Royal Shield Coverall -Type 3-B/4-B /5-B/6-B

Product Code : PS 3455

Documents :

- TECHNICAL SHEET
- EU TYPE EXAMINATION CERTIFICATE
- EU DECLARATION OF CONFORMITY
- FDA CERTIFICATE
- LAB REPORT
- TECHNICAL EVALUATION REPORT
- TECHNICAL FILE

Standards :

- EN 14126 :2003 / AC : 2004
- EN ISO 13688 : 2013
- EN 14605 : 2005 + A1 : 2009
- EN ISO 13982-1 : 2004 / A1 : 2010
- EN ISO 13034: 2005 + A1 : 2009

Preparation date: 14.06.2020

T.002.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
NAME OF THE PRODUCT	Royal Shield Coverall - Type 3-B / 4-B / 5-B / 6-B (NON-STERILE)
PRODUCT CODE	PS 3455

PRODUCT INFORMATION	
Model Description	It is a disposable protective overall with a hood, front zipper, adhesive placket, sleeves, cuffs and hood with rubber, partial rubber in the middle of the waist, all seams with an external stripe band.
Fabric	57 gr PP+PE
Material	Number 120 white polyester yarn.
	Type 5 zipper with white plastic teeth.
	25 mm double-sided adhesive yellow tape.
	16 mm wide welding tape.
	3 mm rubber.

SEWING INSTRUCTIONS, LABEL AND IMPORTANT DETAILS	
General Sewing Instructions	All stitches will be 9 pricks in 2 cm.
	A yellow Groz Beckert needle with a ball tip numbered 9 or 10 will be used. (Gold needle)
	All machines to be used in interlace operations will be used with 5 thread overlock.
	Lengths of sleeves, cuffs and hoods and waistbands will be made according to the size chart.
	The waistband position will be 25 cm below the upper joint.
	The double-sided tape to be used in the placket should be 1 cm from the edge of the placket. Double-sided tape should never exceed the placket.
	The zipper should be balanced on the upper collar. Collar ends should be even when the zipper is closed.
	In front net fastening, the seams at the junction point of the placket and the front net should be joined without slipping. (In case of slipping, the front pile causes the fabric to tear)
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
	The products whose quality control process is finished are shipped to the welding machine park for the banding process. The seams are centered over all inter face seams and the welding strip is welded onto the seams by means of heat. There should not be additions on tapes and make sure that they adhere well.
Labels and Washing Instructions	A chest label is affixed 7 cm above the chest joint and 6 cm from the placket joint.
	The information that should be included on the label: BIOBLOCKED logo, disposable, product type, production and expiry date, size, relevant standards, relevant symbols, read the instructions for use, manufacturer company name, chart number and production lot number. The label must be in the language the product will be shipped to or in English.
CAUTION !!!	

PACKAGING DETAILS	
Folding	Work will be performed in accordance with the folding sample, if the folding sample has not reached you, request it.
Bag	Check that it is the same bag used in the folding sample and that the chart is compatible with the specified product code.
	Make sure the bag is closed properly and that there are no tears or holes.
	30x40 + 5 cm printed bags will be used.
Package	The pieces inside the box should be the same as the ones specified in the color chart.
	There should be one size in a box. Sizes should not be mixed.
	Packages should not be broken, collapsed or torn.
	Packages should be closed with tape written bioblocked.

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1255-R1

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
E5 Karayolu üzeri 5001 Sk. No:6 Selimpaşa Silivri - İSTANBUL / TURKEY

It is certified that the manufacturer's technical file (Dated 08.12.2020 Rev2) 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: BIOBLOCKED, **Model:** PS 3455
Protective coverall (overall) manufactured from white laminated polypropylene non-woven fabric with hood, inside over lock seams and seams are covered with adhesive hotmelt tape, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.

For more details refer technical evaluation report provided to the manufacturer, dated 29.12.2020 and number 2163-KKD-1255/R1.

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)
EN 14605:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type 3, Type 4, limited wear life clothing,
EN ISO 13982-1:2004/A1:2010, (Chemical protective clothing providing protection to the full body against airbone 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 3-B, 4-B, 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 a revision of certificate number 2163-PPE-1255 and issued on **29/12/2020** and will be valid until **11.08.2025**.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

EU DECLARATION OF CONFORMITY

MANUFACTURER
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ

E5 Karayoluüzeri 5001 Sokak. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name : BIOBLOCKED, Models :PS 3455 Protective Clothing against infective agents;
Type 3-B Protection Against Liquid Chemical Substances Liquid Proof
Type 4-B Protection Against Liquid Chemical Substances Spray Proof
Type 5-B - Providing Protection to the Full Body against Airborne Solid Particulates
Type 6-B - Offering Limited Protective Performance against Liquid Chemicals
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 isa 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 2016/425Personel Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards EN 14126:2003/AC:2004, EN 14605 + A1:2010, EN ISO 13982-1:2004/A1:2010, EN 13034:2005+A1:2009.
- EN ISO 13688: 2013 standard Defines basic health and ergonomic requirements, general size definition, size change in washing and dry cleaning, markings, harmlessness, design and general features.
- 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, afterall 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 B) of the PPE Regulation (EU) 2016/425, for quality assurance (Certificate number:2163 PPE 1255 – R1)

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.

Eren YELKENCİ
General Manager
30/12/2020

YELKENCİ HAZIR GİYİM
SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 5001 Sok. No:6/A Silivri / İST.
Tel : (0212) 723 86 50 Fax : (0212) 723 86 15
Silivri Vergi Dairesi : 947 017 7579
Ticaret Sicil No : 457834

CE
2163

2020

CERTIFICATE OF REGISTRATION

This certifies that:

YELKENCI HAZIR GIYIM SANAYI VE TICARET A.S.
E5 Karayolu Uzeri. 5001 Sk No.6 Selimpasa
Silivri Istanbul, TR 34570

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:	**10073829**
Device Classification Name:	**SUIT, SURGICAL**
Product Code:	**FXO**
Regulation Number:	**878.4040**
Official Correspondent and U.S. Agent:	**Registrar Corp** 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 Lennarz
Executive Director
Registrar Corp
Dated: May 19, 2020

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

20018044-ing-Add
07-20

TEST REPORT
DENEY RAPORU

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	15 Temmuz Mah. Gülbahar Cad. No:96 Bağcılar/İSTANBUL
Buyer name:	YELKENCİ HAZIR GİYİM
Contact Person:	SUAT KAÇMAZ
Order No:	-
Article No:	
Name and identity of test item:	White protective overalls.
The date of receipt of test item:	08.06.2020
Re-submitted/re-confirmation date:	-
Date of test:	08.06.2020-03.07.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	Not Specified
Number of pages of the report:	9

Gen.f136-2/03

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
TESTED BY EKOTEKS	03.07.2020	Servin KURTSEVEN	Sevim A. RAZAK

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Abrasion	-	Class 6
Water Permeability	-	Class 6
Tear Strength	-	Class 1
Tensile Strength	-	Class 1
Repellency to Liquids	-	See test result
Resistance To Penetration By Liquids	-	Class 3
Seam Strength	-	Class 1
Surface Resistivity(1)	F	-
Puncture Resistance	-	Class 2
Fabric Weight(2)	-	-
Determination of resistance to damage by flexing(3)	-	Class 5
MICROBIOLOGICAL TESTS		
Wet-Bacterial Penetration	-	Class 3

P: Pass
F: Fail
R: Refer to retailer technologist

Tests were classified according to BS EN 14325:2018
(1)Requirement was given by the vendor.
(2)No requirement was given.
(3) This report was reissued to add this test result.

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified. If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. Tests marked (*) in this report are not included in the accreditation schedule.

TEST RESULTS

Test Method : BS EN 14325:2018 (PROTECTIVE CLOTHING AGAINST CHEMICALS:TEST METHODS AND PERFORMANCE CLASSIFICATION OF CHEMICAL PROTECTIVE CLOTHING MATERIALS,SEAMS,JOINS AND ASSEMBLAGES (*)

ABRASION RESISTANCE AND LEAK TIGHTNESS

Clause 4.4.Abrasion Resistance (EN ISO 12947-2) ANNEX-B

Martindale Test Machine (47.5±2 rpm) with Lissajous Figure.
9 kPa pressure,
Performed in the conditioned room (20±2°C-65%±4).

