Digi Mask

CERTIFICATES

Certificate of Registration
2020

This is to certify that the registration of

DIGISEAT MUSTERI HIZMETLERI VE TEKNOLOJI A.S

ESENTEPE MAH. KORE SEHITLERI CAD. ISTANBLOOM NO: 16/1 IC KAPI NO: 72 SISLI

ISTANBUL, TURKEY- 34394

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd with the information provided by Digiseat Musteri Hizmetleri Ve Teknoloji A.S

Owner/Operator Number	**10076836**
Date of Registration	**July 31, 2020**
Date of Expiration	**December 31, 2020**
US Agent	**Liberty Management Group Ltd.**
Device Listing Numbers	**See Annex**
Certificate Number	**3007310120**

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Liberty Management Group Ltd. is not affiliated with the U.S. Food and Drug Administration.

LMG LIBERTY MANAGEMENT GROUP LTD.

75 Executive Drive, Aurora, Illinois, USA

www.fdahelp.us

Manoj Zacharias

President

Liberty Management Group LTD.

Dated: July 31, 2020

Certificate of Registration
2020

Annex - Device Listings

Listing Number	Code	Device Name - Proprietary Names
D414140	FXO	Suit, Surgical - Digimask coveralls
D414139	OEA	Non-Surgical Isolation Gown - Digimask Gown
D414138	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance - Digimask
D414141	FYF	Cap, Surgical - Digimask Hair Restraint

UNIVERSALCERT.COM

UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-192

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 Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,

the products manufactured by

DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ

at the following address

Esentepe Mahallesi Kore Şehitleri Caddesi İstanbloom No:16/1 İç Kapı No 72 Şişli ISTANBUL / TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: DİGİMASK
Model: DG-01
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 Çevre Endüstriyel 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 22/07/2020 and valid until 21/07/2021 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 –22/07/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Genel Müdür

Verify the validity with the QR Code

EU DECLARATION OF CONFORMITY

MANUFACTURER
DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ
Esentepe Mahallesi Kore Şehitleri Caddesi İstanbloom No:16/1 İç Kapı No 72 Şişli
ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Brand Name: DİGİMASK
Model: DG-01
Type IIR

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Producer's / the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 93/42/EEC Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Bavterial filtration efficiency
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Differential Pressure
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Splash Resistance Pressure

MARKING, LABELLING

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied:
type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered

MEASURES TO ENSURE CONFORMITY

The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

CE

General Manager
22/07/2020

UNIVERSAL
CERTIFICATION

TEKNİK DEĞERLENDİRME RAPORU

RAPOR TARİHİ / NO: 22.07.2020 / 07-2020-T0263

Üretici: DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ

Adres: Esentepe Mahallesi Kore Şehitleri Caddesi İstanbloom No:16/1 İç Kapı No 72 Şişli ISTANBUL / TURKEY

Yukarıda ismi verilen kuruluş tarafından üretimi gerçekleştirilen ürünün ilgili olduğu Avrupa Birliği harmonize ürün standardı olan EN 14683+AC:2019 sandardı Ek ZA tablosu ve 93/42/EEC Tıbbi Cihazlar Yönetmeliğinin Sınıf I gereklilikleri açısından gönüllü olarak yaptığı başvurusu üzerine aşağıdaki incelemeleri yapılmıştır.

Ürün Tanımı: Medikal Yüz Maskesi

Marka: DİGİMASK **Model:** DG-01

Gerçekleştirilen üçüncü taraf incelemeler kapsamında üreticinin sunduğu teknik dosyası incelenmiş ve ürünlerinin EN 14683/AC:2019 standardı ZA Ekinde gösterilen deneyleri gerçekleştirilmiştir. (Ek 1 Çevre Endüstriyel Analiz Laboratuarı tarafından düzenlenmiş 20/07/2020 2015601E tarih ve numaralı deney raporları)

Bu rapor ve bu raporun olumlu olması durumunda düzenlenecek belge, üreticinin 93/42/EEC Tıbbi Cihazlar Yönetmeliği kapsamındaki sorumluluğunu ortadan kaldırmaz veya devralmaz. Üretici 93/42/EEC Sınıf I olan bu ürünle ilgili tüm sorumluluklarını sürekli olarak yerine getirmelidir.

