# estila ® MEDIKAL

"The best protection for health"

# DISPOSABLE PROTECTIVE SUIT





# PRODUCTION CAPACITY

Our company is in the area of 1500 m2 in Turkey 125 with staff constantly meet their needs It serves.

# CERTIFICATION

Our products are internationally valid certifications have been made and It is ready.

# SCIENTIFIC TESTING STAGES

Against all external factors, our products have passed many tests and reached the World standard.

Founded in 2019 in Tokat Turhal Estilo Fashion Textiles, the industry serves as one of Turkey's leading manufacturer of disposable bags.

Our company, which has been carrying the future by combining knowledge, design and technology since its establishment, together with its strong, innovative and professional team, designs and manufactures protective equipment.

Our company, which has an innovative and visionary perspective in the medical protective equipment market, focuses on the needs of our customers and as a solution partner. has adopted to work.

Our company, which is aware of the importance of employee happiness and development, has adopted the principle of investing in its employees with training programs.

Estilo Moda Tekstil respects the rights and values of the entire society, especially its employees, and social responsibility awareness is the basis of all its activities.

# **Production Factory**



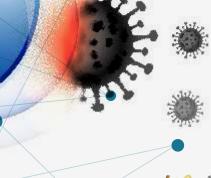
"The best protection for health"

# 99% PROTECTION AGAINST VIRUSES

Disposable laminated coverall is protective feature against external factors. "The laminated fabric has a protective feature against any contact such as wind, water coming from the outside.









# **Product packaging and packaging**

"The best protection for health"





Our company 150,000 pieces daily 3,600,000 pieces per month has the power of production.



Disposable Protective Suit

"The best protection for health"







# **Product View**

"The best protection for health"



# One-piece Hooded Design

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





# Seam sealed tape workmanship

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.





# **Elastic cuff**

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

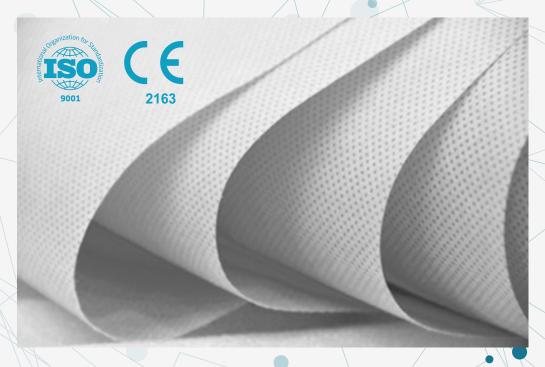








# **Fabric Description**



# **Protective Clothing** Category III













# "The best protection for health"

As a national key responsive supply entity, Estilo Medikal's Procurement of fabric and trims is in accordance with national standards.

The entire process and raw materials are up the highest standards.

The fabrics, seal tapes and zippers are in accordance with national standards. As a national key responsive supply entity, Estilo Moda Textile assists the government in developing various new protective suits.

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, skinfriendly, comfortable to wear, and strong in antistatic performance.

It has good anti-infiltration performance, high filtering efficiency, surface moisture resistance, strength and air permeabilty, which allows it to effectively prevent dust and water.







# **Disposable Protective Coverall**

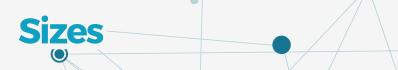




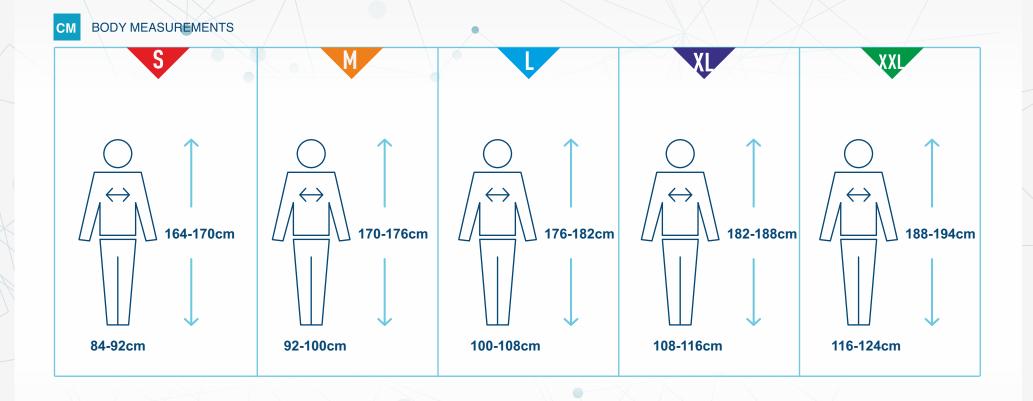
# **Disposable Protective Coverall**







"The best protection for health"





# **Disposable Foot Protector**





# **Disposable Medical Apron**









# **Tight**

The edges are liquid-tight seamless and as one piece
It is produced.
Ball bags with stitched edges
liquid will leak
It is not recommended to use.

