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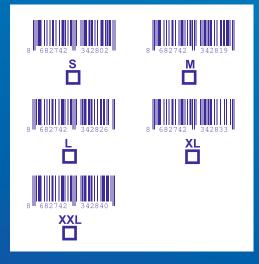
estilo



ES 6124

Protective Coveral









# Protective Clothing Category III



TYPE 3











### ÖZELLİKLERİ

## PROPERTIES / EIGENSCHAFTEN / CBOЙCTBA /



### Kumaş: 53/63 GR / SMS ÖZELLİKLERİ

· Üstün nitelikli-hafif ve givilmesi kolav SMS kumaştan dikilmiştir

- Yumuşak, sağlam, nefes alabilen kumaştır.
- Az tehlikeli kimyasal ve tozlara karşı korunmavı artırmak için kapişonlu ve
- üstü örtülebilen fermuar kullanılmıştır. · Yüz maskesinin üstüne kolayca
- yerleşmesi için esnekleştirilmiş başlık. Giriş çıkışı sınırlamak ve sıvıya karşı korunma icin esneklestirilmis bilek ve
- ayak dikişleri. · Azami konfor ve korunma için esnekleştirilmiş bel.
- Korunmayı azamileştirmek tüvlenmevi ve tel dökülmesini asgarileştirmek için sınır dikişi teknolojisi.

### **KULLANIM ALANLARI**

Bu tulumlar; az tehlikeli maddelerden korunmak ve kirlenmeyi önlemek için kullanılmaktadır.Kişinin üzerine sıçrayabilecek az tehlikeli sıvı atıklardan ve havada bulunan basit toksiklerden korunmak amaçlı üretilmiştir.

### STANDARTLAR

Ürün kategori III olup, toz partikülleri ve belirli sıvı kimyasal sıçramalara karşı koruyucu giysi standartlarına uygundur. Koruyucu Giysi Standartlarına uvaundur.

Ürünler Antistatik Özelliklidir, Silikon içermez ve Alerji yapmaz.

### 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
- Flexible wrist and foot seams to limit entry
- and exit protection. Elastic waist for maximum comfort and
- Border stitching technology to maximize protection and minimize hair growth and hair loss

### **USAGE AREAS**

protection.

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. Conforms to Protective Clothing

Standards.

Products Antistatic

It does not contain silicone and does not cause allergies.



### Stoff: 53/63 GR / SMS EIGENSCHAFTEN

 Es ist aus hochwertigem PP-Vliesstoff genäht leicht und leicht zu tragen. Es ist ein weicher, fester und atmungsaktiver

- Stoff.
- Ein Kapuzenreißverschluss erhöht den Schutz vor weniger gefährlichen Chemikalien und Staub. · Flexibler Kopf zur einfachen Montage auf der
- Flexible Handgelenk- und Fußnähte zur Begrenzung des Ein- und Ausstiegsschutzes.
- Elastische Taille für maximalen Komfort und Schutz.
- Randnähtechnologie zur Maximierung des Schutzes und zur Minimierung von Haarwuchs und Haarausfall.

### NUTZUNGSBEREICHE

Diese Overalls sind; Es dient zum Schutz vor weniger gefährlichen Stoffen und zur Vermeidung von Kontaminationen. Es wird hergestellt, um die Person vor

gefährlichen flüssigen Abfällen und einfachen Giftstoffen in der Luft zu schützen.

### **STANDARDS**

Das Produkt ist Kategorie III und entspricht den Standards für Schutzkleidung gegen Staubpartikel und bestimmte flüssige chemische Spritzer.Entspricht den Standards für Schutzkleidung.Produkte Antistatisch Es enthält kein Silikon und verursacht keine Allergien.



