

estila®
MEDIKAL

“The best protection for health”

DISPOSABLE PROTECTIVE SUIT

ESTILO MEDIKAL IS A ESTILO FASHION TEXTILE BRAND.





PRODUCTION CAPACITY

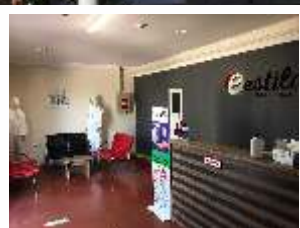
Our company is in the area of 1500 m² in Turkey 125 with staff constantly meet their needs It serves.

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. form.

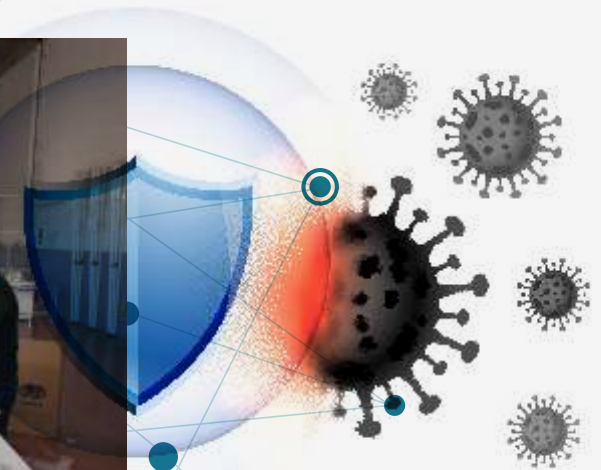
Production Factory



“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 enhance tightness and protection.



Fabric Description

“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.

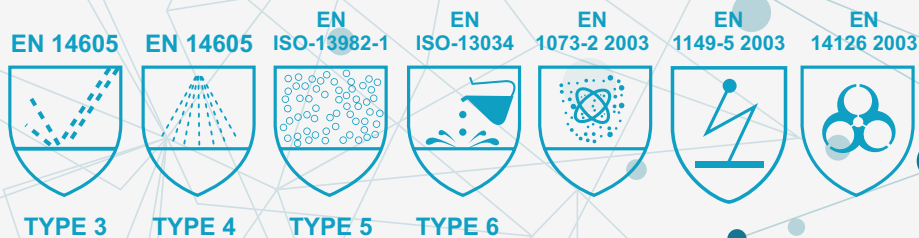
The fabrics, seal tapes and zippers are in accordance with national standards. As a national key responsive supply entity, **Estilo Moda Textile** assists the government in developing various new protective suits.

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, 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.



Protective Clothing Category III



Disposable Protective Coverall

"The best protection for health"

TYPE 5.6

SIZES

S
M
L
XL
XXL



One piece Hooded Design

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

Stitched Tape edges

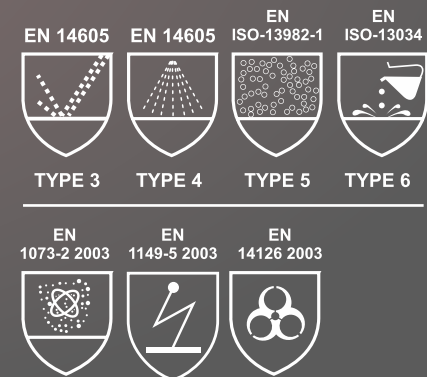
With each seam tape inner elastic tape is applied to the waist
This sewing style apps provides better protection.

Elastic Cuff

Elastic cuff application tense and better provides protection



Protective Clothing Category III



Disposable Protective Coverall

"The best protection for health"

TYPE 3.4

SIZES

S
M
L
XL
XXL



One piece Hooded Design

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

Stitched Tape edges

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

Elastic Cuff

Elastic cuff application tense and better provides protection



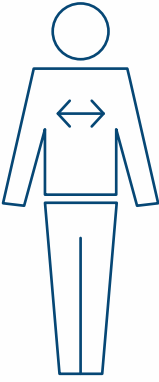
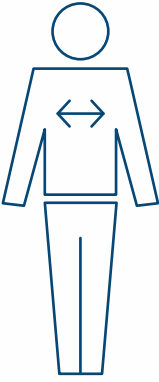
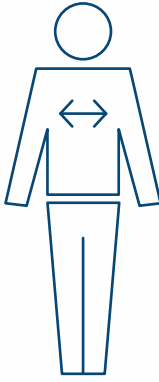
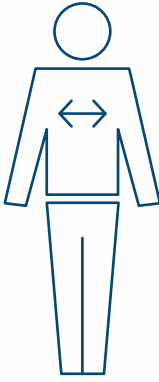
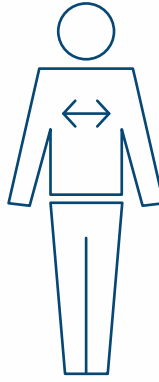
Protective Clothing Category III

