



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 : [REDACTED]

Manufacturer's Name

Üretici

Manufacturer's address

Üretici adresi

Phone (Tel)

E-mail (E-posta)

**Authorised person to compile the relevant
technical documentation**

**Teknik dosyayı hazırlamakta yetkili olan ve
Türkiye'de yerleşik kişinin adı ve adresi**

Product description

Ürün tanımlaması

ESTILO MODA TEKSTİL TARIM HAYVANCILIK INSAAT IC DIS
TIC. VE SAN. LTD. STI.

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

+9

info@estilomodatekstil.com.tr

Halil İbrahim TÜRKDİL

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

Protective Foot Cover (Non-sterile,Class I not sterile or measuring)

Koruyucu Ayaklık (Non-steril,Sınıf I Steril yada ölçme fonksiyonu olmayan)

93/42/EEC and 2007/47/EC - Medical device directive

**ISO 13485:2016 - Medical devices - Quality management systems -
Requirements for regulatory purposes**

**Harmonized European directive(s) ve
Related Standard**

**93/42/EEC and 2007/47/EC - Medical device directive, ISO 13982-
1:2004 -Protective clothing for use against solid particulates(type 5),
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 -
Electrostatic properties**

**İlgili Harmonize AT direktifleri ve İlgili
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 standarts when produced and applied in accordance with production and application instructions contained
in the Technical File documentation.**

Yukarıda tarifli yapılan ürünümüz olan "Koruyucu Ayaklık"ın 93/42/EEC and 2007/47/EC - Tıbbi Cihaz Direktifi ve
standartlar ile uyumlu olarak ve Teknik Dosya yer alan

üretim ve uygulama talimatlarına uygun şekilde, temel sağlık ve güvenlik gerekliliklerini karşıladığını beyan ederiz.

**For and on behalf of the ESTILO MODA TEKSTİL TARIM HAYVANCILIK INSAAT IC DIS TIC. VE SAN.
LTD. STI.;**

ESTILO MODA TEKSTİL TARIM HAYVANCILIK INSAAT IC DIS TIC. VE SAN. LTD. STI. adına;

Halil İbrahim TÜRKDİL, Manufacturing operations and engineering (Üretim operasyonları ve mühendislik)

Issued in (Yayınlanma Yeri): Tokat/TURKEY Issue date (Yayınlanma tarihi): 10.02.2020

Signature/ İmza :

**Gazi
Osman
Pasa
Mah.
Kolej
Sok.
No:2/A
Turhal
/TOKAT
/T.C.
Sic.**

U1



NB

EU TYPE EXAMINATION CERTIFICATE

Certificate No: [REDACTED]

**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 KKI [REDACTED]

Product Definition

Brand Name: ESTİLO, Model: [REDACTED]

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



Suat KAÇMAZ

UNIVERSAL CERTIFICATION
Director

TYP 5.6

VEĽKOSTI

- S
- M
- L
- XL
- XXL



Jednodielný dizajn s kapucňou (kuklou)

Jednodielný overal s otvorom na tvár, kapucňou dookola ukončenou všitou elastickou gumičkou zvyšuje ochranu.

Prilepiteľná záklopka na zips

Oblek má uzatváranie na zips s prilepiteľnou záklopkou. Pás obsahuje všitú elastickú gumičku. Tento štýl aplikácii poskytuje lepšiu ochranu.

Elastické ukončenie

Ukončenie rukávov a členkov pomocou všitej gumičky.



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	

Technický list výrobku

Jednorazový laminovaný ochranný overal



Výrobca

Gazi Osman Paşa Mah. Kolej Sk. No : 2/A Turhal Turecko

Názov produktu a značka

ESTILO MEDİKAL



- Ochranný overal, kat. III OOP, typ 5/6,

Popis produktu

- farba: biela,
- rozsah veľkostí: S, M, L, XL, 2XL
- balenie 1 ks v polyetylénovom sáčku, označenie šarže a dátum výroby.

Hlavné vlastnosti a popis produktu

- jednorazový ultraľahký ochranný overal vyrobený z laminátovej tkaniny poskytuje v rôznych oblastiach spoľahlivú ochranu a prvotriedne pohodlie pri nosení. Oblek je antistatický.

-Jednodielnynyoblekskapučnou(kuklou), predný otvor na zips prekrytý prílepitelnou záklpokou.

- okraj kapucne, pás, nohavice a rukávy sú zakončené elastickou gumičkou, bežec zipsu je uzamknuteľný a nedá sa sám rozopnúť.

- kombinéza slúži ako ochrana proti prachu a tekutinám. Priepustná pre vzduch, vodoodpudivá, nehorľavá, odolná voči časticiam, ľahká a mäkká.



