayın Tarihi / ***Certificate Issue Date***	**: 21.04.2020**
Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 21.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

Certification Manager
Belgelendirme Müdürü

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SERTİFİKA / CERTIFICATE

AREA TEKNOLOJİ SİST. DAĞ. PAZ. VE SAN. DIŞ TİC. LTD. ŞTİ.
MALTEPE MAH. LONDRA ASFALTI CAD. NO:38/4
ZEYTİNBURNU / İSTANBUL / TURKEY

Kuruluşunun "TEK KULLANIMLIK CERRAHİ MASKE, TEK KULLANIMLIK YÜZ MASKESİ, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK MEDİKAL ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK ELDİVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONE, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI"

Kapsamı için

For scope "SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GOWNS, SINGLE USE MEDICAL GOWNS, SINGLE USE SURGICAL DRAPE, SINGLE USE INSPECTION COVERS, SINGLE USE GLOVES, SINGLE USE OVERALLS, SINGLE USE BONNET, WAG, SILICON MASK, FILTERED SILICON MASK, PROTECTIVE GLASSES, SINGLE USE STRETCHER COVER, PRODUCTION AND SALES"

ISO 45001:2018

İŞ SAĞLIĞI VE GÜVENLİĞİ YÖNETİM SİSTEMİ

Occupational Health and Safety Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

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Sertifika Kodu / ***Certificate Code***	**: AREA TEKNOLOJİ**
Sertifika Yayın Tarihi / ***Certificate Issue Date***	**: 21.04.2020**
Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 21.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

Certification Manager
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Kuruluşunun "TEK KULLANIMLIK CERRAHİ MASKE, TEK KULLANIMLIK YÜZ MASKESİ, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK MEDİKAL ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK ELDİVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONE, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI"

Kapsamı için

For scope "SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GOWNS, SINGLE USE MEDICAL GOWNS, SINGLE USE SURGICAL DRAPE, SINGLE USE INSPECTION COVERS, SINGLE USE GLOVES, SINGLE USE OVERALLS, SINGLE USE BONNET, WAG, SILICON MASK, FILTERED SILICON MASK, PROTECTIVE GLASSES, SINGLE USE STRETCHER COVER, PRODUCTION AND SALES"

ISO 22716:2013
GMP
İYİ ÜRETİM UYGULAMALARI
Good Manufacturing Practices

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Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 21.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

Certification Manager
Belgelendirme Müdürü

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T.C.
İSTANBUL VALİLİĞİ
İL SAĞLIK MÜDÜRLÜĞÜ

Belge No **34/TCSM/4234 - 0**
Tarih **20/05/2020**

TIBBİ CİHAZ SATIŞ MERKEZİ YETKİ BELGESİ

MERKEZİN

Adı :**AREA TEKNOLOJİ SİSTEMLERİ DAĞITIM PAZARLAMA VE SANAYİ DIŞ TİC. LTD. ŞTİ.**

Adresi :**Maltepe Mh. Londra Asfaltı Cd. No:38/4 ZEYTİNBURNU / İSTANBUL**

İŞLETME SAHİBİ/SAHİPLERİ

Adı ve Soyadı :**Area Teknoloji Sistemleri Dağıtım Pazarlama ve Sanayi Dış Ticaret Limited Şirketi**

SORUMLU MÜDÜRÜN

Mernis No :**23011072354**

Adı ve Soyadı :**Osman TURAN**

Doğum Yeri ve Tarihi :**ADIYAMAN / 16.01.1980**

Sorumlu Müdür Yeterlilik Belge Tarihi ve Numarası: **30.04.2020 / SM25216**

Yukarıda adı ve adresi belirtilen tıbbi cihaz satiş merkezinin sorumlu müdür **Osman TURAN** sorumluluğunda faaliyet göstermesi uygun görülmüştür.

