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TEST SONUÇLARI

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

TEST REPORT
DENEY RAPORU

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

AB-0583-T
20043818
11-20

Gen.f136-1/03

Müşterinin adı:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Adresi:	NECİP FAZIL BULVARI KEYAP SİTESİ E2 BLOK NO:44/84 YUKARI DUDULLU ÜMRANİYE/İSTANBUL
Alıcı firma:	TOROSDENTAL İNŞAAT İTHALAT İHRACAT SANAYİ VE TİCARET ANONİM
İlgili kişi:	SUAT KAÇMAZ
İstek numarası:	-
Model numarası:	SECURE PLUS
Numunenin adı ve tarifi:	Beyaz dokusuz yüzey maske
Numunenin kabul tarihi:	20.11.2020
İlave numune ve/veya ilave bilgi geliş tarihi:	-
Deneyin yapıldığı tarih:	20.11.2020-30.11.2020
İlave numune ve/veya ilave bilgi geliş tarihi:	-
Açıklamalar:	-
Numune alımı:	Bu raporda verilen sonuçlar müşteri tarafından gönderilen numuneye aittir.
Numunenin son kullanımı:	-
Yıkama talimatı:	Belirtilmedi
Raporun sayfa sayısı:	5

Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınması konusunda Avrupa Akreditasyon Birliği (EA) ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı tanınma antlaşmasını imzalamıştır Deney laboratuvarı olarak faaliyet gösteren EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. TÜRKAK'tan AB-0583-T akreditasyon dosya numarası ile ISO 17025:2017 standardına göre akredite edilmiştir. . Deney ve/ veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri (olması halinde) ve deney metodları bu sertifikanın tamamlayıcı kısmı olan takip eden sayfalarda verilmiştir.

Mühür	*Tarih*	*Müşteri Temsilcisi*	*Laboratuvar Müdürü*
TESTED BY EKOTEKS TEST EDİLMİŞTİR	30.11.2020	YEŞİM ŞAHİN	Sevim A. RAZAK 30.11.2020

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

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İSTENEN TESTLER	SONUÇ	AÇIKLAMA
MİKROBİYOLOJİK TESTLERİ		
Bakteri Filtrasyon EtkinlikTesti-BFE	P	**TİP IIR**
Mikrobiyal Temizlik (Biyoyük)	P	
FİZİKSEL TESTLER		
Basınç Farkı	P	
Kan Sıçrama Direnci	P	

P:Geçer
F:Kalır
R:Alıcı firmanın teknik kişisine başvurunuz.
Test sonuçları EN 14683:2019+AC :2019 Tablo 1 limit değerlerine göre değerlendirilmiştir.

Not: Aksi belirtilmediği taktirde testler ile ilgili kayıtlar 5 yıl, orjinal numuneler 3 ay saklanır. Müşteri tarafından talep edildiğinde testlere ait ölçüm belirsizliği raporlanır fakat "Geçer/Kalır" değerlendirmesinde ölçüm belirsizliği değeri dikkate alınmaz. Raporlanan belirsizlik, genişletilmiş belirsizlik olup standart belirsizlik kapsam faktörü k=2 kullanılarak elde edilmiştir. Güvenilirlik düzeyi % 95'tir. Uygunluk beyanı Basit Kabul Karar Kuralına göre verilmiştir. Bu raporda (*) işaretli deneyler akreditasyon kapsamına dahil değildir.

İmzasız ve mühürsüz raporlar geçersizdir.

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TEST SONUÇLARI
Tıbbi yüz maskeleri – Gereklilikler ve Deney Yöntemleri EN 14683:2019+AC:2019 (TS EN 14683+AC:2019)

BAKTERİ FİLTRASYON VERİMLİLİK TAYİNİ TESTİ- BFV

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

Örnek, aerosol ve mikrobiyal yük örnekleme haznesi arasına sıkıştırılır. Vakum sistemi yardımıyla bakteri içeren aerosol, filtreden geçirilir. Örneğin bakteri filtrasyon etkinliği, örnekten geçen koloni oluşturan birimlerin sayısının bakteri yüklü, aerosolde mevcut olan koloni oluşturan birimlerin sayısının yüzdesi olarak ifade edilir.