RESULT	CLASS
No abrasion @ 2.000 revs	6 Classified according to the Table-1

Determination of the highest number of abrasion rubs which does not cause damage to the material and which shall be used for the performance classification.
The abrasion resistance of sample shall be Classified according to the levels of performance given in Table-1

Table-1 Classification of Abrasion Resistance

Class	*Number of rubs*
6	>2000
5	>1000
4	>400
3	>100
2	>40
1	>10

Clause 4.4.2.3 Hydrostatic head end –point determination (EN 20811)

If the average hydrostatic head exceeds 200mm,then the hydrostatic head method is applicable and the leak tightness shall be determined.

WATER PERMEABILITY ; EN ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model
Temperature of water10.°C. Pressure increase ratio 10 mbar/dk.
Performed in the conditioned room (20±2°C-65%±4)

	RESULT	REQUIREMENT
Sample 1	519.2 mm SS	>200 mmSS
Sample 2	466.1 mm SS	
Sample 3	755.8 mm SS	
Sample 4	575.3 mm SS	
Sample 5	883.3 mm SS	
Average	639.9 mm SS	

TEST RESULT

TRAPEZOIDAL TEAR STRENGTH

Clause: 4.7.Trapezoidal Tear Resistance TS EN ISO 9073-4:2002(*)

Instron 5969 Speed:100±10 mm/min, Gauge length:5cm
The average results are given for width and length direction of five samples.
2 pre-tension applied
Performed in the conditioned room. (20±2°C - 65% ±4)

	RESULT	CLASS
Width	23.0 N	1 Classified according to the Table-4
Length	10.6 N	

Table-4 Classification of Trapezoidal Tear Resistance

Class	*Tear Strength*
6	>150 N
5	>100 N
4	>60 N
3	>40 N
2	>20 N
1	>10 N

Gen.f136-2/03

TENSILE STRENGTH

Clause 4.9.Tensile Strenght EN ISO 13934-1:2013

Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. Without wetting samples.
The average results are given for width and length direction of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	CLASS
Width	77.5 N	1 Classified according to the Table-5
Length	38.5 N	

Table-4 Classification of Tensile Strenght

Class	*Tensile Strength*
6	>1000 N
5	>500 N
4	>250 N
3	>100 N
2	>60 N
1	>30N

TEST RESULT
REPELLENCY TO LIQUIDS

Clause 4.12 Repellency to Liquids (EN ISO 6530:2005)

When tested in accordance with EN ISO 6530 for repellency to the liquid chemicals given in Table -9, the material shall be classified According to the levels performance in given Table-10 for each chemical tested.
Use those liquids against which protection is required, water is also cenvenient and safe liquid for general screening purposes.
Performed in the conditioned room (20±2°C-65%±4).

For each test liquid ,cut six test specimens of (360±2)mm by (235±5)mm from the sample.
Chemicals shall be of analytical purity grade.
Discharged the test liquid (10cm 3) within (10±1)s

Table-9 List of reference chemicals for absorption ,penetration and repellency testing

Chemical	*Concentration weight %*	*Temperature of chemical (±2°C)*
Sulfuric Acid (H2SO4)	30	20
Sodium Hydroxide (NaOH)	10	20
o-Xylene	Undiluted	20

Table 10- Classification of Repellency to liquids

Class	*Repellency Index (I_R)*
3	> 90 %
2	>80 %
1	>70 %

Clause 4.13 Resistance to penetration by liquids (EN ISO 6530)

Table 11- Classification of Resistance to penetration by liquids

Class	*Penetration Index (Ip)*
3	< 1 %
2	< 5 %
1	<10 %

RESULT

Chemical	*Concentration weight %*	*I_P*	*Class*	*I_R*	*Class*
Sulfuric Acid (H2SO4)	30	0 %	3	105.7%	3
Sodium Hydroxide (NaOH)	10	0 %	3	30.6%	-
o-Xylene	Undiluted	0 %	3	69.3 %	-

I_P : index of penetration
I_R : index of repellency
I_A : index of absorbtion

TEST RESULT

SEAM STRENGTH-GRAB METHOD

Clause 5.5 Seam Strength ISO 13935-2: 2014
Jaw Speed: 50±5 mm/min, Gauge Length: 100 mm±1 mm.
Seam Type : 301. 100 % Polyester core-spun sewing-thread was used.
5kN. Load was applied.
The average results are given for width and length direction of five samples.
Performed in the conditioned room(20±2°C-65%±4)

	Seam Strength (N)	Fail	CLASS
Crotch	88.2 N	FTJ	1 Classified according to the Table-13
Inner side seam	75.3 N	FTS	
Front center seam	68.1 N	FTS	
Back center seam	74.2 N	FTS	
Waist	47.7 N	FTJ	
Sleeve	53.0 N	FTS	
Hat	48.1 N	FTS	
Zipper handle	132.2 N	-	

FTS : Fabric Tear At The Seam
FTJ : Fabric Tear At The Jaw

Table 13- Classification of Seam Strength

CLASS	*Seam strength*
6	>500 N
5	>300 N
4	>125 N
3	>75 N
2	>50 N
1	>30 N

TEST RESULT

SURFACE RESISTIVITY; EN 1149-1:2006(*)

Ohm meter (METRISO 3000) and ring probe were used.
Original sample was tested as the client's request

Pre-Treatment	-
Atmosphere for conditioning and testing	(23± 1)°C, (25± 5)%RH
Conditioning time	≥ 24 hours
Applied voltage	-
Number of samples tested	5

	RESULT	
Measurement	**Surface Resistivity**	**REQUIREMENT**
Geometrical Mean	$1.20 \times 10^{12}\ \Omega$	$<2.5 \times 10^{9}\ \Omega$

Gen.f136-2/03

FABRIC WEIGHT ; ISO 3801:1977 Method 5

The average results are given of five samples
Performed in the conditioned room (20±2°C-65%±4).

RESULT	REQUIREMENT
$62.1\ g/m^2$	-

TEST RESULT

PUNCTURE RESISTANCE

Clause 4.10.Puncture Resistance EN 863 (*)

RESULT

17.3 N

CLASS

2
Classified according to the Table-6

Table-4 Classification of Puncture Resistance
(Tablo-6)

Class	***Puncture Resistance***
6	>250 N
5	>150 N
4	>100 N
3	>50 N
2	>10 N
1	>5N

DETERMINATION OF RESISTANCE TO DAMAGE BY FLEXING METHOD C (CRUMPLE/FLEX) (*)
Test Metot : ISO 7854 :1995 Rubber- or plastics-coated fabrics -Determination of resistance to damage by flexing Method C (Crumple /Flex Test) (*)Clause 4.5
Two test pieces were prepared each 220 mm long x 190 mm widht
After cycle has finished examine the damage of samples and classified

RESULT

>40 .000 cycles

No damage observed

CLASS

Class 5
Classified according to the Table-2

Table 2-Classification of flex cracking resistance

Class	Number of cycles
6	> 100 000
5	>40 000
4	> 15 000
3	> 5 000
2	> 2 500
1	> 1000

TEST RESULTS

Test Method: BS EN 22610: 2006 (Surgical drapes, garments and fresh air clothes used as medical devices for patients, hospital staff and equipment - Test method for determination of resistance to wet bacterial permeability) (*)
A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are placed on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force (3N ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS

Breakthrough time, *t* min	**Number of Populating Bacteria (cfu)**		**Penetration Rate**	
15	X_1	0	R_{CUM1}	0
30	X_2	0	R_{CUM2}	0
45	X_3	30	R_{CUM3}	0,07
60	X_4	42	R_{CUM4}	0,17
75	X_5	96	R_{CUM5}	0,40
	Z	248		
	T	416		

X1 ..... X5: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: X1 + X2 + X3 + X4 + X5 + Z
RCUM1 = X1/T
RCUM2 = (X2 + X1)/T
RCUM3 = (X3 + X2 + X1)/T
RCUM4 = (X4 + X3 + X2 + X1)/T
RCUM5 = (X5 + X4 + X3 + X2 + X1)/T

EVALUATION

Result	**Class (*)**
30 < *t* ≤ 45	3

(*) BS EN 14126:2003 Protective Clothing —Performance requirements and tests methods for protective clothing against infective agents