UNIVERSAL CERTIFICATION

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

İncelemeye dair sonuçlar aşağıda verilmiştir;

A- Teknik Dosya İncelemesi

Üreticinin 93/42/EEC Tıbbi Cihazlar Yönetmeliğine göre hazırlanmış bir teknik dosyasının mevcut olduğu, yönetmelikte belirtilen temel sağlık ve güvenlik gerekliliklerinin ele alındığı ve bu gerekliliklerin yerine getirilmesi konusunda dokümante edilmiş tanımlamalara sahip olduğu değerlendirilmiştir.

B- Ürün Deney Sonuçları

Üretici tarafından teslim edilen ürünler TS EN 14683/AC:2019 standardı ZA Eki göz önüne alınarak aşağıdaki deneylere tabi tutulmuş ve deney sonuçları değerlendirilmiştir;

1. Biyouyumluluk

Ürüne ait teknik dosya incelemesinde, üreticinin üründe kullanılan malzemelerin tedariğinde biyo uyumluluk şartlarını gözettiği ve malzeme temininde yarı mamül üreticilerinden ürünlerin biyo uyumluluğuna dair gerekli taahhütleri temin ederek kendi ürettiği maskelerin biyo – uyumluluk şartlarını sağladığına dair beyanının bulunduğu, bu süreçlerin yönetimi konusunda dâhili görevlendirmelerin yapılmış olduğuna dair beyanların bulunduğu görülmüş ve yeterli olarak değerlendirilmiştir.

2. Bakteri Filtrasyon Verimliliği

Bakteri Filtrasyon Etkinliği: TS EN 14683/AC:2019 Ek B metodu doğrultusunda suni olarak hazırlanmış bakteri muhtevasının belirli bir akış ile ilgili deney metodunda tanımlanmış bir düzenekte en az 5 maske numunesi bakteri içeren hava geçişine 28.3 L/dak akış hızı ile 2 dakika maruz bırakılmıştır. Değişik partikül büyüklükleri ile elde edilen örneklerin inkübasyonu sonuçları anılan deney raporunda gösterilmiştir.

TS EN 14683/AC standardında verilen performans sınıflarına göre tıbbi maske tiplerinin göstermesi gereken minimum bakteri filtrasyon etkinliği aşağıdaki tabloda verilmiştir;

Test	Tip I*	Tip II	Tip IIR
Bakteri Filtrasyon Verimliliği (BFE), (%)	≥ 95	≥ 98	≥ 98
* Tip 1 tıbbi yüz maskeleri yalnızca hastalar veya diğer kişiler tarafından salgınlar durumunda riskin düşürülmesi amacıyla kullanılmalıdır. Tip 1 maskeler, sağlık sağlık çalışanlarının ameliyat veya benzeri sağlık hizmetlerinin verildiği ortamlarda kullanım amaçlı değildir.			

5 deney numunesi üzerinden yapılan incelemede en düşük bakteri filtrasyon değerinin 98,8 % olarak verildiği görülmüştür. Bu sonuca göre maske performansının standartta verilen Tip I, Tip II ve Tip IIR performans sınıfını sağladığı değerlendirilmiştir.

Laboratuar sonuçlarının güvenliği açısından pozitif ve negatif kontrol verilerinin tutarlı olduğu izlenmiştir.

3. Mikrobiyal temizlik (Bioburden)

Mikrobiyal Temizlik (Bioburden): ISO 11737-1 standardına göre gerçekleştirilen deneyde koloni oluşturan birimlerin sayılması ile gerçekleştirilen deney sonuçlarının tüm

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

performans sınıfları için 30 birimin altında olması beklenmektedir.

İncelenen deney sonuçlarına göre oluşan gram başına en yüksek koloni oluşturan birim sayısı 7 olarak tespit edilmiştir. Bu deney sonucu açısından maske numuneleri tüm performans sınıflarını sağlayabilecek nitelikte değerlendirilmiştir (Tip I, Tip II and Tip IIR).

4. **Diferansiyel Basınç**

Maske numunelerinin soluk alma / soluk verme direncini tespit etmek amacıyla gerçekleştirilen bu deneyde diferansiyel basıncın Tip I ve Tip II performans sınıfı maskeler için 40Pa/cm²'den, Tip IIR maskeler için ise 60 Pa/cm²'den fazla olmaması beklenmektedir.