EN 14605	EN 14605	EN ISO-13982-1	EN ISO-13034
TYPE 3	TYPE 4	TYPE 5	TYPE 6
EN 1073-2 2003	EN 1149-5 2003	EN 14126 2003	

Sizes

“The best protection for health”

CM BODY MEASUREMENTS

S	M	L	XL	XXL
 164-170cm 84-92cm	 170-176cm 92-100cm	 176-182cm 100-108cm	 182-188cm 108-116cm	 188-194cm 116-124cm

Disposable Foot Protector

"The best protection for health"

1 PAIR

FOOT SIZE

42

44

46

50

PP NONWOVEN

Superior quality - lightweight and easy to wear PP NONWOVEN sewn from fabric

Double Floor Base

Less dangerous chemicals and dust to increase protection against;
The base is produced in double layers.



Protective Clothing Category III

EN 14605



TYPE 3

EN 14605



TYPE 4

EN ISO-13982-1



TYPE 5

EN ISO-13034



TYPE 6

EN 1073-2 2003



EN 1149-5 2003



EN 14126 2003



estilo[®]
MEDİKAL

Disposable Medical Apron

"The best protection for health"

STERIL

SIZE

UNISEX



Sterile

The reinforcing fabric is liquid-proof and is a sterile reusable fabric.



100% Cotton

100% Cotton ribs and 65% cotton 35% polyvison terrycotton fabric it is made in two models.



Protective Clothing Category III

EN 14605



TYPE 3

EN 14605



TYPE 4

EN ISO-13982-1



TYPE 5

EN ISO-13034



TYPE 6

EN 1073-2 2003



EN 1149-5 2003



EN 14126 2003



estilo[®]
MEDİKAL

Corpse Bag

“The best protection for health”

SIZES

ADULT

80 X 220 CM

CHILD

70 X 140 CM

Custom Size



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”



Best Filter Performance General features

It has the best possible filter performance for users. Facilitates breathing with its compatible use to the face.

Non-sterile

It is disposable and does not irritate the skin.

Odorless.

It does not contain fiber glass, latex and other allergens.

Easy to breathe, includes bacterial filtration.

It is hygienic.

It does not contain fiberglass.

Flexible and soft with ultrasonic stitching

It provides full harmony with the face. Breathable, easy breathing allows to receive. It does not fluff.



“The best protection for health”



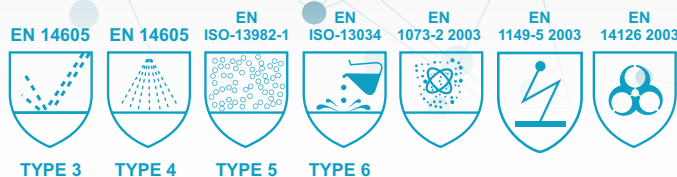
Estilo, with a staff of almost 500, daily manufactures 50.000 Protective Suits

Directions for use

“The best protection for health”



Protective Clothing Category III



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.

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 standards against 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
- EN 1149-1: 2006
- EN 1149-5: 2008
- Products Antistatic
- It does not contain silicone and does not cause allergies.

SYMBOLS

Do not iron	Do not machine dry	Do not bleach	Do not wash	Do not machine dry	Do not bleach

“The best protection for health”

[illegible]

Certificates

“The best protection for health”

[illegible][illegible][illegible]

Certificates

“The best protection for health”



“The best protection for health”

[illegible]

NVA QUALITY CERTIFICATION



SERTİFİKA / CERTIFICATE
ESTİLO MODA TEKS. TARIM HAYVANCILIK İNŞ. İÇ DİŞ TİC. VE SAN. LTD. ŞTİ.
 GAZİOSMAN PAŞA MAHALLESİ 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 EL DİVENİ, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONFİ, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI" **Kapsamı için**