Štandardy

- Výrobok spadá do kategórie III a zodpovedá štandardu ochranného odevu proti prachovým časticiam a určitým postrekom kvapalnými chemikáliami.

TYP 5: EN 13982-1: 2004 A1: 2010

TYP 6: EN 13034: 2005 A1: 2009

Vyhovuje štandardom ochranného odevu.

EN 14126

EN 14362-1: 2012

EN1149-1: 2006

EN 1149-5: 2008

Materiálové zloženie

- látka: laminovaný polypropylén
antistatická antibakteriálna
netkaná textília

-Neobsahuje silikón a nespôsobuje alergie.

Krajina pôvodu:

Vyrobené v Turecku

Použitie:

- medicínske použitie

Obmedzenie použitia

- riadte sa pokynmi na použitie - nepoužívajte spôsobom, ktorý nie je uvedený v príručke/návode.
- Overal používajte ako vrchný odev na bežný pracovný odev. Nepoužívajte v prostredí s vysokou teplotou, nebezpečenstvom požiaru, pri práci s otvoreným ohňom a pod.



EU DECLARATION OF CONFORMITY

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

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

PRODUCT DESCRIPTION

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 Personal 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.

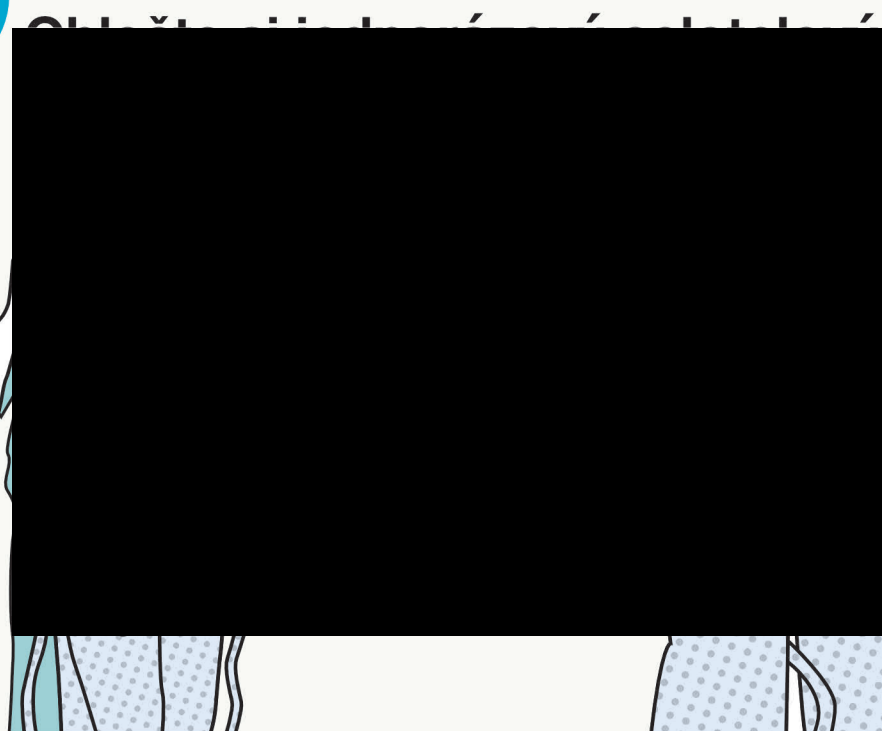
Halil İbrahim TÜRKDİL
General Manager
28/04/2020