Deney Akış Hızı	28,3 L/dk
Toplam Deney Akış Süresi	2 dakika
Numune Ölçüleri	5 adet maske
Test Alanı	4.9 cm^2 (5 replicas)
Test Kondüsyon	(21 ± 5) °C and (85 ± 5) % bağıl nem, 4 saat
Test Mikroorganizması	*Staphylococcus aureus* ATCC 6538
Bakteri konsantrasyonu (kob/ ml)	$5x10^5$ kob/ ml
Inkübasyon süresi, sıcaklık	37 ± 2 °C, 20 - 52 h
Pozitif Kontrol Numune Bakteri Sayısı Ortalaması (C)	**$2.4 x10^3$ kob/ ml**
Ortalama Partikül Boyutu (MPS)	**2.9 µm**

SONUÇLAR			
Deney Numunesi Sayısı	**Deney Numunesi Bakteri Sayısı(kob) (T)**	**Bakteri Filtrasyon Verimliliği (%B)**	**İstenen Değer BFV (%)**
1	45	**%98.1**	**Tip I ≥95** **Tip II ≥98**
2	49	**%98.0**	
3	40	**%98.3**	
4	36	**%98.5**	
5	30	**%98.8**	

kob: koloni oluşturan birim

B= (C-T) / C x 100

%B: Bakteri Filtrasyon Verimliliği

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TEST SONUÇLARI

BASINÇ FARKI (NEFES ALABİLİRLİK)

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

Test Kondüsyon koşulu ve süresi: (21 ± 5) °C ve (85 ± 5) % bağıl nem, 4 saat
2,5 cm çaplı 5 farklı deney numunesi alınır.
8 l/dk hava akışı uygulanır.
Fark Basınç Manometresi üzerinden okunan basınç farkı değeri Pa (Pascal) olarak kayıt edilir.

NUMUNE	BASINÇ PARKI SONUÇ	İSTENEN
1	32,5 Pa/cm^2	< 60 Pa/cm^2
2	27,6 Pa/cm2	
3	35,2 Pa/cm2	
4	32,5 Pa/cm2	
Ortalama Sonuç	32,8 Pa/cm2	

MİKROBİYAL TEMİZLİK (BİYOYÜK)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019)
EN ISO 11737-1:2018 /TS EN ISO 11737-1 :2018

5 numune çalışılır. Numune tartılır ve test çözeltisi içerisine atılarak iyice çalkalanır (250 rpm de 5 dk) ve uygun besiyerlerine ekilir. Toplam aerobik bakteriler için 30±1°C'de 72 saat, küf ve maya için ise 20-25 °C'de 7 gün inkübasyon sonrası agarda oluşan mikroorganizmalar sayılır ve toplam sonuç verilir.Ortalama sonuç verilir.

	SONUÇ	İSTENEN
Mikrobiyal Temizlik (kob/gr)	20 kob/gr	≤30 kob/gr

**kob:Koloni oluşturan birim*

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TEST SONUÇLARI
KAN SIÇRAMA DİRENCİ

Test Metodu: EN 14683:2019+AC :2019 (Madde 5.2.4) tıbbi yüz maskesinin sıvı sıçramalarına nüfuz etmesine karşı direnç ISO 22609 :2004 Giysilerin enfekte edici ajanlara karşı koruma - Tıbbi yüz maskeleri - Sentetik kanın nüfuz etmesine karşı direnç için test yöntemi (sabit hacim, yatay olarak yansıtılmış)
Test Kondüsyon koşulu ve süresi: (21 ± 5) °C ve (85 ± 5) % bağıl nem, 4 saat , 32 farklı deney numunesi alınır.