Class	**Breakthrough time, *t* min**
6	*t* > 75
5	60 < *t* ≤ 75
4	45 < *t* ≤ 60
3	30 < *t* ≤ 45
2	15 < *t* ≤ 30
1	≤ 15 min

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EĞİTİM VE DIŞ TİC. LTD. ŞTİ.
Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025-A/20
28.07.2020

Test Report

Test Owner name / address	UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO. Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY
Manufacturer name/address	YELKENCİ HAZIR GİYİM A.Ş. -
Name and identity of the test item	Protective Clothes
The date of receipt of the test item	7.07.2020
Brand name – model	-
Date of the test	28.07.2020
Sample Number	GTTS-0025-4, GTTS-0025-5, GTTS-0025-6
Number of pages of the report	8

GCNTR ULUS.BELG.GÖZ.EĞT.VE DIŞ.TİC.LTD.ŞTİ *accredited by TÜRKAK under registration number* AB-1272-T *for* EN ISO17025 *as test laboratory"*

The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Date/Seal
28.07.2020

Head of Testing Laboratory
Sebahattin ÇAY

Report No: **GTL-TLM-0025-A/20**

GCNTR ULUSLARARASI BELGELENDİRME, GÖZETİM,
EĞİTİM VE DIŞ TİC. LTD. ŞTİ.
Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

Test Report

Contents

GCNTR ULUSLARARASI BELGELENDİRME, GÖZETİM,
EĞİTİM VE DIŞ TİC. LTD. ŞTİ.
Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025-A/20
28.07.2020

Test Report

1. Documentation

1.1 Description of the EUT

All samples tested

Test samples subject to the test

Product Name	Samples No	Sample Size	Type	Application Tests
Protective Clothing	GTTS-0025-4	Not Writing	Type 4	Pre-exercise Test- Spray Test
Protective Clothing	GTTS-0025-5	Not Writing	Type 4	Pre-exercise Test- Spray Test
Protective Clothing	GTTS-0025-6	Not Writing	Type 4	Pre-exercise Test-Spray Test

1.2 Environmental Condition,Symbol Definitions

- Test case does not apply to the test object .....: N/A
- Test object meets the requirement.....: P (Pass)
- Test object does not meet the requirement.... : F (Fail)
- Environmental Conditions: °C , % RH, m/s

1.3 Test Standards

EN 14605+A1:2009 Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
EN ISO 17491-4 protective clothing – test methods for clothing providing protection against chemical – part 4: Determination of resistance to penetration by a spray of liquid (spray test)

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Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025-A/20
28.07.2020

Test Report

2. Test Result

Clause	Requirement	Result – Remark	Verdict
4.3.2	**Pre-Conditioning**		
	Prior to testing, the chemical protective clothing shall be cleaned, if the manufacturer's instructions indicate that cleaning is allowed. Manufacturer's instructions with regard to number of cleaning cycles, cleaning procedures and possible reapplication of treatments shall be observed. If no maximum number of cleaning cycles is indicated, the clothing shall undergo five cleaning cycles.	Protective clothing are, it's was come in the form of plastic packing by the company. For this reason, no additional cleaning was performed with the suggestion of the company.	PASS
4.3.3	**Conditioning**		
	Protective clothing against all chemicals must be conditioned for at least 24 hours under the same conditions used for the experiment.	All products are conditioned at 24 C° 50% Rh values for 24 hours.	PASS
4.3.4	**Resistance to the penetration of liquits**		
4.3.4.1	**General and Pre-test**		
	Pre-Test	-There are no preventing factors. -No tearing or deformation was observed in the samples Test details are given in table 1.	PASS
4.3.4.2	**Resistance to the penetration of liquits (SprayTest)**	**Type 4**	
EN ISO 17491-4 Article 9	Remove respirator and gloves first before opening the test garment. Remove the chemical protective clothing carefully in order to avoid contamination of the absorbent overall and examine the internal surface of the test garment for signs of penetration, paying special attention to openings, seams, closures and zippers. Mark them.	Three test clothes were dressed tested together with the white absorbent underwear. Regions passing liquid are given in figure 1.	PASS
Clouse 4.3.3.2	Any underwear, of each garment suit. The total stain area on it should not be more than three times the calibrated total stain area.	Calibration stain area: measured as 4.56 cm^2. Sum of stains on the inner white garment given in table 2	PASS

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Dilovası – Kocaeli / TÜRKİYE

Test Report

Table 1

		Pre-Experiment		Liquid Experiment 1		Liquid Experiment 2		Liquid Experiment 3	
Clause	**Requirement**	**PASS**	**FAİL**	**PASS**	**FAİL**	**PASS**	**FAİL**	**PASS**	**FAİL**
	Starting from a standing position in each case, carry out the following movement sequence:								
Movement 1	Kneel on both knees, lean forward and place both hands on the floor (45 ± 5) cm in front of the knees; crawl forward and backwards on hands and knees for a distance of three metres in each direction;	✓		✓		✓		✓	
Movement 2	Climb a vertical ladder at least four steps, rungs to be as encountered on a typical ladder;	✓		✓		✓		✓	
Movement 3	Position hands at chest level, palms out; reach directly overhead, interlock thumbs, extend arms fully upwards;	✓		✓		✓		✓	
Movement 4	Kneel on right knee, place left foot on floor with left knee bent (90 ± 10) 0; touch thumb of right hand to toe of left shoe. Repeat movement with alternate posture, i.e. by kneeling on left knee and placing the right foot on the floor with knee bent at 90°.	✓		✓		✓		✓	
Movement 5	Extend arms fully in front of body, lock thumbs together, twist upper body (90 ± 10) ° left and right.	✓		✓		✓		✓	
Movement 6	Stand with feet shoulder width apart, arms at side; raise arms until they are parallel to the floor in front of the body; squat down.	✓		✓		✓		✓	
Movement 7	Kneel as in movement 4, left arm hanging loosely at side; raise arm fully overhead. Repeat movement with alternate posture by alternating arms.	✓		✓		✓		✓	

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Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025-A/20
28.07.2020

Test Report

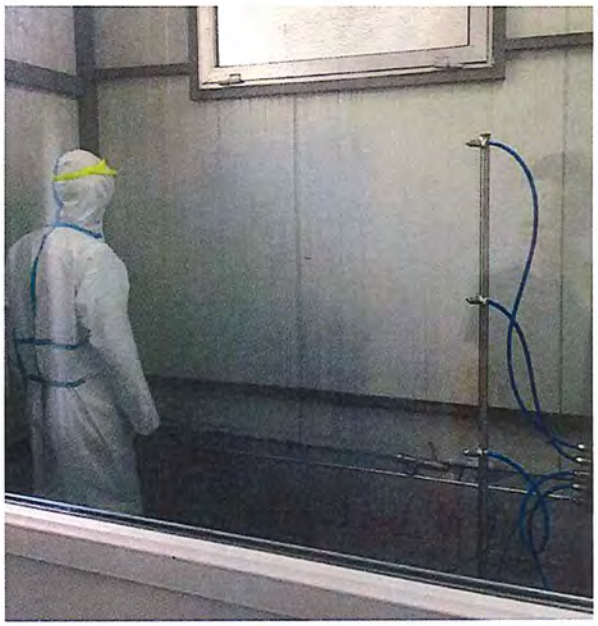
Pre-experiment 1	İ.Ç **Height:** 180 cm **Weight:** 65 kg
Liquid Experiment 1	İ.Ç
Liquid Experiment 2	İ.Ç
Liquid Experiment 3	İ.Ç

Table 2

SPREY EXPERİENCE						
	UPPER BODY			LOWER BODDY		SUM
	Chest (cm^2)	Shoulder (cm^2)	Back (cm^2)	Front (cm^2)	Back (cm^2)	
GTTS-0025						
Sample 4	-	-	-	-	-	0
Sample 5	-	-	-	-	-	0
Sample 6	-	-	-	-	-	0

3. Attachments

3.1 Photos of EUT



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EĞİTİM VE DIŞ TİC. LTD. ŞTİ.
Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025-A/20
28.07.2020