#### **General features**

It is black color.

It is 80x220 cm in size for adults.

Liquid and odor sealing feature.

Optional custom sizes are also produced.

There are 6 handles.

It has a carrying capacity of 200 kg.

Top zipper, 2 cursors.

There is space for ID information in transparent A5 size.





# **Disposable Mask**





"The best protection for health"





Estilo, with a staff of almost 500, daily manufactures 50.000 Protective Suits



# "The best protection for health"

# **Directions for use**







#### SAFETY INSTRUCTION

All protective clothing, before use, torn, hole, ripped, against defects and failures that may cause negativity like dirt should be checked. Waste and dirty should never be worn.

#### **ATTENTION**

Playing with the bag is dangerous. May cause choking. Pleasekeep away from children and infants.

#### Fabric: 53/63 GR / SMS FEATURES

- It is sewn from premium quality PP NonWoven fabric light and easy to wear.
- It is a soft, solid, breathable fabric.
- · A hooded zipper is used to increase protection against less hazardous chemicals and dust .
- Flexible head for easy mounting on face mask.
- Flexible wrist and foot seams to limit entry and exit protection.
- Elastic waist for maximum comfort and protection.
- Border stitching technology to maximize protection and minimize hair growth and hair loss.

#### **USAGE AREAS**

- These overalls are; It is used to protect from less hazardous materials and prevent contamination.
- It is produced to protect the person against hazardous liquid wastes and simple toxins in the air.

#### **STANDARDS**

- The product is category III and complies with protective clothing standardsagainst dust particles and certain liquid chemical splashes.
- TYPE 5: EN 13982-1: 2004 + A1: 2010
- TYPE 6: EN 13034: 2005 + A1: 2009
- Conforms to Protective Clothing Standards.
- EN 14126
- EN 14362-1: 2012
- EN1149-1: 2006
- EN 1149-5: 2008
- Products Antistatic
- It does not contain silicone and does not cause allergies.

#### SYMBOLS





















#### EU TYPE EXAMINATION CERTIFICATE

Certificate Noc 2163 - PPE + 653

Electrostatic Protective Clothing against Infactive Agents; Type 5-th Providing Protection to the Full Body against Airborne Solid Particulation Type 6-B Offering Limited Protective Performance against Liquid Chemicals

SSTEED MODA TEKSTEL TARDE HAVVANCILIE INSAAT IC DIS TIC VESAN, LTD. STE

Gold Owner Pape Mah. Holey Solt. No:2/A Tartist TOKAT / TURKEY are rected and evaluated according to

879 EHIZE:2003/AC:2004, EN ESO E2063-1:2004/A3:2010, EN 13634:2005+A1:2005. EN 1149-8:2008

Based on the type constitution conducted with the evaluation of 3cd reports, included life according to Personal Personive Equipment Regulation (EL7) 2016/ESS Assets 5, it is approved that the predict more than requirement of the regulation. The details of recorded requirement compliance is given to technical open manhood KKD-2163-653

#### Product Definition

Broad Names ESTILO, Model: ES 6124

Resistance to penetration by continuousland liquids under hydrostatic pressure. Class 3. Resistance to peretration by infective agents due to mechanical contact with satisfaces contact and conteminant liquid: Class 2
Resistance to posetration by conteminant liquid screenis: Class 1

Resistance to proceeding by communicated solid particles: Class 2 Here by the manufacturer is offered to any weithed hedy master (2163) and on fix CE mark,

- as shown below, on the Cotegory III product roadels given above, with; booking on appropriate FO Destruction of Conferency according to Personal Protective Equipment Regulation
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This sertificate is teitially insued on 1804/2009 and will be valid for 5 years if there is no change in the relevant humanised standard afferting the econsist health and safety sequencess.