### Ткань: 53/63 ГР / СМС ОСОБЕННОСТИ

- Она пошита из высококачественной ткани РР
- NonWoven легкая и удобная для ношения. • Это мягкая, прочная, дышащая ткань.
- Молния с капюшоном используется для повышения защиты от менее опасных
- химических веществ и пыли.
- Гибкая головка для легкой установки на маску.
- Гибкие швы запястья и стопы для ограничения
- защиты при входе и выходе.
   Эластичная талия для максимального комфорта и защиты.
- Технология сшивания границ для максимальной защиты и минимизации роста и выпадения волос.

### ОБЛАСТИ ИСПОЛЬЗОВАНИЯ

Эти комбинезоны есть; Он используется для защиты от менее опасных материалов и предотвращения загрязнения Он предназначен для защиты человека от

опасных жидких отходов и простых токсинов в воздухе.

### СТАНДАРТЫ

Продукт относится к категории III и соответствует стандартам защитной одежды против частиц пыли и брызг определенных жидкостей.

Соответствует стандартам защитной одежды Продукты Антистатик

Не содержит силикона и не вызывает аллергию.

القماش: ۵۳/۲۳ / GR / ميزات SMS

- مخيط من أقمشة PP غير منسوجة عالية
  - الجودة خفيفة وسهلة الارتداء.
- قماش ناعم ومتين وقابل للتنفس. • يتم استخدام سحاب مقنع لزيادة الحماية ضد المواد
  - الكيميائية والغبار الأقل خطورة. • رأس مرن لسهولة التركيب على قناع الوجه.
- درزات قدم ورسغ مرنة للحد من دخول وخروج
- خصر مرن لأقصى درجات الراحة والحماية. • تقنية خياطة الحدود لزيادة الحماية وتقليل نمو

### وتساقطه.

محالات الاستخدام هذه الملابس هي ؛ يتم استخدامه للحماية من المواد الأقل خطورة ومنع التّلوث. ُ

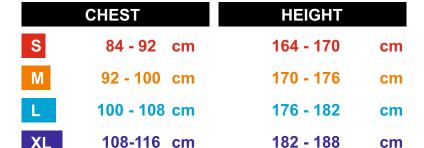
يتم إنتاجه لحماية الشخص من النفايات السائلة الخطرة والسموم البسيطة في الهواء.

المنتج من الفئة الثالثة ويتوافق مع معايير الملابس الواقية ضد جزيئات الغبار وبعض البقع الكيميائية السائلة. يتوافق مع معايير الملابس الواقية.

منتجات آلاستاتيكيه لا يحتوي على السيليكون ولا يسبب الحساسية.







BEDEN ÖLÇÜLERİ / BODY SIZES / KÖRPERGRÖSSEN / РАЗМЕРЫ ТЕЛА / أحجام الجسم

### SYMBOLS / SEMBOLLER

116 - 124 cm

### الاشارات

cm

188 - 194



### **GÜVENLİK TALİMATI**

Bütün koruyucu giysiler, kullanmadan önce yırtık, delik, sökük , kir gibi olumsuzluk yaratabilecek defo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli kesinlikle giyilmemelidir.

### DİKKAT

Poşet ile oynamak tehlikelidir.Boğulmaya sebep olabilir.Lütfen cocuk ve bebeklerden uzak tutunuz.

### **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. Please keep away from children and infants.

### **SICHERHEITSHINWEISE**

Alle Schutzkleidung, vor Gebrauch,

Loch, zerrissen,gegen Mängel und Ausfälle, die Negativität wie Schmutz verursachen können sollte überprüft werden. Abfall und

Schmutz sollten niemals getragen werden.

Das Spielen mit der Tasche ist gefährlich. Kann Ersticken verursachen. Bitte Von Kindern und Kleinkindern fernhalten.

### ИНСТРУКЦИЯ БЕЗОПАСНОСТИ

Вся защитная одежда, перед использованием, порвана, дыра, разорван, от дефектов и сбоев, которые могут привести к отрицательность как грязь должна быть проверена. Отходы и грязные никогда не следует носить.

### ВНИМАНИЕ

Играть с сумкой опасно. Может вызвать задыхаясь. пожалуйста

держаться подальше от детей и младенцев.