İncelenen deney sonuçlarına göre en yüksek diferansiyel basınç değerinin 23,9 Pa/cm² olduğu ve bu itibarla maske numuneleri tüm performans sınıflarını sağlayabilecek nitelikte değerlendirilmiştir (Tip I, Tip II and Tip IIR).

5. **Sıçrama Dayanım Basıncı (kPa)**

Sıçrama Dayanım Basıncı : ISO 22609:2004 standardına göre gerçekleştirilen deneyde sıvıların sıçramaya geçişine karşı direnci Tip IIR sınıfı için ≥ 16 kPa'den fazla olması beklenmektedir.

15 deney numunesi üzerinden yapılan incelemede çalışılan numunelerin hepsi 16 kPa basınçta yapılan testlerde Tip IIR performans sınıfını sağlayabilecek nitelikte olduğu değerlendirilmiştir.

C- Özet Değerlendirme

Değerlendirme Konusu	Gereklilikler	Sonuç	Sınıflandırma
Bakteri Filtrasyon Verimliliği (BFE), (%)	≥ 95 % – Tip I ≥ 98 % – Tip II ≥ 98 % – Tip IIR	98,8 %	Tip I Tip II Tip IIR
Diferansiyel Basınç (Pa/cm2)	< 40 – Tip I < 40 – Tip II < 60 – Tip IIR	23,9	Tip I Tip II Tip IIR
Sıçrama Dayanım Basıncı (kPa)	Gerekli Değil – Tip I Gerekli Değil – Tip II ≥ 16 – Tip IIR	> 16	Tip IIR
Mikrobiyal Temizlik (cfu/g)	≤ 30 – Type I ≤ 30 – Type II ≤ 30 – Type IIR	29	Tip I Tip II Tip IIR
Nihai Performans Sınıflandırması			**Tip IIR**

– Rapor Sonu –

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

EU DECLARATION OF CONFORMITY

MANUFACTURER

DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ
Esentepe Mahallesi Kore Şehitleri Caddesi İstanbloom No:16/1 İç Kapı No 72 Şişli
ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Brand Name: DİGİMASK
Model: DG-01
Type IIR

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- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
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- Other relevant local, national and community standards
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MEASURES TO ENSURE CONFORMITY

The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

CE

General Manager
22/07/2020

DIGISEAT MÜŞTERİ HİZMETLERİ
VE TEKNOLOJİ ANONİM ŞİRKETİ
Esentepe Mah. Kore Şehitleri Cd. İstanbul
Bloom Apt. No: 16/1 D: 72 Şişli/ISTANBUL

S . Y . K
Sınai Yatırımlar ve Kurumsal Danışmanlık Ltd.
"çözüm ortağınız"

DECLARATION OF COMPLIANCE

Name and address of certificate owner : **DİJİSEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ A.Ş.**

Name and address : Esentep Mahallesi Kore Şehitleri Caddesi İstanbloom No :16/1 Iç Kapı No 72 Şişli /İstanbul /Türkiye

Factory Adress : Selimpaşa Mahallesi Ortaköy Sanayi Bölgesi 6205 Sokak No:9 Silivri /İstanbul /Türkiye

Product name : Face Mask With Earloops

Product types : Class I - White, Blue, Green

This declaration confirms that the product meets the essential requirements of the following directive(s) and standard(s). The conformity was based on ;

Applied Directive(s) : Medical Devices Directive 93/42/EEC as amended according to the Directive 2007/47/EC

Applied Standard(s) : EN 14683:2019 Medical face masks - Requirements and test methods

Test	Type IIR	Result	Evaluation
Bacterial filtration efficiency (BFE), (%)	≥ 98	99,21	PASS
Differential pressure (Pa/cm2)	< 60	23	PASS
Splash resistance pressure (kPa)	≥ 16	16	PASS
Microbial cleanliness (cfu/g)	≤ 30	21	PASS

The declaration has been carried out in accordance with Individual rules and conditions. Evaluation has been carried out in accordance with:

Test Report(s) No. : **2020140519**

EUROLAB Laboratory Services — TEST / INSPECTION REPORT — EUROLAB LABORATORY SERVICES — TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

Test Conducted by :

Merkez Mh, Gençosman Cd, No 11 / A GUNGOREN / ISTANBUL
Tel: 0212 702 20 10 Fax: 0212 909 21 10
Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Test Lab. Adres :

Issue Date : **08.05.2020** **Report No:** 5190243IB02 / 2020140519 **Date: 15.05.2020**

UNI EN 14683+AC

Revision Date /No: 2019

The undersigned herewith declarer that the above-mentioned product(s) meet the provisions of the following EC Council Directives and harmonized standards, All supporting documentations are retained under the premises of the manufacturer.