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# "The best protection for health"

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# **Certificates**

# "The best protection for health"

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## SERTIFIKA / CERTIFICATE

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GAZÍOSMAN PASA MAHALLESÍ KOLEJ SOK, NO:2-A TURHAL/TOKAT/TURKEY

Kuruluşunum "TEK KULLANIMLIK CERRAHÎ MASKE, TEK KULLANIMLIK YÛZ MASKESÎ, TEK KULLANIMLIK CERRAHÎ ÖNLÜK, TEK KULLANIMLIK MEDÎKAL ÖNLÜK, TEK KULLANIMLIK CERRAHÎ ÖNLÜK, TEK KULLANIMLIK MUAYENG ÖRTÜLERÎ, TEK KULLANIMLIK ELDÎVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONÎI, GALOŞ, SÎKON MASKE, FÎLTIREÎ Î SÎLKON MASKE, KORUYUUL GÖZLÜK, TEK KULLANIMLIK

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For scope "SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GRAFF, SINGLE USE MEDICAL GOWN, SINGLE USE SURGICAL DRAPE, SINGLE USE INSLITATION, SINGLE USE, SINGLE USE SLEEVE, SINGLE USE COVER, PRODUCTION AND SALES"

ISO 9001:2015
KALİTE YÖNETİM SİSTEMİ
Quality Management System

Kurduğumı ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA if confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / Certificate Nansher Sertifika Kodu / Certificate Code Sertifika Yayın Tarihi / Certificate Issue Date Sertifika Geperlilik Tarihi / Certificate Valldity Date Sertifika Periyadu / Certificate Period : 20041534 : ESTÎLO MODA

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# NVA QUALITY CERTIFICATION



#### SERTIFIKA / CERTIFICATE

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GAZÍOSMAN PASA MARALLESÍ KOLEJ SOKAK NO:2-A TURBAL / TOKAT / TURKEY

Kuruluşunun <sup>46</sup> DIŞ GİYİM EŞYASI İMALATI, DOKUMA, ÖRME (TRİKOTAI) VE TIĞ İŞİ (KROŞS), VIR. KUMAŞTAN OLANLAR (KABAN, PALTA, CEKET, PANTOLOLA, TAKIM ELSEĞ, BÖĞPIYES, ANDRAK, YAĞMUŞBLIK, GERE KIYAFELLEN 'EŞI İŞ GİYSLERİ VE TERZÜLERIN FALLIYETLERİ İMRİÇ)

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#### ISO 13485: 2016

#### TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ Medical Devices Quality Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıdı belirtilen standardın şarılarını kurşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

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# Certificate of Registration 2020

This is to certify that the registration of

### ESTILO MODA TEKSTIL TARIM HAYVANCILIK INSAAT IC DIS TICARET VE SANAYI LIMITED SIRKETI

GAZI OSMAN PASA MH KOLEJ SK NO 2A TURHAL

TOKAT, TURKEY- 60300

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 Estilo Moda Tekstil Tarim Hayvancilik Insaat Ic Dis Ticaret Ve Sanayi Limited Sirketi

Owner/Operator Number 10075514

Date of Registration June 17, 2020

Date of Expiration December 31, 2020

US Agent Liberty Management Group Ltd.

Device Listing Numbers See Annex
Certificate Number 3006170320

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President Liberty Management Group LTD. Dated: June 17, 2020



# Certificate of Registration 2020

#### **Annex - Device Listings**

Listing Number	Code	Device Name - Proprietary Names
D408824	OEA	Non-Surgical Isolation Gown - ESTILO MODA- Disposable Protective Isolation Gown, ESTILO MODA- Disposable Protective Isolation Coverall
D408825	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance - ESTILO MODA - Disposable Medical Mask



# **Certificates**

# "The best protection for health"

#### EC DECLARATION OF CONFORMITY FOLLOWING THE EUROPEAN DIRECTIVES

93/42/EEC and 2007/47/EC - Medical Device Directive

93/42/EEC and 2007/47/EC - Tubbi Cibaz Direktiff. YÖNETMELİKLERİ'NE GÖBE AT UYGUNLUK BEYANI

Certificate No./ Beige No.: UB-PPE 10022020

ESTILO MODA TEKSTIL TARIM HAYVANCILIK INSAAT IC DIS Manufacturer's Name

TIC, VE SAN, LTD, STL.

Manufacturer's address Gazi Osman Pasa Mah. Kolej Sok. No:2/A Turhal/TOKAT/TURKEY

Cretici adresi. Phone (Tel) +00 356 379 88 82

E-mail (E-posts) info@estilomodatekstil.com.tr.