جميع الملابس الواقية ، قبل الاستخدام ، ممز ق ممزق ، ضد العيوب والفشل التي قد تسبد يحب التحقق من السلبية مثل الأوساخ. النفايات القذرة لا ينبغي أن ترتديه.

من الخطورة اللعب مع الحقيبة. يمكن أن يسبب الابتعاد عن الأطفال والرضع.

ÜRETİM TARİHİ PRODUCTION DATE **PRODUKTIONSDATUM** ДАТА ПРОИЗВОДСТВА

: 2020-10

تاريخ الإنتاج

Son kullanma tarihi üretim tarihinden itibaren 3 yıldır. The expiration date is 3 years from the date of manufacture. Das Verfallsdatum beträgt 3 Jahre ab Herstellungsdatum. Срок годности - 3 года с даты изготовления.

تاريخ انتهاء الصلاحية ثلاث سنوات من تاريخ الصنع.













# **Hooded Design** One piece

Stitched Tape edges

Elastic Cuff

band, face shape and protection Face opening with one piece dimensional cut and elastic increase the impact more three hooded around suitable

inner elastic tape is applied provides better protection. This sewing style apps With each seam tape to the waist

Elastic cuff application provides protection tense and better





Protective Clothing









TYPE 5

TYPE 4

TYPE 3

TYPE 6











X K L Z



# EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 653

Electrostatic Protective Clothing against Infective Agents;

Type 5-B Providing Protection to the Full Body against Airborne Solid Particulates

Type 6-B Offering Limited Protective Performance against Liquid Chemicals

ESTİLO MODA TEKSTİL TARIM HAYVANCILIK İNŞAAT İÇ DIŞ TİC. VE SAN. LTD. ŞTİ

Gazi Osman Paşa Mah. Kolej Sok. No:2/A Turhal TOKAT / TURKEY are tested and evaluated according to

EN 14126:2003/AC:2004, EN ISO 13982-1:2004/A1:2010, EN 13034:2005+A1:2009, EN 1149-5:2018

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation. The details of essential requirement compliance is given in technical report numbered KKD-2163-653

### **Product Definition**

Brand Name: ESTILO, Model: ES 6124

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

Resistance to penetration by contaminated liquid aerosols: Class 1 Resistance to penetration by contaminated solid particles: Class 2

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on Annex 7 (Module C2) or Annex 8 (Module D) of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on 28/04/2020 and will be valid for 5 years if there is no change in the relevant harmonised standard affecting the essential health and safety requirements



abottler, 3

UNIVERSAL CERTIFICATION
Director

# EU DECLARATION OF CONFORMITY

# MANUFACTURER ESTİLO MODA TEKSTİL TARIM HAYVANCILIK İNŞAAT İÇ DIŞ TİC. VE SAN. LTD. ŞTİ

Gazi Osman Paşa Mah. Kolej Sok. No:2/A Turhal TOKAT / TURKEY

### PRODUCT DESCRIPTION

ESTILO – ES 6124 Model, Electrostatic Protective Clothing against infective agents; Type 5-B - Providing Protection to the Full Body against Airborne Solid Particulates Type 6-B - Offering Limited Protective Performance against Liquid Chemicals with the following classification;

Resistance to penetration by contaminated liquids under hydrostatic pressure: Class 3

Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids: Class 2

Resistance to penetration by contaminated solid particles: Class 2

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

### The Conformity is ensured 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 13982-1:2004/A1:2010, EN 13034:2005+A1:2009, EN 1149-5:2018
- All required tests referred in above standards are conducted,
- Complies with other relevant harmonized legislation and community standards
- For the assessment of conformity the EU Type Examination certificate is issued, after all technical evaluations for conformity to the regulation and harmonised standards 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 user 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 15223-1:2016 and EN 1041:2008+A1:2013.

### MEASURES TO ENSURE CONFORMITY

The Manufacturer declares 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.

Halil İbrahim TÜRKDİL General Manager 28/04/2020





# 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

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

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LIBERTY
MANAGEMENT
GROUP LTD.