CE

KURULUŞ ONAYI;
Adı Soyadı : Müştak AKDAĞ
Görevi : General Manager
Date : 16.05.2020 / ISTANBUL
İmza /Kaşe :

DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ
Esentepe Mah.Kore Şehitleri Cd.İstanbul
Bloom Apt. No: 16/1 D: 72 Şişli İSTANBUL
Zincirlikuyu V.D. 2750989692

This certificate is valid with the report with 15.05.2020 dated and 2020140519 number, and with the manifacturer's approval.
İş bu sertifika 15.05.2020 tarih ve 2020140519 nolu test raporu ile birlikte, üreticinin onayı içerdiği takdirde geçerlidir.

SYK SINAİ YATIRIMLAR VE KURUMSAL DANIŞMANLIK LİMİTED ŞİRKETİ
T:+90 212 270 74 41 F:+90 212 270 74 54 e-mail: info@sykdanismanlik.com WSP : +90 532 578 18 32
Talatpaşa Caddesi 216/2 Posta Kodu : 34410 Gültepe -Kağıthane- İstanbul / TURKIYE
Vergi Dairesi : Zincirlikuyu Vergi No : 7840301751 Ticaret Sicil : İTO 907642

FIRST QUALITY CERTIFICATION

FIRST QUALITY CERTIFICATION

CERTIFICATE

This certificate is granted to the organization,

DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ

Esentepe Mahallesi Kore Şehitleri Caddesi İstanbloom Apartmanı
No:16/1/72 Şişli / İstanbul / Türkiye
Selimpaşa Mahallesi Ortaköy Sanayi Bölgesi 6205 Sokak No:9 Silivri / İstanbul / Türkiye

MEDICAL PRODUCT MANUFACTURING (STERILE AND NON STERILE, MASK, BONNET, GALOSH, GLOVE, WORK UNIFORM, BODY BAG, MEDICAL TUBUS, MEDICAL APRON, WET NAPKIN, SANITIZER NAPKIN) AND SALE SERVICES, EXPORT AND IMPORT

EA 4, 12, 14, 23

according to the scope,

ISO 9001:2015

to certify that Quality Management System in accordance with standard's clauses is established and being implemented.

First Date of Issue	**: 20.05.2020**
Date of Issue	**: 20.05.2020**
Certificate Period	**: 3 Years**
Reissue Due Date	**: 19.05.2021**
Certificate No	**: 01.20.8532.114140.D**

First Quality Certification
System Certificate Approved
Maltepe / İstanbul / Türkiye

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-19276-01-00

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FQC, Turkey & Critical Location
FQC Uluslar Arası Belgelendirme ve Eğit. Hiz. A.Ş.
Cevizli Mah. Tansel Cad. No:12 Kat:4 D: 28-29 Maltepe / İstanbul / Türkiye
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www.fqc.com.tr info@fqc.com.tr

FIRST QUALITY CERTIFICATION

FQC

FIRST QUALITY CERTIFICATION

CERTIFICATE

This certificate is granted to the organization,

DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ

Esentepe Mahallesi Kore Şehitleri Caddesi İstanbloom Apartmanı No:16/1/72 Şişli / İstanbul / Türkiye
Selimpaşa Mahallesi Ortaköy Sanayi Bölgesi 6205 Sokak No:9 Silivri / İstanbul / Türkiye

MEDICAL PRODUCT MANUFACTURING (STERILE AND NON STERILE, MASK, BONNET, GALOSH, GLOVE, WORK UNIFORM, BODY BAG, MEDICAL TUBUS, MEDICAL APRON, WET NAPKIN, SANITIZER NAPKIN) AND SALE SERVICES, EXPORT AND IMPORT

according to the scope,

ISO 10002:2018

Customer Satisfaction Management System standards that meet the requirements of a management system are established and implemented to confirm.