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

ISO 9001:2015
KALİTE YÖNETİM SİSTEMİ
Quality Management System

Kuruluşunu 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	: 20041534
Sertifika Kodu / Certificate Code	: ESTİLO MODA
Sertifika Yayın Tarihi / Certificate Issue Date	: 15.04.2020
Sertifika Geçerlilik Tarihi / Certificate Validity Date	: 15.04.2021
Sertifika Periyodu / Certificate Period	: 1 Yıl / 1 Year


 Certification Manager
 Belgeleştirici Müdürü

Sistem etkin ve sürekli surveillance audit: this document is valid as long as the 1-years. NVA control the conduct of standards. Although due care and competence, including gross negligence will not accept responsibility. This document is proprietary rights owned by NVA and must be returned upon request.

Sistem etkin ve sürekli surveillance audit ve güncellenen standartlar arasında yapılmış denetimler bu belge 1 yıl geçerlidir. NVA denetim yetkilerine sahiptir. Bu belge NVA'nın malıdır ve sorumluluğu sadece NVA'ya aittir. Bu belgeyi talep edenler NVA'ya geri verilmelidir.

www.estilomoda.com.tr info@estilomoda.com.tr

NVA QUALITY CERTIFICATION

NVA QUALITY CERTIFICATION



SERTİFİKA / CERTIFICATE
ESTİLO MODA TEKSTİL TARIM HAYVANCILIK İNŞAAT İÇ DİŞ TİCARET VE SANAYİ LİMİTED ŞİRKETİ
 GAZİOSMAN PAŞA MAHALLESİ KOLEJ SOKAK NO:2-A TURHAL / TOKAT / TURKEY

Kuruluşunun "DİŞ GİYİM EŞYASI İMALATI, DOKUMA, ÖRME (TRİKOTA) VE TİG İŞİ (KROŞE), VİB. KUMAŞTAN OLANLAR (KABAN, PALTÖ, CEKET, PANTOLON, TAKIM ELİSE, DÖPIYES, ANORAK, YAGMURLUK, GECE KIYAFETLERİ VB.) (İŞ GİYİMLERİ VE TERZİLERİN FAALİYETLERİ HARİCİ) (MEDİKAL ÜRÜN VE KORUYUCU KIYAFETLER DAHİL)" **Kapsamı için**

For scope "OUTDOOR GOODS MANUFACTURING, WEAVING, KNITTING (TRICOTAGE) AND CROCHET (KROŞE), ETC. FROM THE FABRIC (COAT, PANT, JACKET, PANTS, SUIT, DRESS, DÖĞY, ANORAK, RAINCOAT, NIGHT CLOTHING, ETC.) (MEDICAL PRODUCTS AND PROTECTIVE CLOTHES INCLUDED)"

ISO 13485 : 2016
TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ
Medical Devices Quality Management System

Kuruluşunu 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	: 20040203
Sertifika Kodu / Certificate Code	: ESTİLO MODA
Sertifika Yayın Tarihi / Certificate Issue Date	: 15.04.2020
Sertifika Geçerlilik Tarihi / Certificate Validity Date	: 15.04.2021
Sertifika Periyodu / Certificate Period	: 1 Yıl / 1 Year


 Certification Manager
 Belgeleştirici Müdürü

Sistem etkin ve sürekli surveillance audit: this document is valid as long as the 1-years. NVA control the conduct of standards. Although due care and competence, including gross negligence will not accept responsibility. This document is proprietary rights owned by NVA and must be returned upon request.

Sistem etkin ve sürekli surveillance audit ve güncellenen standartlar arasında yapılmış denetimler bu belge 1 yıl geçerlidir. NVA denetim yetkilerine sahiptir. Bu belge NVA'nın malıdır ve sorumluluğu sadece NVA'ya aittir. Bu belgeyi talep edenler NVA'ya geri verilmelidir.

www.estilomoda.com.tr info@estilomoda.com.tr

NVA QUALITY CERTIFICATION

Certificate of Registration 2020

This is to certify that the registration of
**ESTILO MODA TEKSTİL 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.*

*The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food
and Drug Administration recognize a certificate of registration. Liberty Management Group Ltd. is not
affiliated with the U.S. Food and Drug Administration.*

LMG LIBERTY
MANAGEMENT
GROUP LTD.
75 Executive Drive, Aurora, Illinois, USA
www.fdahelp.us

Manoj Zacharias
Manoj Zacharias
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”