Test Report

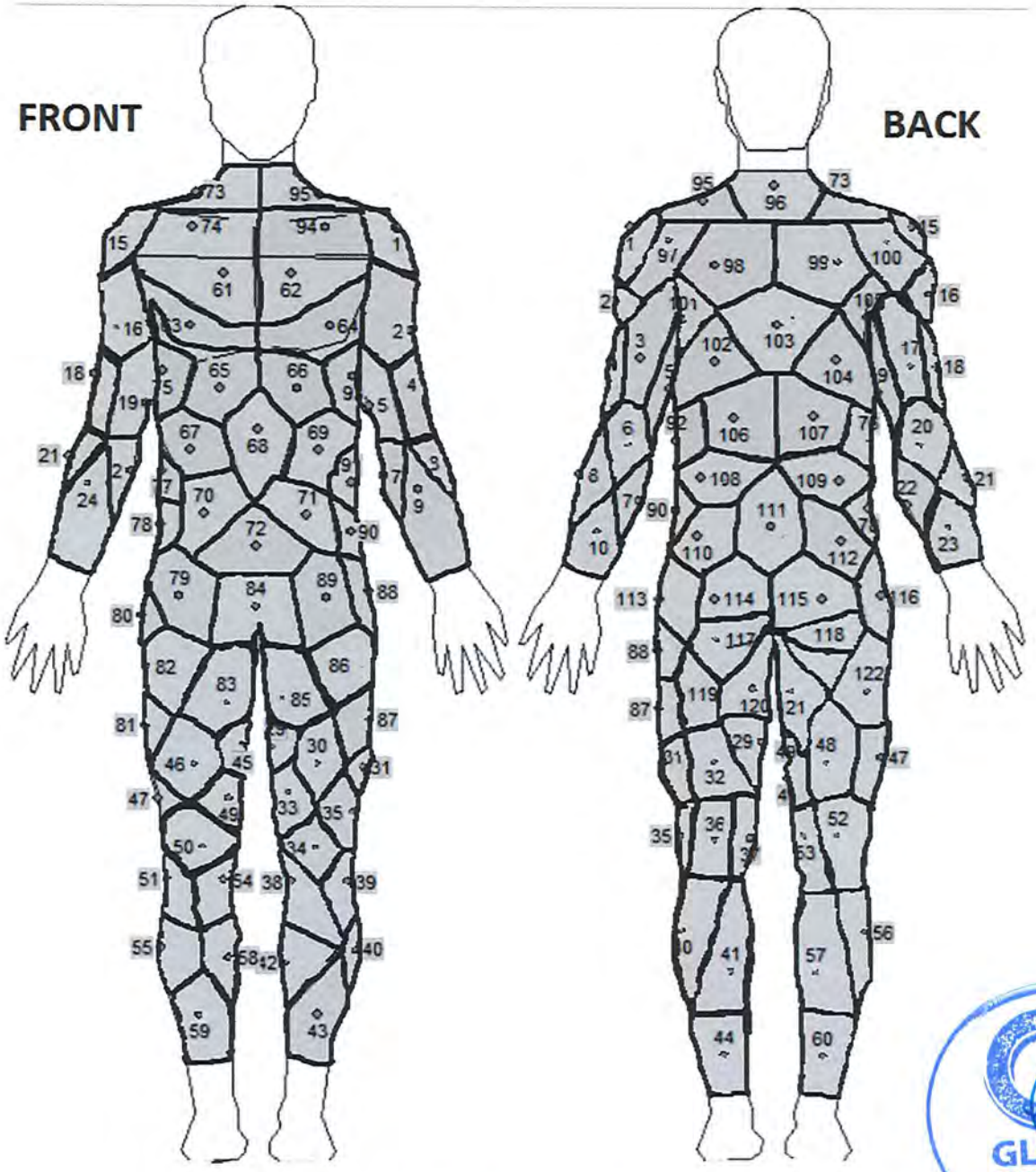

Figure 1 Regions passing liquid

Report No: **GTL-TLM-0025-A/20**

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Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025/20
28.07.2020

Test Report

Test Owner name / address	UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO. Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY
Manufacturer name/address	YELKENCİ HAZIR GİYİM A.Ş. -
Name and identity of the test item	Protective Clothes
The date of receipt of the test item	7.07.2020
Brand name – model	-
Date of the test	28.07.2020
Sample Number	GTTS-0025-1, GTTS-0025-2, GTTS-0025-3
Number of pages of the report	8

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The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Date/Seal
28.07.2020

Head of Testing Laboratory
Sebahattin ÇAY

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Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025/20
28.07.2020

Test Report

Contents

GCNTR ULUSLARARASI BELGELENDİRME, GÖZETİM,
EĞİTİM VE DIŞ TİC. LTD. ŞTİ.
Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025/20
28.07.2020

Test Report

1. Documentation

1.1 Description of the EUT

All samples tested

Test samples subject to the test

Product Name	Samples No	Sample Size	Type	Application Tests
Protective Clothing	GTTS-0025-1	Not Writing	Type 3	Pre-exercise Test Jet Test
Protective Clothing	GTTS-0025-2	Not Writing	Type 3	Pre-exercise Test Jet Test
Protective Clothing	GTTS-0025-3	Not Writing	Type 3	Pre-exercise Test Jet Test

1.2 Environmental Condition, Symbol Definitions

- Test case does not apply to the test object .....: N/A
- Test object meets the requirement.....: P (Pass)
- Test object does not meet the requirement.... : F (Fail)
- Environmental Conditions: °C , % RH, m/s

1.3 Test Standards

EN 14605+A1:2009 Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
EN ISO 17491-3 Protective Clothing – Test methods for clothing providing protection against chemicals – Part3: Determination of resistance to penetration by a jet of liquid (jet test)

2. Test Result

Clause	Requirement	Result – Remark	Verdict
4.3.2	**Pre-Conditioning**		
	Prior to testing, the chemical protective clothing shall be cleaned, if the manufacturer's instructions indicate that cleaning is allowed. Manufacturer's instructions with regard to number of cleaning cycles, cleaning procedures and possible reapplication of treatments shall be observed. If no maximum number of cleaning cycles is indicated, the clothing shall undergo five cleaning cycles.	Protective clothing are, it's was come in the form of plastic packing by the company. For this reason, no additional cleaning was performed with the suggestion of the company.	PASS
4.3.3	**Conditioning**		
	All chemical protective clothing shall be conditioned for at least 24 h at the same conditions as used for the test.	All products are conditioned at 24 C° 50% Rh values for 24 hours.	PASS
4.3.4	**Resistance to the penetration of liquits**		
4.3.4.1	**General and Pre-test**		
	Pre-Test	-There are no preventing factors. -No tearing or deformation was observed in the samples. Test details are given in table 1.	PASS
4.3.4.2	**Resistance to the penetration of liquits (Jet Test)**	**Type 3**	
EN ISO 17491-4 Article 9	Three new suits, pre-conditioned in accordance with 4.3.2, shall be tested in accordance with EN 463. If applicable, the suits shall be worn with the additional personal protective equipment specified in the manufacturer's instructions.	Three test clothes were dressed tested together with the white absorbent underwear. Regions passing liquid are given in figure 1.	PASS
	All suits shall pass the test, i.e. the total stain area on any one undergarment of each suit shall be less than or equal to three times the total calibrated stain area.	Calibration stain area: measured as 4.56 cm^2. Sum of stains on the inner white garment given in table 2	PASS

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Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025/20

28.07.2020

Test Report

Table 1

		Pre-Experiment		Liquid Experiment 1		Liquid Experiment 2		Liquid Experiment 3	
Clause	**Requirement**	**PASS**	**FAİL**	**PASS**	**FAİL**	**PASS**	**FAİL**	**PASS**	**FAİL**
	Starting from a standing position in each case, carry out the following movement sequence:								
Movement 1	Kneel on both knees, lean forward and place both hands on the floor (45 ± 5) cm in front of the knees; crawl forward and backwards on hands and knees for a distance of three metres in each direction;	✓		✓		✓		✓	
Movement 2	Climb a vertical ladder at least four steps, rungs to be as encountered on a typical ladder;	✓		✓		✓		✓	
Movement 3	Position hands at chest level, palms out; reach directly overhead, interlock thumbs, extend arms fully upwards;	✓		✓		✓		✓	
Movement 4	Kneel on right knee, place left foot on floor with left knee bent (90 ± 10) 0; touch thumb of right hand to toe of left shoe. Repeat movement with alternate posture, i.e. by kneeling on left knee and placing the right foot on the floor with knee bent at 90°.	✓		✓		✓		✓	
Movement 5	Extend arms fully in front of body, lock thumbs together, twist upper body (90 ± 10) ° left and right.	✓		✓		✓		✓	
Movement 6	Stand with feet shoulder width apart, arms at side; raise arms until they are parallel to the floor in front of the body; squat down.	✓		✓		✓		✓	
Movement 7	Kneel as in movement 4, left arm hanging loosely at side; raise arm fully overhead. Repeat movement with alternate posture by alternating arms.	✓		✓		✓		✓	

