



*Multi-use Mask*

Bio



*Protect ourselves without  
damaging our planet.*



### ***Construction***

100% Tencel



### ***Dimensions***

1750x950mm



### ***Washing instructions***



Hand Wash  
Normal



Wash at or  
Below 60°



Tumble Dry,  
Low Temp



Do Not  
Dry Clean



Do Not  
Iron



Maximum  
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



**FACE MASK TYPE I  
TECHNICAL SPECIFICATIONS**

**Designation** Face mask

**Description** Multiple-use face mask, 2-ply, woven,  
Non-sterile, with fixation lace,

**Destination / use** Daily-use

**Composition** %100 tencel,  
Woven

**Characteristics** Fitting way : with fixation lace  
Lenght : 175mm  $\pm$ 5mm  
Width : 95mm  $\pm$ 5mm  
Earloop lenght : 400mm  $\pm$ 5mm  
Nastiril 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

 <b>ideacare</b>	<b>TECHNICAL SPECIFICATIONS</b>
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**Manufacturing**

By IDEAMODA – registered ISO 9001 and 13485

<b>TECHNICAL PERFORMANCES</b>	
<b>Characteristics</b>	<b>Datas</b>
Outlayer	Weight : 150 gr/m <sup>2</sup> ±5%
Inner layer	Weight : 150 gr/m <sup>2</sup> ±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

# AT UYGUNLUK BEYANI

## EC DECLARATION OF CONFORMITY

**İMALATÇI:** 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. 470 056 7938





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

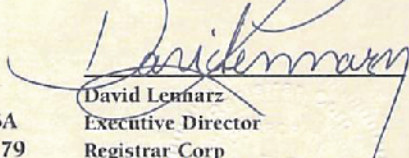
*Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does 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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David Lemarz  
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 ÇHAZLARIN 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 WHOLESALE 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 13485:2016

### 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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SURGICAL, MEDICAL AND ORTHOPEDIC TOOLS AND DEVICES WHOLESAL TRADE

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

Belge No/ Certification Number	:KYS-2020-215
İlk Kayıt Tarihi	:10.04.2020
Basım Tarihi	:14.04.2020
Geçerlilik tarihi	:10.04.2021

Belgelendirme Müdürü / Certification Manager

Kaynes Uluslararası Eğitim Belgelendirme Dan Ltd. Şti.