First Date of Issue	**: 20.05.2020**
Date of Issue	**: 20.05.2020**
Certificate Period	**: 3 Years**
Reissue Due Date	**: 19.05.2021**
Certificate No	**: 01.20.8532.114141**

First Quality Certification
System Certificate Approved
İstanbul, 2020.05.20

Cevizli Mah. Tansel Cad. No. 12/18 K:4 D:28 Maltepe / İSTANBUL Tel:444 21 41 Fax: 457 98 69 Küçükyalı V.D. 338 068 78 81 FQC Uluslararası Belgelendirme ve Eğitim Hizmetleri A.Ş.

FIRST QUALITY CERTIFICATION

FQC®

FIRST QUALITY CERTIFICATION

CERTIFICATE

This certificate is granted to the organization,

DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ

Esentepe Mahallesi Kore Şehitleri Caddesi İstanbloom Apartmanı
No:16/1/72 Şişli / İstanbul / Türkiye
Selimpaşa Mahallesi Ortaköy Sanayi Bölgesi 6205 Sokak No:9 Silivri / İstanbul / Türkiye

MEDICAL PRODUCT MANUFACTURING (STERILE AND NON STERILE, MASK, BONNET, GALOSH, GLOVE, WORK UNIFORM, BODY BAG, MEDICAL TUBUS, MEDICAL APRON, WET NAPKIN, SANITIZER NAPKIN) AND SALE SERVICES, EXPORT AND IMPORT

EA 4, 12, 14, 23

according to the scope,

ISO 14001:2015

to certify that Enviromental Management System in accordance with standard's clauses is established and being implemented.

First Date of Issue	**: 20.05.2020**
Date of Issue	**: 20.05.2020**
Certificate Period	**: 3 Years**
Reissue Due Date	**: 19.05.2021**
Certificate No	**: 02.20.8532.7479.D**

First Quality Certification
System Certificate Approved
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FIRST QUALITY CERTIFICATION

FIRST QUALITY CERTIFICATION

CERTIFICATE

This certificate is granted to the organization,

DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ

Esentepe Mahallesi Kore Şehitleri Caddesi İstanbloom Apartmanı No:16/1/72 Şişli / İstanbul / Türkiye
Selimpaşa Mahallesi Ortaköy Sanayi Bölgesi 6205 Sokak No:9 Silivri / İstanbul / Türkiye

MEDICAL PRODUCT MANUFACTURING (STERILE AND NON STERILE, MASK, BONNET, GALOSH, GLOVE, WORK UNIFORM, BODY BAG, MEDICAL TUBUS, MEDICAL APRON, WET NAPKIN, SANITIZER NAPKIN) AND SALE SERVICES, EXPORT AND IMPORT

according to the scope,

ISO 45001:2018

to certify that Occupational Health and Safety System in accordance with standard's clauses is established and being implemented.

First Date of Issue	**: 20.05.2020**
Date of Issue	**: 20.05.2020**
Certificate Period	**: 3 Years**
Reissue Due Date	**: 19.05.2021**
Certificate No	**: 03.20.8532.0162**

First Quality Certification
System Certificate Approved
İstanbul,2020.05.20

Cevizli Mah. Tansel Cad. No. 12/18 K:4 D:28 Maltepe / İSTANBUL Tel:444 21 41 FQC Uluslararası Belgelendirme ve Eğitim Hiz. A.Ş. Küçükyalı V.D. 388 068 78 81

CERTIFICATE
of Registration

This is to Certify that the

Medical Devices – Quality Management System

of

DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ

MERKEZ ADRESİ: ESENTEPE MH. KORE ŞEHİTLERİ CAD. İSTANBLOOM NO:16/1 İÇ KAPI NO:72 ŞİŞLİ / İSTANBUL / TÜRKİYE

ŞUBE ADRESİ: SELİMPAŞA MAH. ORTAKÖY SANAYİ BÖLGESİ 6205 SOK. NO:9 SİLİVRİ / 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 SALES OF SERVICES, IMPORT AND EXPORT OF MEDICAL PRODUCTS (STERILE AND NON STERILE MASK, BONNET, OVERSHOE, GLOVE, WORK CLOTHING, DEAD BODY BAG, MEDICAL OVERALLS, WET WIPES, DISINFECT WIPES) MEDİKAL ÜRÜNLERİN (STERİL VE NON STERİL MASKE, BONE, GALOŞ, ELDİVEN, İŞ KIYAFETİ, CESET TORBASI, MEDİKAL TULUM, ISLAK MENDİL, DEZENFEKTAN MEDİL) ÜRETİMİ VE SATIŞI HİZMETLERİ, İTHALATI VE İHRACATI

:: Certificate No :: TR52502H

Date of initial registration	**30 May 2020**
Date of this Certificate	**30 May 2020**
Surveillance audit on or before	**29 May 2021**
Recertification Due / Certificate expiry	**29 May 2023**

This Certificate is property of Staunchly Management & System Services Ltd. and remains valid subject to satisfactory surveillance audits.