Bu Belge 15/05/2014 tarih ve 29001sayılı Resmî Gazete de yayımlanan "Tıbbi Cihaz Satış,Reklam ve Tanıtım Yönetmeliği" hükümlerine göre düzenlenmiştir.
NOT: Söz konusu satış merkezinin mezkur Yönetmelik 14 üncü maddesi ikinci fıkrası gereği bireysel kullanıma ve doğrudan bireysel kullanıcıya yönelik cihaz satış yetkisi yoktur.

Filiz ERAYDIN
Güvenli Elektronik İmzalı Aslı ile Aynıdır.
22/05/2020

e-imzalıdır
Uz. Dr. Hasan Basri VELİOĞLU
Vali a.
Başkan

Bu belge 5070 sayılı elektronik imza kanuna göre güvenli elektronik imza ile imzalanmıştır.
"Evrakın elektronik imzalı suretine http://e-belge.saglik.gov.tr adresinden 9f248242-5a10-4e23-b3c7-5733f3fa0299 kodu ile erişebilirsiniz."

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
20011163
03-20

TEST REPORT
DENEY RAPORU

Gen.f136-2/03

Customer name:	KURT KUMAŞ SAN.VE TİC.A.Ş
Address:	2. OSB 83228 Nolu CAD. NO:16 ŞEHİTKAMİL/GAZİANTEP
Buyer name:	-
Contact Person:	MURAT ERBAĞCI
Order No:	-
Article No:	-
Name and identity of test item:	One sample of white nonwoven fabric. (Claimed to be; 25 GSM MELTBLOWN)
The date of receipt of test item:	19.03.2020
Re-submitted/re-confirmation date:	-
Date of test:	19.03.2020-23.03.2020
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:	3

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.

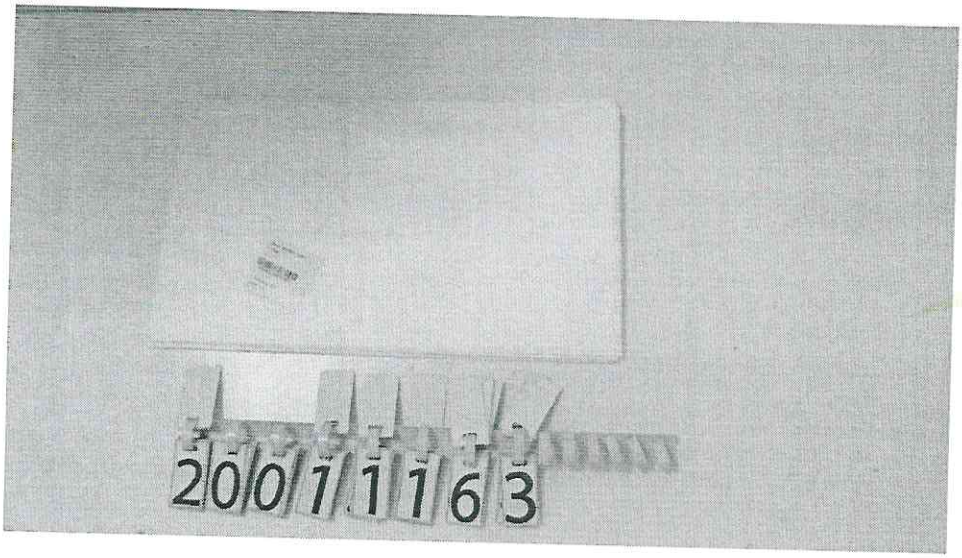
TESTED BY Seal EKOTEKS TESTEDİLMİŞTİR

Date	*Customer Representative*	*Head of Testing Laboratory*
23.03.2020	Ahmet GİRKİN	Sevim A. RAZAK 23.03.2020

AB-0583-T
20011163
03-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Bacterial Filtration Efficiency (BFE)	-	
No requirements were given by vendor.		

