



MEDICALGLOVES & MASK

CERTIFICATE THE TYP II R MASKE



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

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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



MEDICALGLOVES & MASK



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



MEDICALGLOVES & MASK



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 İstanbul No:16/1 İç Kapı No 72 Şişli İSTANBUL / TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: DIGIMASK

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.

İSTANBUL –22/07/2020



Suat KACMAZ

UNIVERSAL CERTIFICATION

Genel Müdür



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 executed annually following the surveillance audits, updating the publication date without changing the certificate number.



MEDICALGLOVES & MASK

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
İSTANBUL / TURKEY

PRODUCT DESCRIPTION

Layered and molded medical device classified in the Class 1 - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Brand Name: DIGIMASK

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 Bacterial 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.

General Manager
22/07/2020





MEDICALGLOVES & MASK



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 dokümanle 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 tedarikçilerinde biyo uyumluluk şartlarını gözetdiği 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 multivasının 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 I tıbbi yüz maskeleri yalnızca hastalar veya diğer kişiler tarafından salgınlar durumunda riskin düşürülmesi amacıyla kullanılmalıdır. Tip I maskeler, 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.

Laboratuvar 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





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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	Gereklikler	Sonuç	Sınıflandırma
Bakteri Filtrasyon Verimliliği (BFE), (%)	≥ 95 % – Tip I	98,8 %	Tip I
	≥ 98 % – Tip II		Tip II
	≥ 98 % – Tip IIR		Tip IIR
Diferansiyel Basınç (Pa/cm ²)	< 40 – Tip I	23,9	Tip I
	< 40 – Tip II		Tip II
	< 60 – Tip IIR		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	29	Tip I
	≤ 30 – Type II		Tip II
	≤ 30 – Type IIR		Tip IIR
Nihai Performans Sınıflandırması			Tip IIR

– Rapor Sonu –

Suat KACMAZ
UNIVERSAL CERTIFICATION
Director



UFR-383 12.12.2018 Rev.01



MEDICALGLOVES & MASK

EU DECLARATION OF CONFORMITY

MANUFACTURER

DIGISEAT MÜŞTERİ HİZMETLERİ VE TEKNOLOJİ ANONİM ŞİRKETİ
Esentepe Mahallesi Kore Şehitleri Caddesi İstanbul No:16/1 İç Kapı No 72 Şişli
İSTANBUL / 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: DIGIMASK

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
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- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Splash Resistance Pressure

MARKING, LABELLING

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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.

General Manager
22/07/2020

**DIGISEAT MÜŞTERİ HİZMETLERİ
VE TEKNOLOJİ ANONİM ŞİRKETİ**
Esentepe Mahallesi Kore Şehitleri Caddesi İstanbul
No:16/1 İç Kapı No 72 Şişli-İSTANBUL





MEDICALGLOVES & MASK



DECLARATION OF COMPLIANCE

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

Name and address : Esentepe Mahallesi Kore Şehitleri Caddesi İstanbul
No : 16/1 İç Kapı No 72 Şişli /İstanbul /Türkiye

Factory Address : 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/cm ²)	≤ 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



TEST / INSPECTION REPORT
EUROLAB LABORATORY SERVICES
TÜRKİYE TESTİ KONTROL VE BELGELEME A.Ş.



Test Conducted by :

Merkez Mh. Gençosman Cd. No 11 / A. GÜNGÖREN / İSTANBUL
Tel: 0212 702 20 50 Fax: 0212 909 21 10
Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Test Lab. Adres :

5190243E002

Issue Date : 08.05.2020 **Report No:** 3020040519 **Date:** 15.05.2020

UNI EN 14683+AC

Revision Date /No: 2019

The undersigned herewith declares 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.

KURULUŞ ONAYI; Adı Soyadı : Müştak AKDAG
Görevi : General Manager
Date : 16.05.2020 / İSTANBUL
İmza /Kaşe :

CE



This certificate is valid with the report with 15.05.2020 date, and with the manufacturer's approval.