Director

STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.
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For precise and updated information concerning the present certificate mail to info@staunchlyservices.com

EUROLAB Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

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2020140519

Report No:	2020140519
Applicant:	**DİGİSEAT MÜŞTERİ HİZM. VE TEKN. A.Ş.** Esentepe Mh, Kore Şehitleri Cd, İstanbloom, No 16/1, No 72 Şişli, İstanbul, TURKEY
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Sample Accepted on:	08.05.2020
Report Date:	15.05.2020
Total number of pages:	9 (Pg)

Sample ID: **FACE MASK**

Medical surgical protective masks (3ply) – Üç katlı medikal cerrahi koruma maskesi

	TEST	METHOD	Specimen	RESULT
*	**Medical face masks - Requirements and test methods**	**UNI EN 14683+AC 2019**	**Medical and surgical mask (3ply)**	**PASS** **TYPE IIR**

Seal

Customer Representative
Hasan KUTLU

Laboratory Manager
Hava SARIAYDIN

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EUROLAB ® (TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.)

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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Requirements and test methods

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. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

General

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

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

General

Describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.

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 B.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.

Incubate all the plates at (37 ± 2) °C for (48 ± 4) h.

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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;

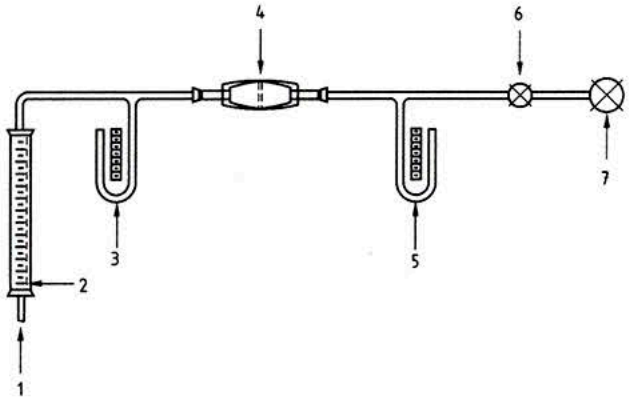
C is the mean of the total plate counts for the two positive control runs;

T is the total plate count for the test specimen.

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.

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.

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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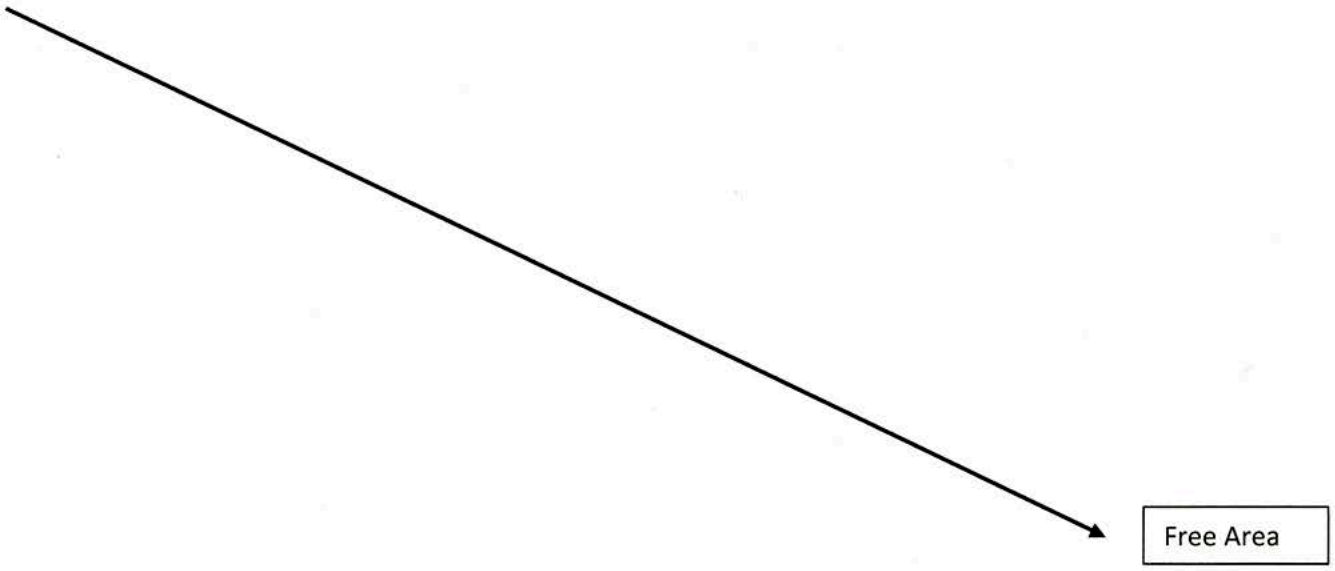
TEST RESULTS