NUMUNE	SIÇRAMA DİRENCİ BASINCI (kPa)	SONUÇ	İSTENEN
1	>21.3 kPa	GEÇER	≥16 kPa Tip IIR maske
2	>21.3 kPa	GEÇER	
3	>21.3 kPa	GEÇER	
4	>21.3 kPa	GEÇER	
5	>21.3 kPa	GEÇER	
6	>21.3 kPa	GEÇER	
7	>21.3 kPa	GEÇER	
8	>21.3 kPa	GEÇER	
9	>21.3 kPa	GEÇER	
10	>21.3 kPa	GEÇER	
11	>21.3 kPa	GEÇER	
12	>21.3 kPa	GEÇER	
13	>21.3 kPa	GEÇER	
14	>21.3 kPa	GEÇER	
15	>21.3 kPa	GEÇER	
16	>21.3 kPa	GEÇER	
17	>21.3 kPa	GEÇER	
18	>21.3 kPa	GEÇER	
19	>21.3 kPa	GEÇER	
20	>21.3 kPa	GEÇER	
21	>21.3 kPa	GEÇER	
22	>21.3 kPa	GEÇER	
23	>21.3 kPa	GEÇER	
24	>21.3 kPa	GEÇER	
25	>21.3 kPa	GEÇER	
26	>21.3 kPa	GEÇER	
27	>21.3 kPa	GEÇER	
28	>21.3 kPa	GEÇER	
29	>21.3 kPa	GEÇER	
30	>21.3 kPa	GEÇER	
31	>21.3 kPa	GEÇER	
32	>21.3 kPa	GEÇER	
Ortalama Sonuç	>21.3 kPa	GEÇER	

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İstanbul/ TÜRKİYE

TEST REPORT
DENEY RAPORU

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

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20043818 -ing
11-20

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	NECİP FAZIL BULVARI KEYAP SİTESİ E2 BLOK NO:44/84 YUKARI DUDULLU ÜMRANİYE/İSTANBUL
Buyer name:	TOROSDENTAL İNŞAAT İTHALAT İHRACAT SANAYİ VE TİCARET ANONİM
Contact Person:	SUAT KAÇMAZ
Order No:	-
Article No:	SECURE PLUS
Name and identity of test item:	White non woven mask
The date of receipt of test item:	20.11.2020
Re-submitted/re-confirmation date:	-
Date of test:	20.11.2020-30.11.2020
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*
	30.11.2020	YEŞİM ŞAHİN	Sevim A. RAZAK 30.11.2020

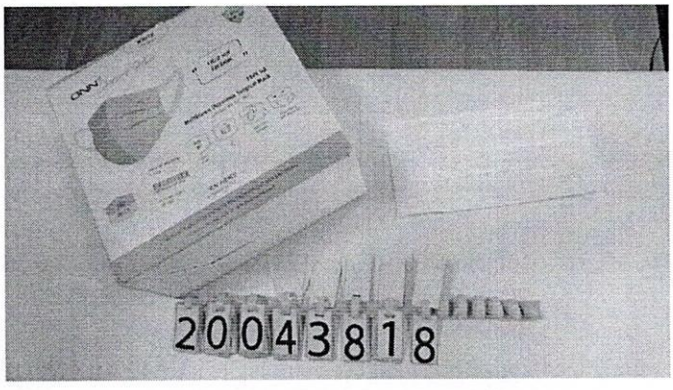
Gen.f136-2/03

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

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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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)	$2.4 x10^3$ cfu/ ml
Mean particle size (MPS)	2.9 µm

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	45	**%98.1**	**Type I ≥95** **Type II ≥98**
2	49	**%98.0**	
3	40	**%98.3**	
4	36	**%98.5**	
5	30	**%98.8**	

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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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	32,5 Pa/cm^2	< 60 Pa/cm^2
2	27,6 Pa/cm2	
3	35,2 Pa/cm2	
4	32,5 Pa/cm2	
Average Result	32,8 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)	20 cfu/g	≤30 cfu/g

*cfu= Colony forming unit.

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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	

EUROLAB® Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

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2020030976

Report No:	2020030976
Applicant:	**TOROSDENTAL İNŞ. İTH. İHR. SAN. VE TİC. A.Ş.** Tahılpazarı Mah. 459 Sk. No:20/101 Karaboğa Melli İşh.Muratpaşa /Antalya
Contact Person:	Mehmet Özçelik
Contact Telephone:	0242 247 7616
Contact e-mail:	mehmet@torosdental.com
Sample Accepted on:	17.08.2020
Report Date:	03.09.2020
Total number of pages:	9 (Pg)

Sample ID: **Surgical Mask / Cerrahi Maske**

	TEST	METHOD	Specimen	RESULT
*	**Medical face masks - Requirements and test methods**	**EN 14683+AC 2019**	**Surgical Mask**	**PASS** **TYPE IIR**

Seal

Customer Representative
Hasan KUTLU

Laboratory Manager
Hava SARIAYDIN

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL
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Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

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Scope

This European Standard specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements.

