



MULTI-USE MASK



CONSTRUCTION
100% Cotton



DIMENSIONS
1750x950mm



WASHING INSTRUCTIONS



Hand Wash
Normal



Wash at or
Below 60°



Tumble Dry,
Low Temp



Do Not
Dry Clean



Do Not
Iron



Minimum
5 Washing



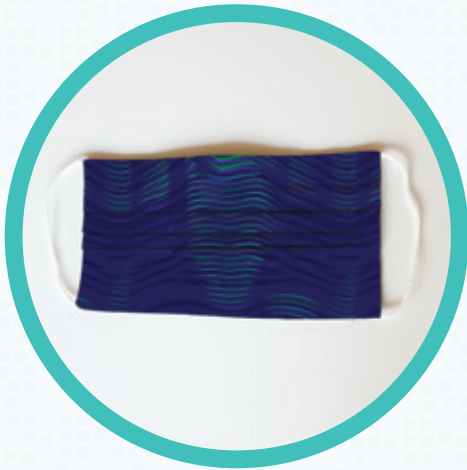
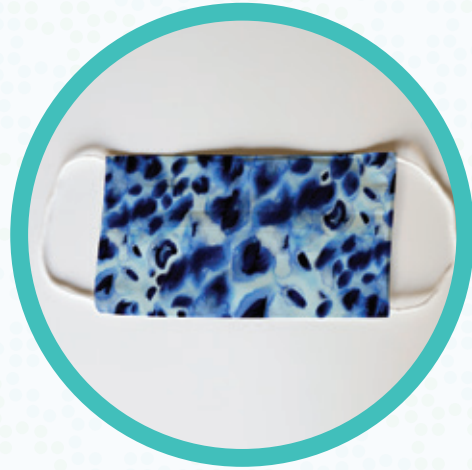
PROPERTIES

Suitable for all-day use
Comfortable breathing
Sitting on the face providing nose metal



CERTIFICATES

CE Mark,
FDA,
ISO 13485:2016, ISO 9001:2015
Type I Technical Specification









AT UYGUNLUK BEYANI

EC DECLARATION OF CONFORMITY

İMALATCI: İDEA MODA KONFEKSİYON SANAYİ TİCARET LİMİTED ŞİRKETİ
Manufacture: İDEA MODA KONFEKSİYON SANAYİ TİCARET LİMİTED ŞİRKETİ

ADRES: MERKEZ MH. GÜVENÇ SK. BOMONTI IS MRK.NO.3 İÇ KAPI NO: 18 ŞİŞLİ / İSTANBUL
Address: MERKEZ MH. GÜVENÇ SK. BOMONTI IS MRK.NO.3 İÇ KAPI NO: 18 ŞİŞLİ / İSTANBUL

TEKNİK DOSYAYI DERLEYEN YETKİLİ KİŞİNİN ADI: GÜNAY BİREL
Name of the person authorized to compile the technical file: GÜNAY BİREL

Aşağıda tanımlanmış olan ürünler için 93/42/EEC Tıbbi Cihaz Yönetmeliğinde uygulanabilen gerekliliklerin yerine getirildiğini ve sorumluluğun alınmış olduğunu beyan ederiz.

The undersigned company certifies under its sole responsibility that the item of building materials specified below satisfies the requirements of the 93/42/EEC Medical Device Directive

Aşağıda tanımlanan ürünler, iç üretim kontrollerine ait proseslerle İDEA MODA KONFEKSİYON SANAYİ TİCARET LİMİTED ŞİRKETİ sorumluluğunda kontrol edilmiştir.

The item of equipment identified below has been subject to internal manufacturing check with monitoring of the final assessment by İDEA MODA KONFEKSİYON SANAYİ TİCARET LİMİTED ŞİRKETİ

ÜRÜN:

Product:

MASKE

MASK

MODEL - TİP:

Model - Type:

MASKE, 3 KATLI VE TEK KULLANIMLIK
3-PLY, SINGLE USE DISPOSABLE MASK

YÖNETMELİKLER:

Directives:

93/42/EEC Tıbbi Cihaz Yönetmeliği
93/42/EEC MEDICAL DEVICE DIRECTIVE

SINIF:

Class:

SINIF 1 (STERİL VE ÖLÇME FONKSİYONLARI OLMAYAN)
CLASS 1 (NON-STERILE FACE MASK)

UYGULANAN HARMONİZE STANDARTLAR:

Applicable Harmonized Standards:

TS EN 14683:2019+AC
EN 14683:2019+AC

DÜZENLENME TARİHİ:

Date of issue:

22.05.2020
22.05.2020

YETKİLİ KİŞİNİN ADI VE GÖREVİ:

Name and position of authorized person:

GÜNAY BİREL / GENEL MÜDÜR
GÜNAY BİREL / GENERAL MANAGER

KURULUŞ YETKİLİSİNİN İMZASI

Signature of authorized person


İDEA MODA®
İDEA MODA KONFEKSİYON SANAYİ
TİCARET LİMİTED ŞİRKETİ
MERKEZ MH. GÜVENÇ SK. BOMONTI IS MRK.
NO.3 İÇ KAPI NO: 18 ŞİŞLİ / İSTANBUL
T.C. V.D. 478 054 7300





2020

CERTIFICATE OF REGISTRATION

This certifies that:

IDEA MODA KONFEKSIYON SAN. TIC. LTD. STI.
Siracevizler Cad. Guvenc Sok No.3 Bomonti Ismerkezi
Kat 2, D:18-23 Sisli
Istanbul , TR 34381

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	10074087
Device Classification Name:	MASK, SURGICAL
Product Code:	FXX
Regulation Number:	878.4040
Official Correspondent and U.S. Agent:	Registrar Corp 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

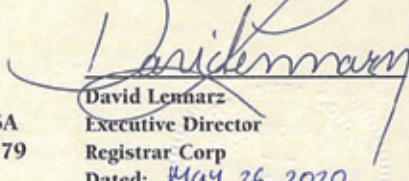
Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

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Registrar Corp

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info@registrarcorp.com • www.registrarcorp.com



David Lennarz
Executive Director

Registrar Corp
Dated: May 26, 2020

 **KAYNES®**

Sertifika

Certificate

İDEA MODA KONFEKSİYON SANAYİ TİCARET LİMİTED ŞİRKETİ

ISO 9001:2015

Kapsam/ Scope

TEKSTİL VE TEKSTİL PROMOSYON ÜRÜNLERİ, DIŞ GIYİM EŞYASI İMALATI, DOKUMA, ÖRME (TRİKAJ) VE TIĞ İŞİ (KROŞE), VB KUMAŞTAN OLANLAR (KABAN, PALTO, CEKET, PANTOLON, TAKIM ELBİSE, DÖPIYES, ANORAK, YAĞMURLUK, GECE KIYAFETİ VB.)

CERRAHİ , TIBBİ VE ORTOPEDİK ALET VE CİHAZLARIN TOPTAN TİCARETİ

PRODUCTION OF TEXTILE AND TEXTILE PROMOTION PRODUCTS, WOVEN WEAR, WEARING, KNITTING (TRICOTAGE) AND JEWELRY (KROSE), ETC. SHOES, PALO, JACKET, TROUSERS, TOOL DRESS, DIPPERS, ANORAK, RAINFALL, NIGHT CLOTHES ETC.

SURGICAL, MEDICAL AND ORTHOPEDIC TOOLS AND DEVICES WHOLESAL TRADE

Bu sertifika ile yukarıda adı geçen kuruluşun Kalite Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.

Belge No/ Certification Number	:KYS-2020-740
İlk Kayıt Tarihi	:10.04.2020
Basım Tarihi	:14.04.2020
Geçerlilik tarihi	:10.04.2022

Belgelendirme Müdürü / Certification Manager

Kaynes Uluslararası Eğitim Belgelendirme Dan Ltd. Şti.

 KAYNES®

Sertifika

Certificate

İDEA MODA KONFEKSİYON SANAYİ TİCARET LİMİTED ŞİRKETİ

ISO 10002:2018

Kapsam/ Scope

TEKSTİL VE TEKSTİL PROMOSYON ÜRÜNLERİ, DIŞ GIYİM EŞYASI İMALATI, DOKUMA, ÖRME (TRİKAJ) VE TIĞ İŞİ (KROŞE), VB KUMAŞTAN OLANLAR (KABAN, PALTO, CEKET, PANTOLON, TAKIM ELBİSE, DÖPIYES, ANORAK, YAĞMURLUK, GECE KIYAFETİ VB.)

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PRODUCTION OF TEXTILE AND TEXTILE PROMOTION PRODUCTS, WOVEN WEAR, WEARING, KNITTING (TRICOTAGE) AND JEWELRY (KROSE), ETC. SHOES, PALO, JACKET, TROUSERS, TOOL DRESS, DIPPERS, ANORAK, RAINFALL, NIGHT CLOTHES ETC.

SURGICAL, MEDICAL AND ORTHOPEDIC TOOLS AND DEVICES WHOLESALE TRADE

Bu sertifika ile yukarıda adı geçen kuruluşun Müşteri Memnuniyet Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.

Belge No/ Certification Number	:KYS-2020-876
İlk Kayıt Tarihi	:09.04.2020
Basım Tarihi	:14.04.2020
Geçerlilik tarihi	:10.04.2021

Belgelendirme Müdürü / Certification Manager

Kaynes Uluslararası Eğitim Belgelendirme Dan Ltd. Şti.

 ideacare	FACE MASK TYPE I TECHNICAL SPECIFICATIONS
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Designation	Face mask
Description	Multiple-use face mask, 2-ply, woven, Non-sterile, with fixation lace,
Destination / use	Daily-use

Composition	%100 cotton, Woven
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Characteristics	Fitting way : with fixation lace Lenght : 175mm \pm 5mm Width : 95mm \pm 5mm Earloop lenght : 400mm \pm 5mm Nastril piece lenght : between 120mm and 140mm \pm 3mm
Packing	Dispenser box of 50 masks 12 x 21 x 8 cm
Packaging	Carton of 60 boxes 60 x 42 x 45 cm
Limit date of storage	6 months

 ideacare	TECHNICAL SPECIFICATIONS
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Manufacturing

By IDEAMODA – registered ISO 9001 and 13485

TECHNICAL PERFORMANCES	
Characteristics	Datas
Outlayer Inner layer	Weight : 140 gr/m ² ±5% Weight : 140 gr/m ² ±5%
Bacterial filtration efficiency BFE	≥ 95% (BFE medium 95,4%)
Mean particle size MPS	3µm ±0,3µm
Respiratory resistance	Differential Pressure ΔP < 29,4 Pa
Assembling	Stitching