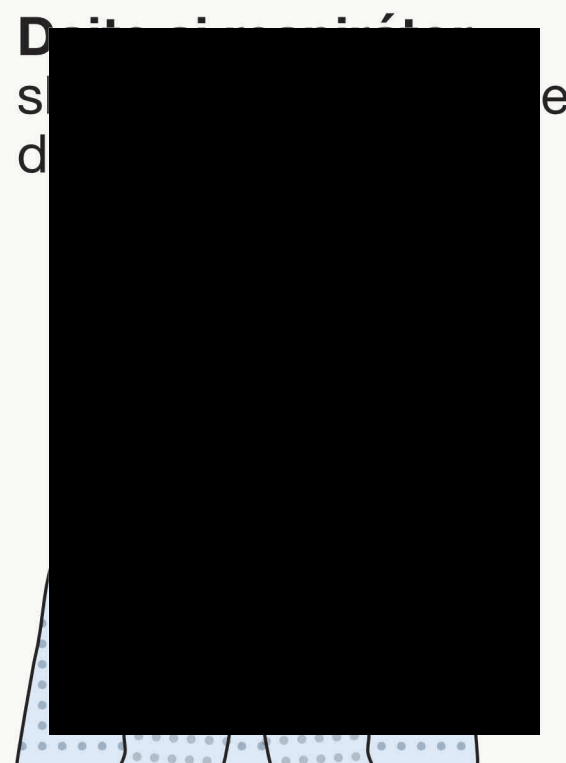
NÁVOD NA POUŽITIE OCHRANNÉHO OVERALU

Pred nasadením
OOPP vykonajte
hygienu rúk

1



2



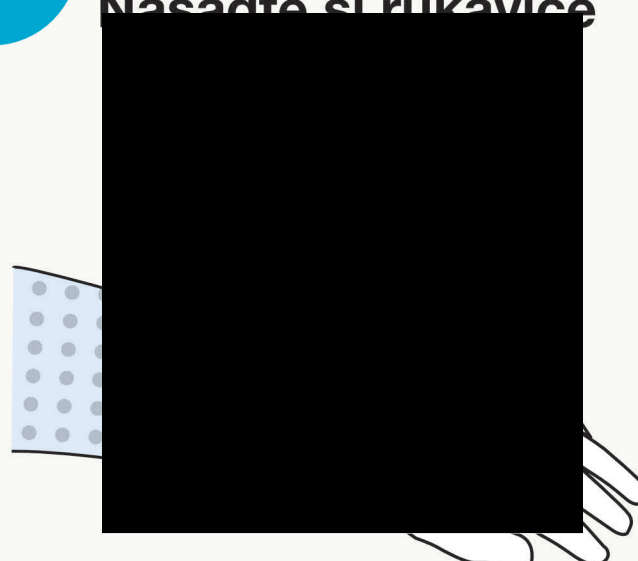
3

Nasadte ochranu očí



4

Nasadte si rukavice





Príloha č. 2 - Návrh na plnenie kritéria na vyhodnotenie ponúk a identifikačné údaje uchádzača

Obchodné meno uchádzača:	STATUS S, s.r.o.
Sídlo uchádzača:	Lipová 10927/21, 036 08 Martin
IČO:	44015828
Meno a priezvisko štatutárneho zástupcu	Igor Pramuk, konateľ
IČ DPH:	SK2022560287
Názov banky:	Tatra Banka, a.s.
Číslo účtu (IBAN):	[REDACTED]
Telefónne číslo:	+4 [REDACTED]
E-mailová adresa:	pramukova.status@gmail.com

Predmet zákazky: „Ochranné obleky s kapucňou“

Kritérium na vyhodnotenie ponúk: najnižšia cena za celý predmet zákazky v EUR s DPH.

Celková cena za predmet zákazky v EUR bez DPH	Výška DPH 20%	Celková cena za predmet zákazky v EUR s DPH
Ochranné obleky s kapucňou na jednorazové použitie v celkovom množstve 3 000 ks v súlade s opisom predmetu zákazky tejto výzvy	2784,00	16704,00

Z toho:	Cena v EUR bez DPH	Výška DPH	Cena v EUR s DPH
Ochranné obleky s kapucňou v množstve 1 800 ks (veľkosť L)	8352,00	1670,40	10022,40
Ochranné obleky s kapucňou v množstve 1 200 ks (veľkosť XL)	5568,00	1113,60	6681,60

Cena uvedená uchádzačom obsahuje všetky náklady, ktoré uchádzačovi vzniknú v súvislosti s plnením predmetnej zákazky.

Som ~~Nie som~~ platiteľom DPH (nehodiace sa preškrtnite)

Ak uchádzač nie je platiteľom DPH, na túto skutočnosť upozorní verejného obstarávateľa. Ak uchádzač nie je platcom DPH, ním uvedená cena bude považovaná za konečnú aj v prípade, ak by sa počas plnenia predmetu zákazky stal platiteľom DPH. V prípade, ak uchádzač je platiteľom DPH, avšak jeho sídlo je v inom členskom štáte EÚ alebo sídli mimo EÚ, uvedie v ponuke cenu, ktorá bude rozdelená na ním navrhovanú cenu bez DPH, výšku DPH a aj cenu s DPH podľa slovenských právnych predpisov (20%), aj keď samotnú DPH nebude fakturovať.

V Martine, dňa 07.12.2020


Igor Pramuk, konateľ

EU TYPE EXAMINATION CERTIFICATE**Certificate No:** [REDACTED]**BOİNC TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ**

Beğelsiz Mahallesi Semiha Şakir Caddesi No: 63/67 Zeytinburnu İstanbul / TURKEY

It is certified that the manufacturer's technical file (Dated 20.06.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment**Brand Name:** PROPHYLACTIC, **Model:** [REDACTED]

Protective coverall manufactured from laminated polypropylene non-woven fabric with hood, inside bound seams, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.