Esentepe Mah. Kore Şehitleri Caddesi İstanbul No: 16/1 İç Kapı No 72 Şişli /İstanbul /Türkiye onayı içerdiği takdirde geçerlidir.

SYK SINAİ YATIRIMLAR VE DANIŞMANLIK LİMİTED SİRKETİ

T: +90 212 270 74 43 F: +90 212 270 74 54 e-mail: info@sykdanismanlik.com WSP : +90 532 578 16 32
Teletipa Caddesi 236/2 Post.Kodu : 34110 Gültape -Kağıthane- İstanbul / TÜRKİYE
Vergi Dairesi : Zincirlikuyu Vergi No : 1840501751 Ticaret Sicil : 170 967642



MEDICALGLOVES & MASK

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



FQC, India & Head Office
FQC First Quality Certification Pvt. Ltd.
SDD 37, Sector 12, Panchkula - 134106, Haryana, India
T: +91 172 6535975 / F: +91 172 4416601
www.fqc.com info@fqc.com

FQC, Turkey & Critical Location
FQC Maslak Anası Belgeleendirme ve Eğit. Hiz. A.Ş.
Cevizli Mah. Tansel Cad. No:12 Kat:4 D: 28-29 Maltepe / İstanbul / Türkiye
T: +90 216 444 21 41 / +90 216 457 89 08 F: +90 216 457 98 00
www.fqc.com.tr info@fqc.com.tr

Bu belge, müşterinin FQC ile kurulan ve sözleşme partisinin uyguladığı sürece geçerlidir. Sertifika geçerlilik durumu FQC'nin internet sitesinden izlenebilir.
This document shall remain valid as long as the customer abides FQC rules and terms of the contract. Certificate validity may be checked on FQC website.



MEDICALGLOVES & MASK

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



FQC Uluslararası Belgelendirme ve Eğitim Hizmetleri Anonim Şirketi
Ceviz Mahallesi Tarsal Caddesi No:12 K:4 D:28-29 Maltepe / İSTANBUL / TÜRKİYE T: +90 216 444 21 41 / +90 216 457 69 08 F: +90 216 457 98 89
Bu belge, müşterinin FQC'nin kurallarına ve sözleşme şartlarına uyduğu sürece geçerlidir. Sertifika geçerlilik durumu FQC internet sitesinden takip edilebilir.
This document shall remain valid as long as the customer obeys FQC rules and terms and the contract. Certificate validity may be checked on FQC website.
www.fqc.com.tr info@fqc.com.tr



MEDICALGLOVES & MASK

FIRST QUALITY CERTIFICATION



CERTIFICATE

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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 Environmental 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
Maltepe / İstanbul / Türkiye



FQC, India & Head Office
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FQC, Turkey & Critical Location
FQC Global Aracı Belgelendirme ve Eğit. Şirk. A.Ş.
Cemilî Mah. Taneli Cad. No:12 Kat:4 D: 28-29 Maltepe / İstanbul / Türkiye
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www.fqc.com.tr info@fqc.com.tr

Bu belge, müşterinin FQC'nin kurallarına ve sözleşme şartlarına uyduğu sürece geçerlidir. Sertifika geçerlilik durumu FQC'nin internet sitesinde takip edilir.
This document shall remain valid as long as the customer obeys FQC rules and terms of the contract. Certificate validity may be checked on FQC website.