Requirements and Test Methods

1. Bacterial Filtration Efficiency
2. Differantial Pressure
3. Splash Resistance Pressure
4. Microbial Cleanliness

All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.

1. Method for in-vitro determination of bacterial filtration efficiency (BFE)

Principle

A specimen of the mask material is clamped between a six-stage cascade 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.

Reagents and materials

Describe commercially available solutions of tryptic soy agar, tryptic soy broth and peptone water.

Tryptic soy agar

Formula/liter:	
Enzymatic digest of casein	15 g
Enzymatic digest of soybean meal	5 g
Sodium chloride	5 g
Agar	15 g
Final pH	7,3 ± 0,2 at 25 °C

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Tryptic soy broth

Formula/liter:

Enzymatic digest of casein	17 g
Enzymatic digest of soybean meal	3 g
Sodium chloride	5 g
Dextrose	2,5 g
Final pH	7,3 ± 0,2 at 25 °C

Peptone Water

Formula/liter:

Peptone	1 g
Sodium chloride	5 g
Final pH	7,3 ± 0,2 at 25 °C

Preparation of bacterial challenge

Staphylococcus aureus shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of (37 ± 2) °C for (24 ± 2) h. The culture shall then be diluted in peptone water to give a concentration of approximately 5 × 105 cfu/ml.

The bacterial challenge shall be maintained at (2 200 ± 500) cfu per test. The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see B.6.3) and the dilution of the challenge suspension adjusted accordingly. The mean particle size in the bacterial challenge shall be maintained at (3,0 ± 0,3) µm (see B.6.9).

Procedure

Assemble the apparatus in accordance with the flow chart shown in Figure 1.

Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.

Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28,3 l/min. Deliver the bacterial challenge for 1 min. Maintain the airflow through the impactor for 2 min. Then remove the plates from the impactor. Ensure that each plate is numbered to indicate its position in the impactor.

Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.

Repeat this procedure for each test specimen.

After the last test specimen has been tested, perform a further positive control run.

Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.

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Incubate all the plates at (37 ± 2) °C for (48 ± 4) h. For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of cfu collected by the impactor using the "positive hole" conversion Table1 in accordance with the instructions of the cascade impactor manufacturer. For the two positive control runs, take the mean of the two totals. From the positive control plates calculate the mean particle size of the bacterial challenge aerosol using the "positive hole" conversion table in accordance with the instructions of the cascade impactor manufacturer.

Calculation of bacterial filtration efficiency

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$$B = (C - T) / C \times 100$$

Where;

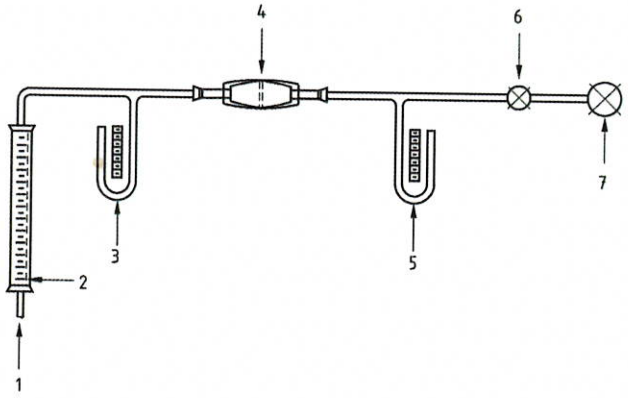
C is the mean of the total plate counts for the two positive control runs;

T is the total plate count for the test specimen.

2. Method For Determination of Breathability (Differential Pressure)

Principle

A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure 1. Water-filled manometers (M1 and M2) are used to measure the differential pressure. A flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the airflow rate.



Key

1 air inlet
2 flow meter
3 manometer M1
4 filter material
5 manometer M2
6 valve
7 vacuum pump

Figure 1 — Apparatus for measuring air resistance

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Procedure

The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm2) and clamped into place so as to minimise air leaks and that the tested area of the specimen will be in line and across the flow of air.
The pump is started and the flow of air adjusted to 8 l/min.
The manometers M1 and M2 are read and recorded.
The procedure described in steps 1 through 3 is carried out on 5 (or appropriate number of) different areas of the mask and the readings averaged.