EN 14683 Inspection

SAMPLE : FACE MASK

Test	Type IIR	Result	Evaluation
Bacterial filtration efficiency (BFE), (%)	≥ 98	99,21	PASS
Differential pressure (Pa/cm2)	< 60	23	PASS
Splash resistance pressure (kPa)	≥ 16	16	PASS
Microbial cleanliness (cfu/g)	≤ 30	21	PASS



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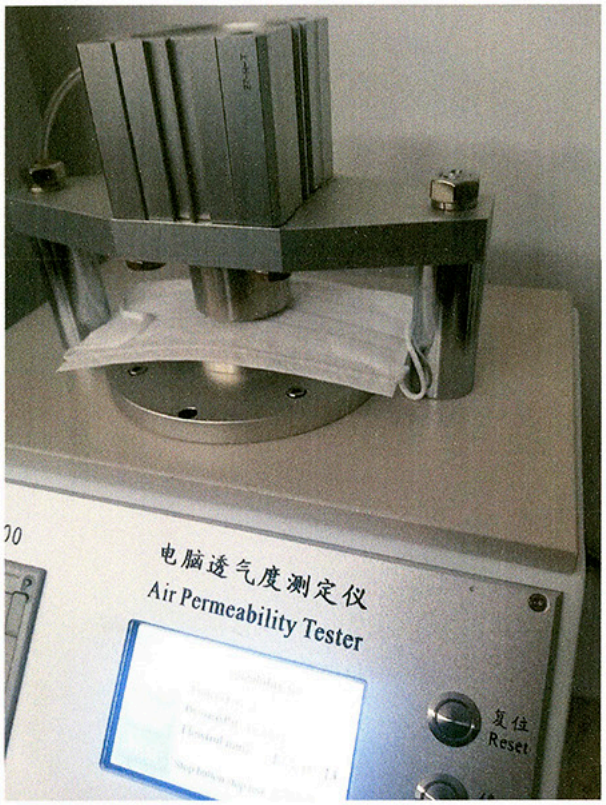
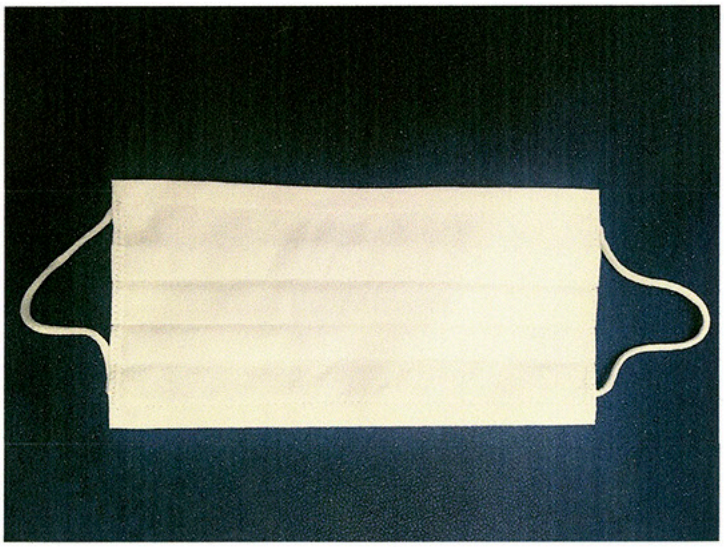
MASK IMAGES UNDER TEST





End of Report

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