Authorised person to compile the relevant Halil Ibrahim TÜRKIDİL technical documentation

Toknik dosyayı hazırlamakta yetkili olan ve

Gazi Osman Pasa Mah. Kelej Sok. Ner 2/A Turhal/TOKAT/ TURKEY

Türkiye'de yerleşik kişinin adı ve adresi Product description

Crite tenentenase Kongucu Ayaklık (Non-staril,Senf I Staril yada öleme fonksiyona olmayari)

93/43/EEC and 2007/47/EC - Medical device directive ISO 13485:2016 - Medical devices - Quality management systems -

Protective Fact Cover (Non-sterile, Class Lost sterile or measuring)

Requirements for regulatory purposes

93/42/EEC and 2007/47/EC - Medical device directive, 1SO 13982-Harmonized European directive(s) vs 1:2004 -Protective clothing for use against solid particulates(type 5). Related Standard EN 13034:2005+A1:2009 -Protective clothing against liquid chemicals (Type6), EN 14126:2003+AC:2004 - Protective clothing -

Performance requirements and tests methods for protective clothing against infective agents, EN 1149-5: 2018 - Protective clothing -

Bgili Harmonize AT direktiflert ve Bgili Electrostatic properties

herewith declare that the product "Protective Foot Cover" are in confirmity with the provisions of the following assential requirements of 93/42/EEC and 2007/47/EC - MEDICAL DEVICE DIRECTIVE

and standarts when produced and applied in accordance with production and application instructions contained in the Technical File documentation.

Yukanda tarifi yapılan ürtinizmüz olan "Konzyucu Ayaklık"ın 93/42/EEC and 2007/47/EC - Tabbi Cânaz Direktifi ve. standartlar ile uyumla olarak ve Teknik Dosyu yer alan

öretiin ve uygulama talimatlanna uygun şekilde, temel sağlık ve gövenlik gerekliliklerini karşıladığını beyan ederiz.

For and on behalf of the ESTILO MODA TEKSTIL TARIM HAYVANCILIK INSAAT IC DIS TIC, VE SAN,

ESTILO MODA TEKSTIL TARIM HAYVANCILIK INSAAT IC DIS TIC, VE SAN, LTD. STI. adma;

theil Beshies TORKOIL, Manufacturing operations and engineering Octiva operacyculars to militaryleliky

Bassed in (Yayushama Yeri); Tokat/TURNEY Jases that (Yayushama turbi); 10.62,2020

Signature Inza : "Sestion!



#### EU DECLARATION OF CONFORMITY

#### MANUFACTURER ESTILO MODA TEKSTIL TARIM HAYVANCILIK INSAAT IC DIS TIC. VE SAN, LTD, STI

Gool Osman Paga Mah. Kolej Sok, No 2/A Turhol TOKAT / TURKEY.

#### PRODUCT DESCRIPTION

ESTILO - ES 6124 Model, Electrostatic Protective Clothing against infective arenis: Type 5-B - Providing Protection to the Full Body against Airbonic Solid Particulates Type f-B - Offering Limited Protective Performance against Liquid Chemicals with the following classification;

Resistance to paractitation by contaminated liquids under hydrostatic pressure: Class 3 Resistance to penetration by infective agents due to mechanical contact with substances containing contaminates Equids: Class 2

Resistance to penetration by communicated solid particles: Class 2.

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal our and conditions defined by the Manufacturer, safe and meets all the accessory legal conditions and requirements. The product is a personal protective equipment that is intended for single use and solely in accordance with the Manufacturur's instructions.

#### The Conformity is resurred with the following mechanism:

- Complies with EU 2016/425 Personel Protective Equipment Regulation establishing technical requirements for Category III products.
- Complies with Technical harmonised standards. EN 14126/AC:2004, EN ISO 13982-1:2006/A1:2010. EN 13634:2005+A1:2009, EN 1149-5:2018
- All required tests referred in above standards are conducted.
- Compiles with other relevant harmonized legislation and community standards
- For the assessment of conformity the EU Type Examination certificate is issued, after all technical exalinations for conformity to the regulation and humaniscal mandards conducted, by:
  - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co. as Notified Body number 2163
- The product is under surveillance of same Notified Body, NB 2163 according to the Annex III (Module D) of the PPE Regulation (EU) 2016/425, for quality assurance.

#### MARKING, LABELLING

Marking, labelling and mer information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and the harmonised product standards given above. The information is supplied with the product considering EN ISO 15223-1:2816 and EN 1041:2008+A1:2013.

#### MEASURES TO ENSURE CONFORMITY

The Manufacturer dockres that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and technical requirements for this type of product.

> Halif İbrahim TÜRKDİL General Manager 28/04/2020

> > 2163





www.estilomedikal.com







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