The following harmonised standards have been applied:

- EN ISO 13688:2013, (General requirements for protective clothing)
- EN ISO 13982-1:2004/A1:2010, (Chemical protective clothing providing protection to the full body against airborne solid particulates) Type 5, limited wear life clothing,
- EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type 6, limited wear life clothing,
- EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type 5-B, 6-B

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 the below requirements:

- 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

This certificate is initially issued on **05/08/2020** and will be valid for 5 years from the issue date.



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



EU DECLARATION OF CONFORMITY

MANUFACTURER

BOİNC TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Beşelsiz Mahallesi Semiha Şakir Caddesi No: 63/67 Zeytinburnu İstanbul / TURKEY

PRODUCT DESCRIPTION

Brand Name: PROPHYLACTIC, Model: [REDACTED]

Protective coverall manufactured from laminated polypropylene non-woven fabric with hood, inside bound seams, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.

Type 5 - Providing Protection to the Full Body against Airborne Solid Particulates
Type 6 - Offering Limited Protective Performance against Liquid Chemicals
Type 5-B, Type 6-B, Protective clothing against infective agents

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 assessed with the following mechanism:

- Complies with EU 2016/425 Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards in accordance the Essential Health and Safety Requirements referenced to EU 2016/425 PPE Regulation, EN ISO 13688:2013, EN 14126:2003/AC:2004, EN ISO 13982 1:2004/A1:2010, EN 13034:2005+A1:2009
- 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 under supervision of:
 - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co,
Notified Body number 2163

MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and EN 14126. 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.

Murat FIRAT
General Manager
08/08/2020



Prophylactic

Prophylactic type 5/6
classic coverall



Technický list výrobku

Jednorazový laminovaný ochranný overal

Výrobca

Boinc Tekstil San. Ve Tic. LLC., Turecko

Názov produktu a značka

PROPHYLACTIC



- Ochranný overal, kat. III OOP, typ 5/6,

Popis produktu

- farba: biela, s logom alebo bez loga
- **extra hrubý** materiál zdôrazňujúci nadštandardnú kvalitu
- **široký rozsah** veľkostí: S, M, L, XL, 2XL, 3XL
- balenie 1 ks v polyetylénovom sáčku, označenie šarže a dátum výroby.

Hlavné vlastnosti a popis produktu

- jednorazový ultraľahký ochranný overal vyrobený z laminátovej tkaniny poskytuje v rôznych oblastiach spoľahlivú ochranu a prvotriedne pohodlie pri nosení. Oblek je antistatický.
- Jednodielný oblek s kapucňou (kuklou), predný otvor na zips prekrytý prilepitelnou záklopkou.
- okraj kapucne, pás, nohavice a rukávy sú zakončené elastickou gumičkou, bežec zipsu je uzamknuteľný a nedá sa sám rozopnúť.
- kombinéza slúži ako ochrana proti prachu a tekutinám. Priepustná pre vzduch, vodoodpudivá, nehorľavá, odolná voči časticiam, ľahká a mäkká.

Materiálové zloženie

- látka: laminovaný polypropylén
antistatická antibakteriálna
netkaná textília
65 gsm

- Neobsahuje silikón a nespôsobuje alergie

Obmedzenie použitia

- riadte sa pokynmi na použitie - nepoužívajte spôsobom, ktorý nie je uvedený v príručke/návode.
- Overal používajte ako vrchný odev na bežný pracovný odev. Nepoužívajte v prostredí s vysokou teplotou, nebezpečenstvom požiaru, pri práci s otvoreným ohňom a pod.

Krajina pôvodu:

Vyrobené v Turecku

Štandardy

- Výrobok spadá do kategórie III a zodpovedá štandardu ochranného odevu proti prachovým časticiam a určitým postrekom kvapalnými chemikáliami.

TYP 5: EN 13982-1: 2004 A1: 2010

TYP 6: EN 13034: 2005 A1: 2009

Vyhovuje štandardom ochranného odevu.

EN 14126

EN 14362-1: 2012

EN1149-1: 2006

EN 1149-5: 2008

Prophy

Prophylactic type 5/6 classic coverall

DISPOSABLE LAMINATED PROTECTIVE COVERALL "The best protection for health"

TYPE 5/6



Protective coverall with one-piece hood

Hooded three-dimensional cut and elastic band around the face opening with one piece, it is more convenient to increase the face shape and protection effect.

Stitched Tape edges

Each seam is sealed with tape. Internal elastic band is applied to the waist. These sewing style applications provide better protection.

Elastic cuff

Elastic cuff application provides a tighter and better protection.



Protective Clothing Category III



SIZE CHART

SIZE	CHEST	HEIGHT
S		
M		
L		
XL		
XXL		
XXXL		