MEDIZINISCHE OP-MASKEN – FFP2 MASKE – FFP3 MASKEN – KINDER MASKEN – HAND DEZENFEKTION



MEDICALGLOVES & MASK

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



FQC Uluslararası Belgelendirme ve Eğitim Hizmetleri Anonim Şirketi
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MEDICALGLOVES & MASK

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
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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 KİYAFETİ, CESET TORBASİ, 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



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MEDIZINISCHE OP-MASKEN – FFP2 MASKE – FFP3 MASKEN – KINDER MASKEN – HAND DEZENFEKTION



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



Report No: 2020140519
Applicant: DİĞİSEAT MÜŞTERİ HİZM. VE TEKN. A.Ş.
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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 SARAYDIN



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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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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;

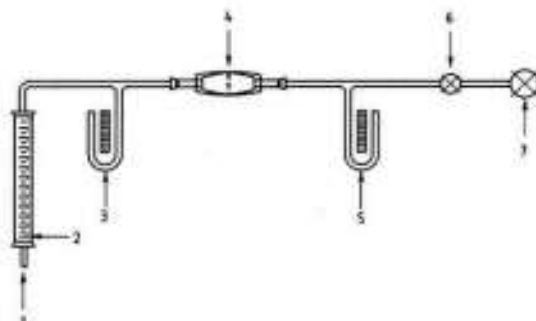
C is the mean of the total plate counts for the two positive control runs;

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/cm ²)	< 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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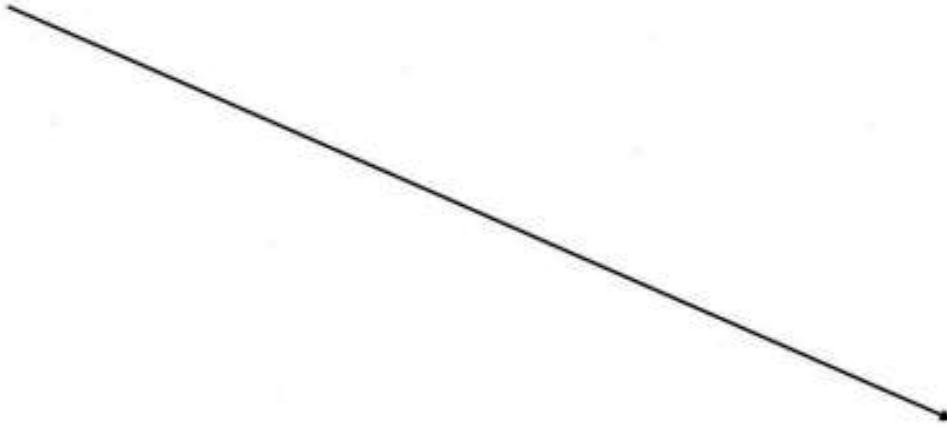


TEST RESULTS

EN 14683 Inspection

SAMPLE : FACE MASK

Test	Type IIR	Result	Evaluation
Bacterial filtration efficiency (BFE), (%)	≥ 98	99,21	PASS
Differential pressure (Pa/cm ²)	< 60	23	PASS
Splash resistance pressure (kPa)	≥ 16	16	PASS
Microbial cleanliness (cfu/g)	≤ 30	21	PASS



Free Area

FRS3-POD8-10-2018/004



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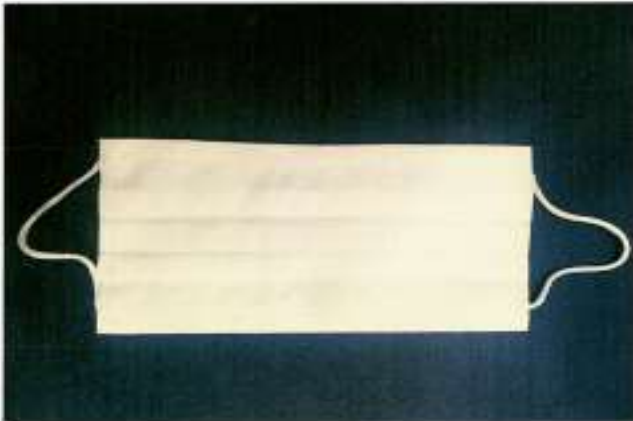
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MASK IMAGES UNDER TEST



End of Report



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VOLKS MASKEN BESTE SICHERHEIT