



Disposable Protective Suit



With one piece hooded elastic band around the face opening, the hood can better fit the shape of face and enhance the protection effect.

The cuff uses an internal elastic band to further enhance tightness and protection.



Each seam is sealed with tape, and the waist is applied with an internal elastic band, which better enhance the seam protection and the fitness of the suit.



Elasticated waist and ankle for convenience and freedom of movement for extra comfort.



The protective suit is made of PP spunbond non-woven fabric laminated with PE film. The raw material is high in strength, soft in touch, skin-friendly, comfortable to wear, and strong in antistatic performance. It has good anti-infiltration performance, high filtering efficiency, surface moisture resistance, strength and air permeability, which allows it to effectively prevent dust and water.

ISO 13485:2016  
ISO 9001:2015  
ISO 10002:2018  
ISO 14001:2015  
ISO 45001:2018



## RAW MATERIAL SPECIFICATIONS

Composition	PP spunbond non-woven fabric laminated with PE film
Film	Breathable
Color	White

## TEST RESULTS

SPECIFICATION	UNIT	VALUE	TOLERANCE	TEST METHOD
Nonwoven Weight	g/m <sup>2</sup>	20	± %5	EDANA 40.3.90
PE Film Weight	g/m <sup>2</sup>	35		
Hotmelt Weight	g/m <sup>2</sup>	2		
Total Weight	g/m <sup>2</sup>	57		
Tensile Strength MD (at peak)	N /1 inch	40	± %20	EDANA 20.2.89
Tensile Strength CD (at peak)	N /1 inch	15	± %20	EDANA 20.2.89
Elongation MD (at peak)	%	80	± %20	EDANA 20.2.89
Elongation CD (at peak)	%	70	± %20	EDANA 20.2.89
Water Vapour Transfer Rate (WVTR)	38°C-90% RH 24h (Macon)	2000	± %20	WSP 70.5
Hydro Head	mmSS	2400	± %10	DIN-EN 20811
Lam.Peeling Strength (Nonprinted area)	N /1 inch	1,3	± %20	

Storage Condition ; Keep in cool,dry place away from open flame and sunshine  
 Guaranteed storage time: 1 year after manufacturing



SIZE	CHEST SIZE	LENGHT
S	118 cm	170-178cm
M	122 cm	176-184cm
L	125 cm	182-190cm
XL	130 cm	182-190cm
XXL	136 cm	194-202cm

## DIRECTIONS FOR USE

### Main Use Areas

5/6 model Protective coveralls of type KEEP protect workers against hazardous material particles (type 5) as well as against chemical liquid splashes (Type 6).

### Restrictions Of Use

Attention should be paid when removing the coveralls exposed to liquid or dirty and the contact with hazardous materials should be avoided. It is not designed for extreme hazardous conditions and toxic chemical substances. The coverall's seams do not constitute a barrier against infectious substances and are not protective. The user is the sole responsible and shall take the final decision regarding the usability for any application of the Protective coverall. In case that the coverall is used in combination with other personal protective products, it is necessary to tie the cuffs to the gloves, the Wristbands to the boots and the respiratory device to the cap. The user is the sole decision maker regarding the conformity of the combination. It is absolutely necessary for the person wearing the coverall to be properly grounded. These conditions can easily be created by wearing the appropriate shoes. If the characteristics of the clothing are not considered, wearing the chemical protective clothing can create a heat stress. The product life cycle and the effect of the working environment on the usage comfort should be planned in advance. Appropriate underwear measures will help to reduce the heat stress.

### How To Wear It?

Be sure that the current area is clean. Open properly the packaging without damaging the product. Open the zipper of the product and then, pass firstly your feet through the coverall not crumple and break too much the coverall when doing this operation. Close the zipper after wearing the coverall's cap. Remove the adhesive tape on the zipper side and paste it to the coverall. Do not fold it. In this way the permeability of the zipper will be avoided.

### Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °. If stored on suitable conditions, it is recommended to use it within 3 years after the production date.

### Destruction! Recycling

The uncontaminated products can be treated as general waste or can be recycled. And the contaminated products should be treated as hazardous wastes and should be disposed of in accordance with the rules laid down by law.



Do not iron



Do not machine dry



Do not bleach



Do not wash



Do not dry clean



Single use



2020

**CERTIFICATE OF REGISTRATION**

*This certifies that:*

**IDEA MODA KONFEKSIYON SAN. TIC. LTD. STI.**  
**Siracevizler Cad. Guvenç Sok No.3 Bomonti İsmarkezi**  
**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>SUIT, SURGICAL</b>
Product Code:	<b>FXO</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

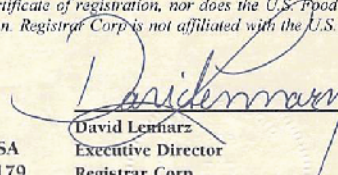
*Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does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

Registrar Corp

Dated: May 26, 2020



# 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 TİĞ 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 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.



# 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 TİĞ 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 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.



# 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. )

CERRAHİ, TIBBİ VE ORTOPEDİK ALET VE CİHAZLARIN TOPTAN TİCARETİ

PRODUCTION OF TEXTILE AND TEXTILE PROMOTION PRODUCTS, WOVEN WEAR, WEARING, KNITTING (TRICOTAGE) AND JEWELRY (KROŞE), 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 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.



# Sertifika

Certificate

İDEA MODA KONFEKSİYON SANAYİ TİCARET LİMİTED ŞİRKETİ

## ISO 14001:2015

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

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

Belge No/ Certification Number	:KYS-2020-879
İlk Kayıt Tarihi	:11.04.2020
Basım Tarihi	:14.04.2020
Geçerlilik tarihi	:10.04.2021

Belgelendirme Müdürü / Certification Manager

Kaynes Uluslararası Eğitim Belgelendirme Dan Ltd. Şti.

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# Sertifika

Certificate

İDEA MODA KONFEKSİYON SANAYİ TİCARET LİMİTED ŞİRKETİ

## ISO 45001:2018

### Kapsam/ Scope

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Bu sertifika ile yukarıda adı geçen kuruluşun İş Güvenliği Kültür Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.

Belge No/ Certification Number	:KYS-2020-987
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.