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Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025/20
28.07.2020

Test Report

Pre-experiment 1	İ.Ç **Height:** 180 cm **Weight:** 65 kg
Liquid Experiment 1	İ.Ç
Liquid Experiment 2	İ.Ç
Liquid Experiment 3	İ.Ç

Table 2

SPREY EXPERİENCE						
	UPPER BODY			LOWER BODDY		SUM
	Chest (cm^2)	Shoulder (cm^2)	Back (cm^2)	Front (cm^2)	Back (cm^2)	
GTTS-0025						
Sample 1	2	-	-	-	-	2
Sample 2	1,5	-	-	-	-	1,5
Sample 3	-	-	-	-	-	0

3. Attachments

3.1 Photos of EUT






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Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0025/20
28.07.2020

Test Report

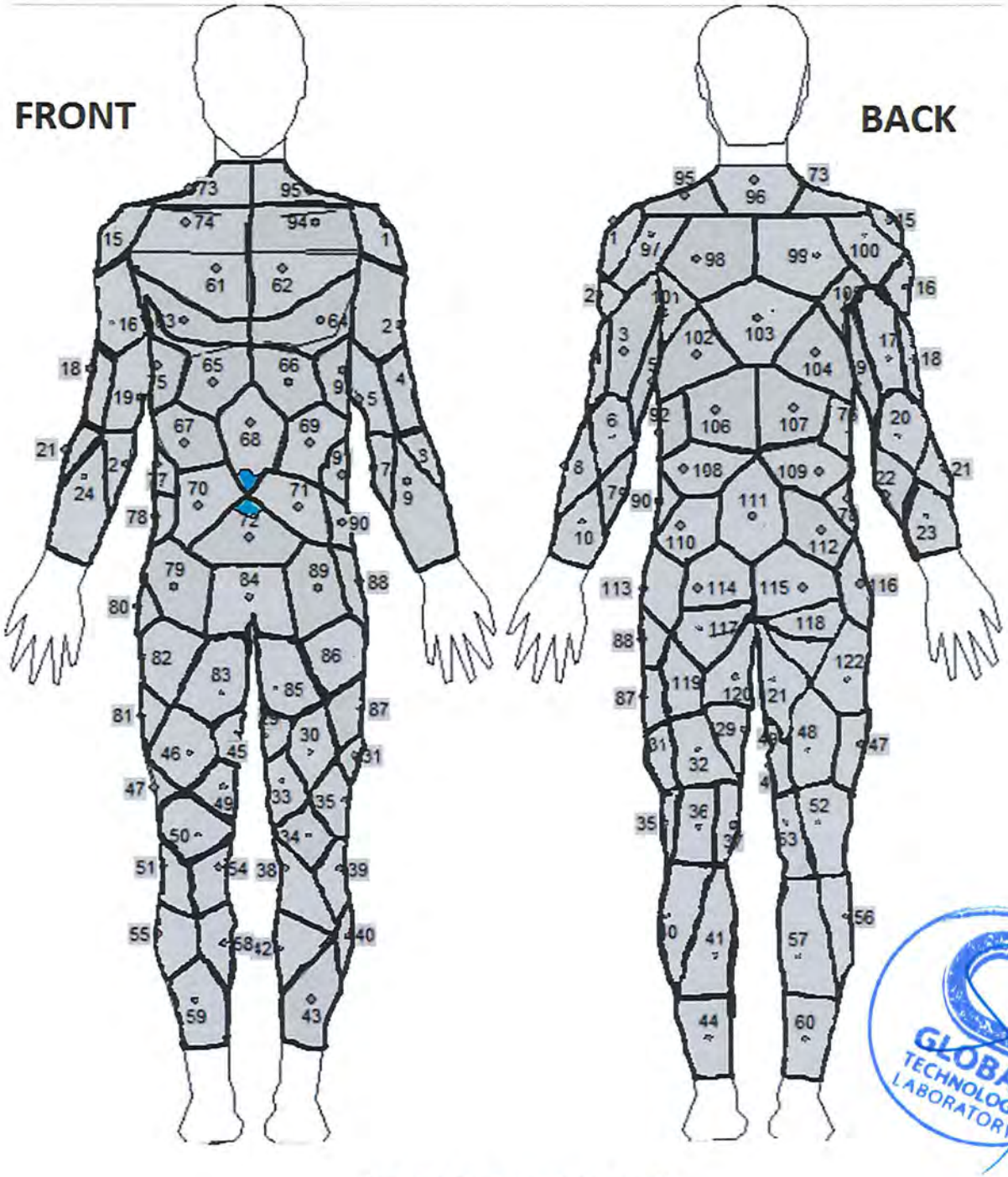

Figure 1 Regions passing liquid

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GCN TURK
GLOBAL CERTIFICATION NETWORK

GCNTR ULUSLARARASI BELGELENDİRME, GÖZETİM, EĞİTİM VE DIŞ TİC. LTD. ŞTİ.
Atak Plaza-Tavukçuyolu Cad. Demirtürk Sok. No:10 Yukari Dudullu Umraniye, Istanbul / TURKEY

TEST REPORT

Report Date: 21.12.2020
Report Number: GTL-TLM-0097A/20

CLIENT and SAMPLE INFORMATION

TEST OWNER	UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO		
ADDRESS	Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY		
MANUFACTURER	YELKENCİ HAZIR GİYİM A.Ş.		
ADDRESS	E5 KARAYOLU ÜZERİ 5001 SK.NO:6 SELİMPAŞA SİLİVRİ/İSTANBUL		
SAMPLE DESCRIPTION	Protective Clothes		
BRAND NAME – MODEL	-		
TESTING STANDARD	EN 13982-1:2018		
SAMPLE RECEIVE DATE	16.12.2020	TESTING START DATE	18.12.2020

GLOBAL TECHNOLOGY LABORATORY

Mr. Sebahattin ÇAY
General Coordinator

GLOBAL TECHNOLOGY LABORATORY

GCN TURK
GLOBAL CERTIFICATION NETWORK

1. *REPORT SUMMARY*

TEST STANDARD	*TEST NAME*	*RESULT*
EN 13982-1:2018 clause 4.3.2 ISO 13982-2	Inward Leakage Testing	**Pass**

2. *TEST RESULTS and EVALUATION*

4.3.2 Inward leakage of aerosols of solid particles

Test Method: ISO 13982-2

Temperature and relative humidity measurements were recorded in the test chamber immediately after each test and these ranged from 20.2 to 22.5 ^{O}C and 30.2 to 34.8%, respectively

Before testing a suit according to ISO 13982-2, the subject shall be except that he must repeat the following three rows of moves three times:

- Movement 1: Both knees collapse, lean forward and hands are placed on the floor at a distance of 45 cm from the front of the knees. It is crawled forward on the hands and knees for 3 m and the same distance is crawled back again.

- Movement 2: Standing with feet wide and arms on the side. Arms in front of the body

It is removed until it is parallel to the ground. It crouches down as much as possible.

- Movement 3: Kneel down on the right knee, knee bent 90° and place the left foot on the ground, hang loosely from the edge with the left arm. The left arm is lifted completely over the head

REQUIREMENT	RESULTS	COMMENT
Ljmn,82/90 ⩽% 30, LS,8/10 ⩽ % 15.	Pass	Detail refer to Annex I In response to the question "does the suit fit", all test subjects answered "Yes". After testing in accordance with the movements defined in clause 4.3.2 of EN 13982-1 : 2018, no damage to the suit was observed.

