



Disposable Surgical Mask

With two soft elasticated loops for fixing behind the ears,
one size, non-sterile

 ideacare	SURGICAL MASK TYPE II TECHNICAL SPECIFICATIONS
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Designation	Surgical mask
Description	Single-use surgical mask, 3-ply, non woven polypropylene, Non-sterile, with fixation lace, class 1
Destination / use	Protection device for working environment for surgery, medical and dental examinations, industry

Composition	Latex free Mask : non woven POLYPROPYLENE Glass fiber free Filter layer meltblown
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Characteristics	Fitting way : with fixation lace Length : 175mm \pm 5mm Width : 95mm \pm 5mm Earloop length : 400mm \pm 5mm Nastril piece length : between 120mm and 140mm \pm 3mm
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Conformity	CE marking according to Rules (EU) 2017/745 Class : I According to Standard EN 14683
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Packing	Dispenser box of 50 masks 18,5x7,5x9,9
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Packaging	Carton of 50 boxes 50x38x38
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Limit date of storage	3 years
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 ideacare	TECHNICAL SPECIFICATIONS
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Manufacturing

By IDEAMODA – registered ISO 9001 and 13485

TECHNICAL PERFORMANCES	
Characteristics	Datas
Outlayer	Weight : 30g/m ² ±10%
Filter layer meltblown	Weight : 25g/m ² ±10%
Inner layer	Weight : 20g/m ² ±10%
Bacterial filtration efficiency BFE	≥ 98% (BFE medium 98,6%)
Mean particle size MPS	3µm ±0,3µm
Assembling	Ultrasonic welding
Wearing time recommended	5 hours maximum Change mask between two procedures After using the mask : see to disinfect one's hand



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:	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

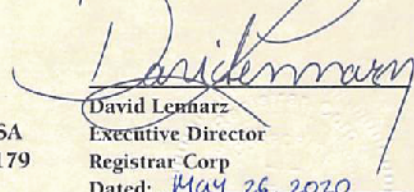
Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does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

Dated: May 26, 2020

 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.)

CERRAHİ, TIBBİ VE ORTOPEDİK ALET VE CİHAZLARIN TOPTAN TİCARETİ

PRODUCTION OF TEXTILE AND TEXTILE PROMOTION PRODUCTS, WOVEN WEAR, WEAVING, 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 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.

 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.)

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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.