Calculation of differential pressure

For each test specimen calculate the differential pressure ΔP as follows:

$$\Delta P = (Xm1 - Xm2)/4,9$$

Where;

Xm1 is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;
Xm2 is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;
4,9 is the cm2 area of the test material;
ΔP is the differential pressure per cm2 of test material expressed in Pa.

3. Splash Resistance

When tested in accordance with ISO 22609 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.

4. Microbial Cleanliness (Bioburden)

When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested (see Table 1).

To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below:

The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.

Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]).

The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µ filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively.

The total bioburden is expressed by addition of the TSA and SDA counts.

In the report, indicate the total bioburden per mask and based on the mask weigh, the total bioburden per gram tested.

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TEST REQUIREMENTS

Test	Type I[a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

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TEST RESULTS

EN 14683 Inspection

SAMPLE : Surgical Mask

Test	Type			Result		Evaluation
Bacterial filtration efficiency (BFE), (%)	1 ≥ 95	2 ≥ 98	2R ≥ 98	98.03 98.03 98.06 98.05 98.06	**98.04**	PASS
Differential pressure (Pa/cm2)	< 40	< 40	< 60	**29**		PASS
Splash resistance pressure (kPa)	N/A	N/A	≥ 16,0	**17**		Type IIR
Microbial cleanliness (cfu/g)	≤ 30			**26**		PASS

Free Area

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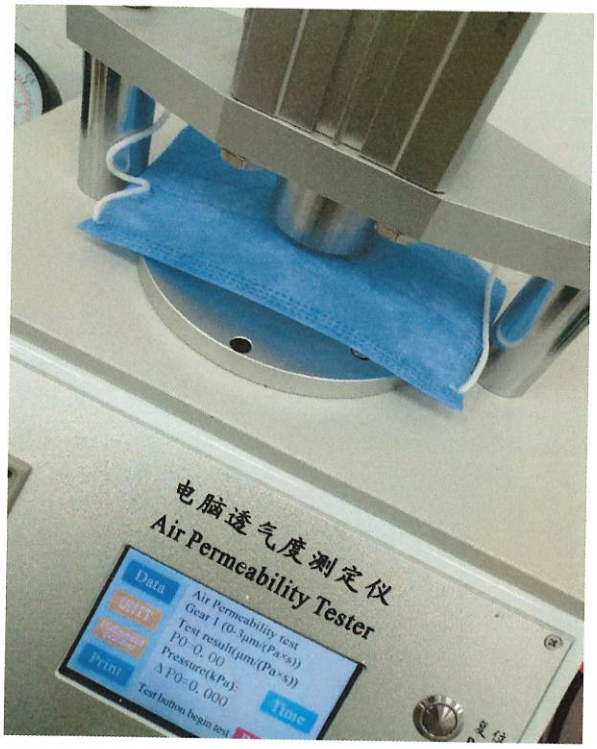
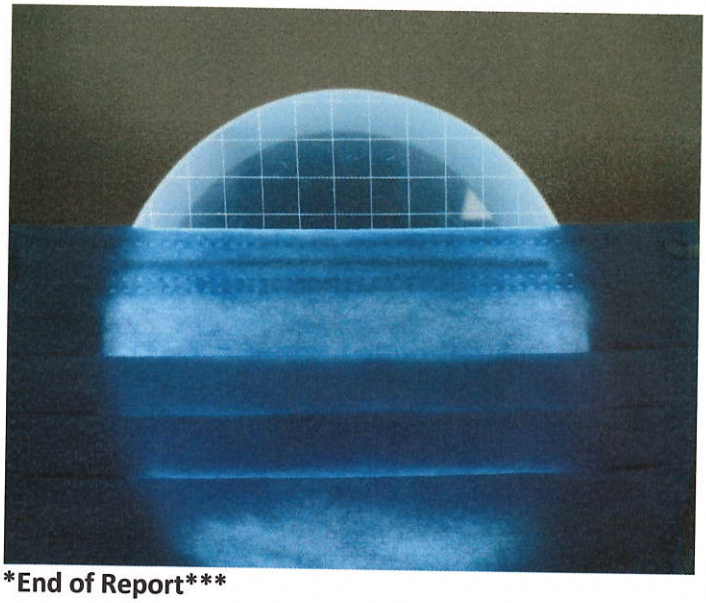
MASK IMAGES UNDER THE TEST





End of Report

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