Annex I-Test Result:

Table 1 NaCl inward leakage (%) individual results

Wearer	Position	Knee	Waist back	Chest	Average
1	Stand	13,74	14,73	15,81	14,76
	Walk	14,69	16,92	12,52	14,71
	Squat	13,47	14,58	13,39	13,81
	Average	13,97	15,41	13,91	14,43
1	Stand	14,33	13,83	13,02	13,73
	Walk	14,62	12,65	13,81	13,69
	Squat	15,51	11,79	14,70	14,00
	Average	14,82	12,76	13,84	13,81
2	Stand	14,61	13,91	13,65	14,05
	Walk	14,04	12,23	13,36	13,21
	Squat	9,35	11,45	14,04	11,61
	Average	12,66	12,53	13,68	12,96
2	Stand	14,05	13,79	13,11	13,65
	Walk	14,81	12,35	13,00	13,39
	Squat	10,25	11,42	14,69	12,12
	Average	13,04	12,52	13,60	13,05
3	Stand	14,08	13,53	13,78	13,79
	Walk	14,89	12,19	13,51	13,53
	Squat	15,62	11,20	14,85	13,89
	Average	14,86	12,30	14,05	13,74
3	Stand	14,67	14,41	13,73	14,27
	Walk	14,56	12,13	13,64	13,44
	Squat	11,03	11,80	14,12	12,32
	Average	12,79	12,78	13,83	13,24
4	Stand	14,51	14,21	13,57	14,09
	Walk	14,77	12,27	13,79	13,61
	Squat	17,85	11,01	14,97	14,61
	Average	15,71	12,49	14,11	14,10
4	Stand	14,27	13,76	13,31	13,78
	Walk	14,80	12,38	13,36	13,52
	Squat	8,04	11,33	14,24	11,20
	Average	12,37	12,49	13,64	12,83
5	Stand	14,99	13,63	13,37	14,00
	Walk	14,56	12,99	13,87	13,81
	Squat	14,05	11,94	14,10	13,36
	Average	14,53	12,86	13,78	13,72
5	Stand	14,82	13,94	13,70	14,15
	Walk	14,49	12,44	13,44	13,46
	Squat	11,39	11,71	14,50	12,53
	Average	13,57	12,70	13,88	13,38

Table 2: Total inward leakage (%) (overall average, all wearers)

Position	Knee	Waist back	Chest	Average
Stand	14,39	13,97	13,70	14,02
Walk	14,27	12,85	13,43	13,52
Squat	12,65	11,82	14,36	12,95
Average	13,77	12,88	13,83	13,50

Table 3: Total inward leakage per test subject

Wearer	Average
1	14,12
2	13,01
3	13,49
4	13,47
5	13,55
Average	13,53

The physical dimensions of the wearers are shown below:

Wearer	Height (cm)	Chest (cm)	Suit size
1	182	104	-
2	183	99	-
3	182	95	-
4	186	98	-
5	184	97	-

Pass	*Requirement satisfied.*
NCR	*Requirement not satisfied. Refer to the "Result details" section for more information.*
NAs	*Assessment not carried out.*
N/A	*Requirement not applicable.*

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Sample Photo

- End of Report -

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Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0097/20
21.12.2020

Test Report

Test Owner name / address	UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO. Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY
Manufacturer name/address	YELKENCİ HAZIR GİYİM A.Ş. E5 KARAYOLU ÜZERİ 5001 SK.NO:6 SELİMPAŞA SİLİVRİ/İSTANBUL
Name and identity of the test item	Protective Clothes
The date of receipt of the test item	16.12.2020
Brand name – model	-
Date of the test	18.12.2020
Sample Number	GTTS-0097-1, GTTS-0097-2, GTTS-0097-3
Number of pages of the report	8

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The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Date/Seal
21.12.2020

Head of Testing Laboratory
Sebahattin ÇAY

Report No: **GTL-TLM-0097/20**

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EĞİTİM VE DIŞ TİC. LTD. ŞTİ.
Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

Test Report

Contents

GCNTR ULUSLARARASI BELGELENDİRME, GÖZETİM,
EĞİTİM VE DIŞ TİC. LTD. ŞTİ.
Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

Test Report

1. Documentation

1.1 Description of the EUT

All samples tested

Test samples subject to the test

Product Name	Samples No	Sample Size	Type	Application Tests
Protective Clothing	GTTS-0097-1	2XL-3XL	Type 6	Pre-exercise Test- Spray Test
Protective Clothing	GTTS-0097-2	2XL-3XL	Type 6	Pre-exercise Test- Spray Test
Protective Clothing	GTTS-0097-3	2XL-3XL	Type 6	Pre-exercise Test-Spray Test

1.2 Environmental Condition, Symbol Definitions

- Test case does not apply to the test object .....: N/A
- Test object meets the requirement.....: P (Pass)
- Test object does not meet the requirement.... : F (Fail)
- Environmental Conditions: °C , % RH, m/s

1.3 Test Standards

EN 13034+A1:2011 Protective clothing against liquid chemicals – Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment).
EN ISO 17491-4 protective clothing – test methods for clothing providing protection against chemical – part 4: Determination of resistance to penetration by a spray of liquid (spray test)

Test Report

2. Test Result

Clause	Requirement	Result – Remark	Verdict
TS EN 14325 4.2	**Pre-Treatment**		
Ts EN 14325 Article 4.2.1	Prior to testing, the chemical protective clothing shall be cleaned, if the manufacturer's instructions indicate that cleaning is allowed. Manufacturer's instructions with regard to number of cleaning cycles, cleaning procedures and possible reapplication of treatments shall be observed. If no maximum number of cleaning cycles is indicated, the clothing shall undergo five cleaning cycles.	Protective clothing are, it's was come in the form of plastic packing by the company. For this reason, no additional cleaning was performed with the suggestion of the company.	PASS
TS EN 14325 4.3	**Conditioning**		
	All chemical protective clothing shall be conditioned for at least 24 h at the same conditions as used for the test.	All products are conditioned at 24 C° 50% Rh values for 24 hours.	PASS
TS EN 13034+A1 5.2	**Pre-Test**	In the exercise test deformations were. Deformation details is given in the table 1.	PASS
TS EN 13034+A1 5.2	**Resistance to the penetration of liquits (SprayTest)**	**Type 6**	
EN ISO 17491-4 Article 9	Remove respirator and gloves first before opening the test garment. Remove the chemical protective clothing carefully in order to avoid contamination of the absorbent overall and examine the internal surface of the test garment for signs of penetration, paying special attention to openings, seams, closures and zippers. Mark them.	Three test clothes were dressed tested together with the white absorbent underwear. Region passing of liquid are given in figure 1.	PASS
TS EN 13034+A1 Article 5.2	Any underwear, of each garment suit The total stain area on it should not be more than three times the calibrated total stain area.	Calibration stain area: measured as 4.56 cm^2. sum of stains on the inner white garment are given in table 2	PASS

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Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

Test Report

Table 1

		Pre-Experiment		Liquid Experiment 1		Liquid Experiment 2		Liquid Experiment 3	
Clause	Requirement	PASS	FAİL	PASS	FAİL	PASS	FAİL	PASS	FAİL
	Starting from a standing position in each case, carry out the following movement sequence:								
Movement 1	Kneel on both knees, lean forward and place both hands on the floor (45 ± 5) cm in front of the knees; crawl forward and backwards on hands and knees for a distance of three metres in each direction;	✓		✓		✓		✓	
Movement 2	Climb a vertical ladder at least four steps, rungs to be as encountered on a typical ladder;	✓		✓		✓		✓	
Movement 3	Position hands at chest level, palms out; reach directly overhead, interlock thumbs, extend arms fully upwards;	✓		✓		✓		✓	
Movement 4	Kneel on right knee, place left foot on floor with left knee bent (90 ± 10) 0; touch thumb of right hand to toe of left shoe. Repeat movement with alternate posture, i.e. by kneeling on left knee and placing the right foot on the floor with knee bent at 90 .	✓		✓		✓		✓	
Movement 5	Extend arms fully in front of body, lock thumbs together, twist upper body (90 ± 10) ° left and right;	✓		✓		✓		✓	
Movement 6	Stand with feet shoulder width apart, arms at side; raise arms until they are parallel to the floor in front of the body; squat down as far as possible;	✓		✓		✓		✓	
Movement 7	Kneel as in movement 4, left arm hanging loosely at side; raise arm fully overhead. Repeat movement with alternate posture by alternating arms.	✓		✓		✓		✓	

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Çerkeşli OSB Mah. İMES OSB 18. Cad. A4/2 No.41/2
Dilovası – Kocaeli / TÜRKİYE