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
20011163
03-20

TEST RESULTS

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metod: EKOTEKS 70 (In-House Method-Bacterial Filtration Efficiency Testing /Ref: TS EN 14683:2019 Medica 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	20x20 cm^2
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)	$2.6x10^3$ cfu/ ml

RESULTS		
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu/ml)**	**Bacterial Filtration Efficiency (% B)**
1	15	99.4 %
2	10	99.6 %
3	25	99.0 %
4	24	99.1 %
5	26	99.0 %

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

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.9% Specimen 2#: 99.9% Specimen 3#: 99.8% Specimen 4#: 99.8% Specimen 5#: 99.7%
2	Differential Pressure Test	25.3 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 22 CFU/g Specimen 2#: 14 CFU/g Specimen 3#: 10 CFU/g Specimen 4#: 8 CFU/g Specimen 5#: 10 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Surgical masks
Specification : M
Lot Number : 200318
Sample Receiving Date : 2020-03-28

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

TEST REPORT

Sample Description	:	Surgical masks
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	200318
Specification	:	M
Size	:	/
Type of Mask	:	Type IIR
Brand Name	:	/

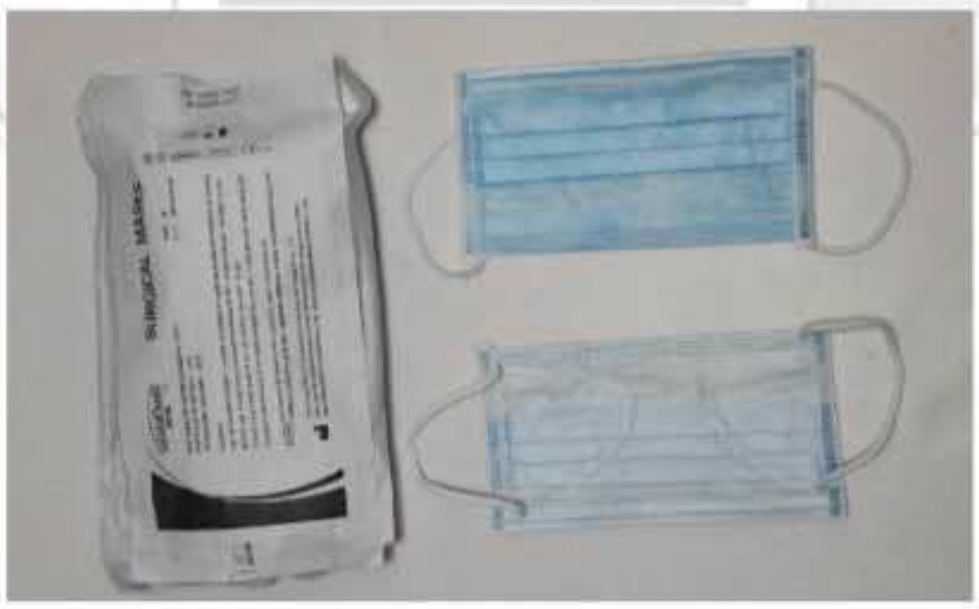
Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples



Chemical/Microbiology Laboratory:
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Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

HOHENSTEIN Textile Testing Institute GmbH & Co. KG
Schlosssteige 1, 74357 Bönnigheim, Germany

OEKO-TEX®
INSPIRING CONFIDENCE

CERTIFICATE

The company

MOGUL TEKSTIL SAN. VE TIC. A.S.
2. Organize San. Bölgesi 83228 Nolu Cad. No. 8
27120 Baspinar - Gaziantep, TURKEY

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report **19.0.74330**

OEKO-TEX®
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STANDARD 100
09.HTR.66245 HOHENSTEIN HTTI
Tested for harmful substances
www.oeko-tex.com/standard100

for the following articles:

MOTEX spun bonded, MICROFIL melt blown, spun bonded and melt blown fabrics thermally calendared and ultrasonic bonded among each other made of 100 % polypropylene in white, AQUALACE nonwoven spun lace fabrics made of 100 % viscose, 100 % Lenzing™ Lyocell, 100 % polyester, 100 % polypropylene and their blends among each other in colour white as well as MOPET spun bonded and BUFFALO bicomponent spun bonded fabrics made of 100 % polyester; produced by using material certified according to STANDARD 100 by OEKO-TEX®.