CE

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 - Tıbbi Cihaz Direktifi
YÖNETMELİKLERİNE GÖRE AT UYGUNLUK BEYANI

Certificate No / Belge No : **UB-PPE 10022020**

Manufacturer's Name (Ticari)	ESTİLO MODA TEKSTİL TARIM HAYVANCILIK İNŞAAT İÇ DİŞ TİC. VE SAN. LTD. STİ.
Manufacturer's address (Ticari)	Gazi Osman Paşa Mah. Kule Sok. No:2/A Tuzhal/TOKAT/ TURKEY
Phone (Tel)	+90 356 276 88 82
E-mail (E-posta)	info@estilomodatekstil.com.tr
Authorised person to compile the relevant technical documentation	Habib İbrahim TÜRKDİL
Teknik dosyayı hazırlamakta yetkili olan ve Türkiye'de yerleşik kişinin adı ve adresi	Gazi Osman Paşa Mah. Kule Sok. No:2/A Tuzhal/TOKAT/ TURKEY
Product description	Protective Foot Cover (Non-sterile, Class I not sterile or measuring)
Ürün tanıtılması	Koruyucu Ayakkabı (Non-steril, Sınıf I Steril yada Ölçme Özelliklerine Sahip)

93/42/EEC and 2007/47/EC - Medical device directive
ISO 13485:2016 - Medical devices - Quality management systems -
Requirements for regulatory purposes
93/42/EEC and 2007/47/EC - Medical device directive, ISO 15982-
1:2004 - Protective clothing for use against solid particulates (type 5),
EN 13024:2005+A1:2009 - Protective clothing against liquid
chemicals (Type 6), EN 14126:2003+AC:2004 - Protective clothing -
Performance requirements and tests methods for protective clothing
against infective agents, EN 1348-5 : 2018 - Protective clothing -
Electrostatic properties

Harmonized European directive(s) vs
Related Standard

İlgili Harmonize AT direktifleri ve ilgili
Standart

herewith declare that the product "Protective Foot Cover" are in conformity with the provisions of the following
essential requirements of 93/42/EEC and 2007/47/EC - MEDICAL DEVICE DIRECTIVE
and standards when produced and applied in accordance with production and application instructions contained
in the Technical File documentation.

Yukarıda tanımlanan ürünün, 93/42/EEC and 2007/47/EC - Tıbbi Cihaz Direktifi ve
standartlar ile uyumlu olarak ve Teknik Dosya yer alan
özellik ve uygulama talimatlarına uygun şekilde, temel sağlık ve güvenlik gerekliliklerini karşıladığını beyan ederiz.

For and on behalf of the ESTİLO MODA TEKSTİL TARIM HAYVANCILIK İNŞAAT İÇ DİŞ TİC. VE SAN. LTD. STİ.
ESTİLO MODA TEKSTİL TARIM HAYVANCILIK İNŞAAT İÇ DİŞ TİC. VE SAN. LTD. STİ. adına;

Habib İbrahim TÜRKDİL, Manufacturing operations and engineering (Üretim operasyonları ve mühendislik)
Based in (Yerleşim Yeri): Tokat/TURKEY Issue date (Yayınlanma tarihi): 10.02.2020

Signature/ İmza : 

EU DECLARATION OF CONFORMITY

MANUFACTURER
ESTİLO MODA TEKSTİL TARIM HAYVANCILIK İNŞAAT İÇ DİŞ
TİC. VE SAN. LTD. ŞTİ
Gazi Osman Paşa Mah. Kule Sok. No:2/A Tuzhal/TOKAT / TURKEY

PRODUCT DESCRIPTION
ESTİLO - ES 6124 Model, Electronic 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 Personal Protective Equipment Regulation establishing technical
requirements for Category III products,
- Complies with Technical harmonized standards: EN 14126/AC:2004, EN ISO 13982-1:2004/A1:2010,
EN 13024:2005+A1:2009, EN 1349-5:2018
- 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 harmonized standards conducted by:
i) 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.

Habib İbrahim TÜRKDİL
General Manager
28/04/2020

CE
2163

estilo® MEDİKAL

www.estilomedikal.com



estilomedikal



estilomedikal



www.estilomodatekstil.com.tr

Gazi Osman Paşa Mah. Kolej Sk. No : 2/A
Turhal / TOKAT - TÜRKİYE
+90 356 276 88 82

MADE IN