Test Report

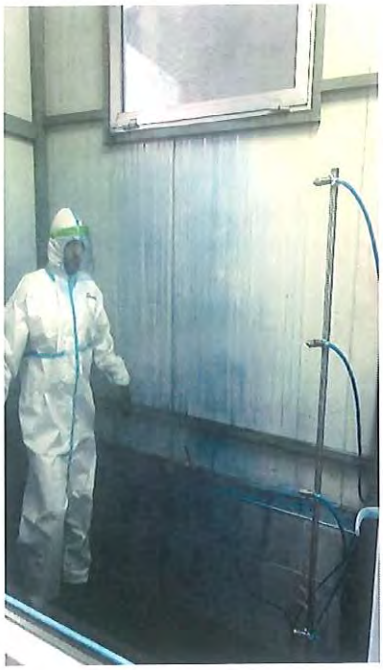
Pre-experiment 1	M.A Height: 170 cm Weight: 70 kg
Liquid Experiment 1	M.A
Liquid Experiment 2	M.A
Liquid Experiment 3	M.A

Table 2

SPREY EXPERİENCE						
	UPPER BODY			LOWER BODDY		SUM
	Chest (cm^2)	Shoulder (cm^2)	Back (cm^2)	Front (cm^2)	Back (cm^2)	
GTTS-0097						
Sample 1	-	-	-	-	-	0
Sample 2	-	-	-	-	-	0
Sample 3	-	-	-	-	-	0

3. Attachments

3.1 Photos of EUT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Dilovası – Kocaeli / TÜRKİYE

GTL-TLM-0097/20
21.12.2020

Test Report

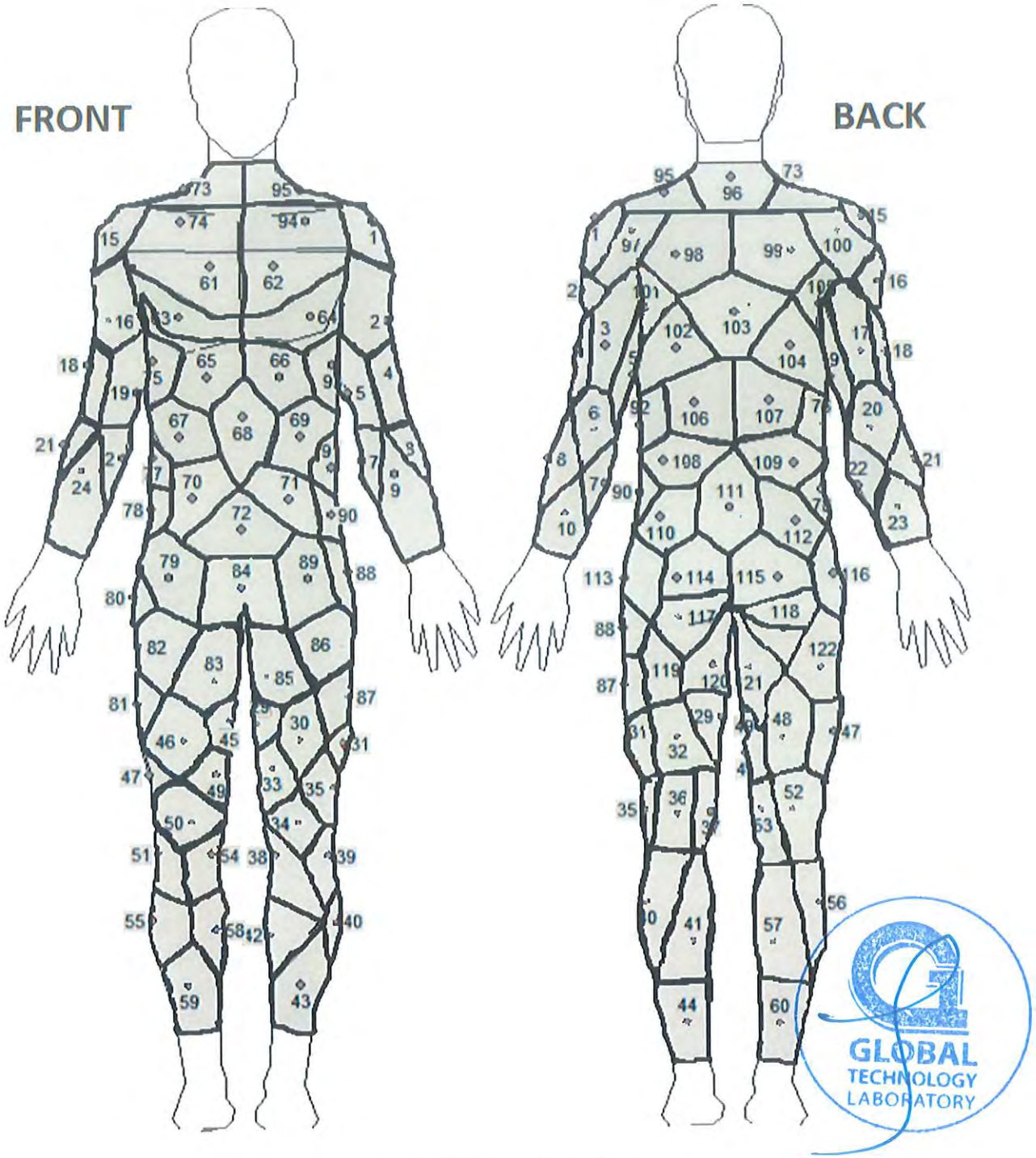

Figure 1 Region passing liquid

ANALYSIS REPORT

Report No. **: 2013885E** Report Date **:** 08/07/2020

Applicant **:** UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.

Address **:** Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye/İstanbul/Turkey

Sample **:** Overalls (2XL-3XL) Sample Code: 1972 - Product: PS 5657 - Class: 5-6 - BioBlocked

Sample Package **:** Original poly packing

Sample Amount **:** 4 pieces

Sampling Point **:** -

Sampling Date **:** 08/06/2020

Sample Lot No. **:** -

Sample Carrying Conditions / Preservation Technique **:** -

Production Date **:** -

Packing Date **:** -

Expire Date **:** 05/2023

Producer Company **:** Yelkenci Hazır Giyim Sanayi ve Ticaret A.Ş.

Sample Receiving Time **:** 08/06/2020 16:15:00

Analysis Beginning Time **:** 25/06/2020 10:00:00

Analysis Completion Time **:** 08/07/2020

Following analysis results were obtained from the specimen which was delivered to Çevre Laboratory by hand to hand

Parameters	Unit	Finding	Method	Information
Sentetik Kanın Nüfuzuna Karşı Direnç				
The Average Thickness of the Material Tested	mm	0,19	ISO 16603	148
The Average Mass of the Material Tested	g	0,337	ISO 16603	148
Sample Test 1: 0 kPa	-	Succeed	ISO 16603	149
Sample Test 1: 1,75 kPa	-	Succeed	ISO 16603	149
Sample Test 1: 3,5 kPa	-	Succeed	ISO 16603	149
Sample Test 1: 7 kPa	-	Succeed	ISO 16603	149
Sample Test 1: 14 kPa	-	Succeed	ISO 16603	149
Sample Test 1: 20 kPa	-	Succeed	ISO 16603	149
Sample Test 2: 0 kPa	-	Succeed	ISO 16603	149
Sample Test 2: 1,75 kPa	-	Succeed	ISO 16603	149

Merve BİRAH
Assistant Laboratory Responsible of Microbiology Laboratory

Approved by
08/07/2020
Ömer Yasin BALIK
Laboratory Manager

ANALYSIS REPORT

Report No. **: 2013885E** Report Date **:** 08/07/2020

Following analysis results were obtained from the specimen which was delivered to Çevre Laboratory by hand to hand