75 Executive Drive, Aurora, Illinois, USA

www.fdahelp.us

Manoj Zacharias

President

Liberty Management Group LTD.

Dated: June 17, 2020



# SERTIFIKA / CERTIFICATE

ESTİLO MODA TEKSTİL TARIM HAYVANCILIK İNŞAAT İÇ DIŞ TİCARET VE SANAYİ LİMİTED ŞİRKETİ

GAZİOSMAN PAŞA MAHALLESİ KOLEJ SOKAK NO:2-A TURHAL / TOKAT / TURKEY

Kuruluşunun 66 diş giyim eşyası İmalatı, dokuma, örme (trikotaj) ve tiğ işi (kroşe), vb. Kumaştan olanlar (kaban, palto, ceket, pantolon, takim elbise, döpiyes, anorak, yağmurluk, gece kiyafetleri vb.) (İş giysileri ve terzilerin faaliyetleri hariç)

( MEDÎKAL ÛRÛN VE KORUYUCU KIYAFETLER DAHÎL) 66 Kapsamı için

For scope 66 OUTDOOR GOODS MANUFACTURING, WEAVING, KNITTING (TRICOTAGE) AND CROCHET (KROŞE), ETC. FROM THE FABRIC (COAT, PALO, JACKET, PANTS, SUIT, DRESS, DOGY, ANORAC, RAINCOAT, NIGHT CLOTHING, ETC.) (MEDICAL PRODUCTS AND PROTECTIVE CLOTHES INCLUDED) 59

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 yukarıda belirtilen standardın şartlarını karşıladığını 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.

Sertifika Numarası / Certificate Number Sertifika Kodu / Certificate Code Sertifika Yayın Tarihi / Certificate Issue Date Sertifika Geçerlilik Tarihi / Certificate Validity Date Sertifika Periyodu / Certificate Period : 20040203 : ESTILO MODA

: 02.04.2020

: 02.04.2021 : 1 Yıl / 1 Year

> Certificati in Manager Belgelene ime Müdürü

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Sistem etkin bir şekilde sürdürüldükçe ve gözetim tetkikleri zamanında yapıldığı müddetçe bu belge 1 yıl geçerlidir. NVA denetim yürütülmesinde gerekli itina ve yetkinlik göstermesine rağmen büyük ihtimallerde dahil sorumluluk kabul etmeyecektir. Bu belgenin mülkiyet hakkı NVA aittir ve istenildiğinde iade edilmelidir.



www.nvakalite.com info@nvakalite.com

# S S



# SERTIFIKA / CERTIFICATE

ESTİLO MODA TEKS. TARIM HAYVANCILIK İNŞ. İÇ DIŞ TİC. VE SAN. LTD. ŞTİ.

GAZĪOSMAN PAŞA MAHALLESĪ KOLEJ SOK. NO:2-A TURHAL/TOKAT/TURKEY

Kuruluşunun "TEK KULLANIMLIK CERRAHİ MASKE, TEK KULLANIMLIK YÜZ MASKESİ, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK MEDİKAL ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK ELDİVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONE, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK

SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI" Kapsamı için

For scope <sup>66</sup>SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GRAFT, SINGLE USE MEDICAL Gowns, SINGLE USE SURGICAL DRAPE, SINGLE USE INSULATION, SINGLE USE, SINGLE USE, SINGLE USE SLEEVE, SINGLE USE. COVER, PRODUCTION AND SALES <sup>99</sup>

# ISO 9001:2015 KALİTE YÖNETİM SİSTEMİ Quality Management System

Kurduğunu 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 it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / Certificate Number Sertifika Kodu / Certificate Code Sertifika Yayın Tarihi / Certificate Issue Date Sertifika Geçerlilik Tarihi / Certificate Validity Date Sertifika Periyodu / Certificate Period : 20041534

: ESTILO MODA

: 15.04.2020

: 15.04.2021 : 1 Yıl / 1 Year

> Certificat en Manager Belgelenderne Müdürü



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