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Appendix 4, **product class I** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Appendix 4 for baby articles.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

The certificate 09.HTR.66245 is valid until 30.04.2020

Boennigheim, 28.06.2019

Dipl.-Ing. (FH) Elisabeth Panian
Head of Certification Body OEKO-TEX®

Nelson Labs.
A Sotera Health company

Sponsor:
Idil Güner
Kurt Kumas Sanayi Ve Ticaret A.S.
2.O.S.B.83228 Nolu Cadde No: 16
Baspinar, Gaziantep, 27055
TURKEY

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	Sample 1 (25 gsm Meltblown) Sample 2 (25 gsm Meltblown)
Study Number:	1313637-S01
Study Received Date:	24 Jun 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Either
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.5 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

Sean Shepherd electronically approved for James Luskin
Study Director

22 Jul 2020 20:00 (+00:00)
Study Completion Date and Time

Nelson Labs.
A Sotera Health company

Sponsor:
Idil Güner
Kurt Kumas Sanayi Ve Ticaret A.S.
2. O.S.B. 83228 Nolu
Cadde No: 16
Baspinar/Gaziantep/Turkiye
Gaziantep, 27055
TURKEY

Water Resistance: Impact Penetration Final Report

Test Article:	Sample 1 40 gsm SS Medical Blue Sample 2 40 gsm SMS Blue Sample 3 40 gsm SMS Medical Green
Study Number:	1321360-S01
Study Received Date:	17 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0072 Rev 12
Deviation(s):	None

Summary: This test method was performed to evaluate the resistance of a material to the penetration of water by impact using the Type I Tester apparatus. The impact penetration test method complies with AATCC Test Method 42 and is in accordance with ANSI/AAMI PB70. Sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Article Preparation:	Cut from the Material at Random
Test Article Size:	~178 x 330 mm (7 x 13 in)
Test Article Side Tested:	Either Side
Blotter Paper:	Grade 989 (Lot #112645/003)
Blotter Paper Size:	150 x 225 mm
Average Flow Rate:	22 sec

Results:

Sample 1 40 gsm SS Medical Blue:

Test Article Number	Visual Penetration	Amount of Penetration (g)
1	Yes	>5.0
2	Yes	>5.0
3	Yes	>5.0
4	Yes	>5.0
5	Yes	>5.0

Average Amount of Penetration: >5.0 g

Jennifer Jorgenson electronically approved
Study Director — Jennifer Jorgenson

13 Aug 2020 21:30 (+00:00)
Study Completion Date and Time

Sample 2 40 gsm SMS Blue:

Test Article Number	Visual Penetration	Amount of Penetration (g)
1	Yes	0.2
2	Yes	0.3
3	Yes	0.2
4	Yes	0.1
5	Yes	0.4

Average Amount of Penetration: 0.2 g

Sample 3 40 gsm SMS Medical Green:

Test Article Number	Visual Penetration	Amount of Penetration (g)
1	Yes	0.3
2	Yes	0.2
3	Yes	0.3
4	Yes	0.3
5	Yes	0.4

Average Amount of Penetration: 0.3 g

Results:

Test Article: Sample 1 (25 gsm Meltblown)

Test Article Number	Percent BFE (%)
1	99.0
2	98.7
3	98.7
4	99.0
5	99.0

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	2.2	22.0
2	2.1	20.2
3	2.1	20.1
4	1.9	18.5
5	2.0	19.8

Test Article: Sample 2 (25 gsm Meltblown)

Test Article Number	Percent BFE (%)
1	99.5
2	99.5
3	99.6
4	99.7
5	99.6

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	2.9	28.8
2	2.9	28.5
3	2.7	26.3
4	2.6	25.4
5	2.7	26.8

The filtration efficiency percentages were calculated using the following equation:

$$\%\ BFE = \frac{C - T}{C} \times 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request