Parameters	Unit	Finding	Method	Information
Sample Test 2: 3,5 kPa	-	Succeed	ISO 16603	149
Sample Test 2: 7 kPa	-	Succeed	ISO 16603	149
Sample Test 2: 14 kPa	-	Succeed	ISO 16603	149
Sample Test 2: 20 kPa	-	Succeed	ISO 16603	149
Sample Test 3: 0 kPa	-	Succeed	ISO 16603	149
Sample Test 3: 1,75 kPa	-	Succeed	ISO 16603	149
Sample Test 3: 3,5 kPa	-	Succeed	ISO 16603	149
Sample Test 3: 7 kPa	-	Succeed	ISO 16603	149
Sample Test 3: 14 kPa	-	Succeed	ISO 16603	149
Sample Test 3: 20 kPa	-	Succeed	ISO 16603	149
The Procedure Selected	-	D	ISO 16603	
Microbial Penetration - Dry Bacterium	log cfu	<1	ISO 22612	150, 151
Pathogen Penetration				
The Procedure Selected	-	D	ISO 16604	155
Hydrostatic Pressure	kPa	20	ISO 16604	156
Test Spicemen 1	-	Succeed	ISO 16604	157
Test Spicemen 2	-	Succeed	ISO 16604	157
Test Spicemen 3	-	Succeed	ISO 16604	157
Pre-test Bacteriophage Titer	pfu/mL	$3,2*10^8$	ISO 16604	
Post-test Bacteriophage Titer	pfu/mL	$3*10^8$	ISO 16604	
Negative Control	-	Succeed	ISO 16604	
Positive Control	-	Fail	ISO 16604	
Microbial Penetration - Wet Bacterium				
Test Spicemen 1 - Colony Count	cfu	<1	ISO 22610	154
Test Spicemen 2 - Colony Count	cfu	<1	ISO 22610	154
Test Spicemen 3 - Colony Count	cfu	<1	ISO 22610	154
Test Spicemen 4 - Colony Count	cfu	<1	ISO 22610	154
Test Spicemen 5 - Colony Count	cfu	<1	ISO 22610	154
Test Spicemen 1 - Barrier Index	-	6	ISO 22610	154

Merve BİRAH
Assistant Laboratory Responsible of Microbiology Laboratory

Approved by
08/07/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul

ANALYSIS REPORT

Report No. **: 2013885E** Report Date **:** 08/07/2020

Following analysis results were obtained from the specimen which was delivered to Çevre Laboratory by hand to hand

Parameters	Unit	Finding	Method	Information
Test Spicemen 2 - Barrier Index	-	6	ISO 22610	154
Test Spicemen 3 - Barrier Index	-	6	ISO 22610	154
Test Spicemen 4 - Barrier Index	-	6	ISO 22610	154
Test Spicemen 5 - Barrier Index	-	6	ISO 22610	154
Test Spicemen 1 - Percentage of Penetration	%	0	ISO 22610	154
Test Spicemen 2 - Percentage of Penetration	%	0	ISO 22610	154
Test Spicemen 3 - Percentage of Penetration	%	0	ISO 22610	154
Test Spicemen 4 - Percentage of Penetration	%	0	ISO 22610	154
Test Spicemen 5 - Percentage of Penetration	%	0	ISO 22610	154
Average Penetration Percentage	%	0	ISO 22610	
Bacillus atrophaeus Concentration	spores/mL	$7*10^3$	ISO 22610	

Source of Limit Ranges **:** El ve Kol Koruması ve Can Yeleği Dahil Koruyucu Kıyafetler (EN 14126)

A: Acceptable NA: Not Acceptable

MU: Measurement Uncertainty

Method ISO : International Organization for Standardization

Information

148 : Test sample-1 is sampled from the right arm, test sample-2 left leg, test sample-3 body part. The thickness and mass given are the average of the results for these three samples.

149 : The retaining screen has 50% open area

150 : Test Conditions : 65±5 relative humidity and 20±2°C
ATCC 9372 Bacillus subtilis spores were used in the concentration of ethyl alcohol.
Talc concentration 10^8 cfu/g
200 mm x 200 mm 12 test pieces used
The vibrator was operated in an air flow with a vibration frequency of 20800 per minute.

151 : EN 14126 standard provides Class 3 values according to Table 4.

154 : Test Conditions : 65±5 relative humidity and 20±2°C minimum 24 hours
The distance to the distance agar-to-brim is 3.0 mm.
25 cm x 25 cm 5 test pieces were used.
The tests were carried out from the outside of the sample.
ATCC 9372 Bacillus atrophaeus spore suspension was used.
Incubator Control <4 cfu
Test Environment Control <25 cfu

155 : Test Conditions: Minimum 24 hours at 21 ± 5 ° C and 60 ± 10% relative humidity
Sample size and number: 3 test samples in size 75x75mm
Name of test microorganism: ATCC 13706-B1 Escherichia coli bacteriophage Phi X174
PFU: Plate forming unit

Merve BİRAH
Assistant Laboratory Responsible of Microbiology Laboratory

Approved by
08/07/2020
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Laboratory Manager

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ANALYSIS REPORT

Report No. **: 2013885E** Report Date **:** 08/07/2020

156 : The application pressure was chosen over the values obtained as a result of the procedure applied according to the ISO 16603 method.

157 : Test sample-1 right arm, test sample-2 left leg, test sample-3 were sampled from the body part.

Note

1. When request, the conformit assessment is carried out in accordance with the legal regulations and standards or the decision rules which are agreed with the customer.
2. Descriptive information about the samples / sampling in the analysis report has been declared by the customer. Our laboratory is not responsible for the legal losses.
3. Analysis report covers samples/sampling that comes to the laboratory.
4. This report and results don't not be copied and printed partially or completely without permission of Cevre Industrial Analysis Laboratory for any commercial and advertising purposes.
5. This report shall not be used official purposes related to Enviromental Regulations.
6. The test report without sign is not valid.

End of Report

Merve BİRAH
Assistant Laboratory Responsible of Microbiology Laboratory

Approved by
08/07/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul

UNIVERSAL
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TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 29.12.2020 / 2163-KKD-1255/R1 **Revised Report Date/No:** 12.08.2020 / 2163-KKD-1255
Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Address: E5 Karayolu üzeri 5001 Sk. No:6 Selimpaşa Silivri - İSTANBUL / TURKEY

Introduction

This coverall product (PS 3455) was checked and certified as a Tye 3-B / 4-B on 12.08.2020. Upon the manufacturer request the coverall is also tested and evaluated according to Type 5-B and Type 6-B requirements based on the relevant EN standards and Essential Health and Safety Requirements of PPE Regulation EU 2016/425. The fabric used in the model is changed and the manufacturer used a fabric which is used in another coverall model (PS 5657) which is evaluated and certified by us. This technical evaluation report is updated accordingly.

This report is prepared based on the evaluations on the technical file of the manufacturer dated 08.12.2020 version 2, and the test reports obtained from the laboratories for the analysis referenced by the applied harmonised standards for the personal protective equipment identified below. A list to the test reports is given below which are referenced within this report. The samples for evaluation are provided by the manufacturer for type examination and samples are delivered to the laboratories under UNIVERSAL supervision. The test results and all evaluations within this report belongs to the samples provided.

This report is prepared for the PPE with the guidance of the harmonised standards which are claimed to be applied by the manufacturer and the evaluation is conducted for the verification of fulfilment of Essential Health and Safety Requirements of PPE regulation, those applies for the product.

PPE Identification: Protective coverall (overall) manufactured from white laminated polypropylene non-woven fabric with hood, inside over lock seams and seams are covered with adhesive tape, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.
The PPE fabric is 20 gsm nonwoven, 35 gsm PE breathable film, 2 gsm hotmelt, total 57 gsm. Seams are covered with blue 16mm hotmelt tape. Polyester woven white zipper.
Coverall Type: Type 3-B / Type 4-B / Type 5-B / Type 6-B
Brand Name: BIOBLOCKED Model: PS 3455 **Sizes Available:** S - M – L – XL – XXL - XXXL

Applied Harmonised Standards

EN ISO 13688:2013, (General requirements for protective clothing)
EN 14605:2005+A1:2009, (Chemical protective clothing protective performance against chemicals in the forms liquid and spray) Type 3 and Type 4, limited wear life clothing,
EN ISO 13982-1:2004/A1:2010, (Chemical protective clothing providing protection to the full body against airbone 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 3-B, 4-B, 5-B, 6-B

This report is prepared on the basis of applicable Essential Health and Safety Requirements with the references annexed to each applied harmonised standard given above.

TEST REPORT INFORMATION

Report #	Laboratory Name	Report Date and Number	Competency Reference
1	Ekoteks Laboratuar ve Gözetim Hizmetleri A.Ş.	Dated 03.07.2020 Number: 20018044-Ing	Holds TURKAK Accreditation with No: AB-0583-T
2	GCNTR – Global Technology Laboratory	Dated 28.07.2020 # GTL-TLM-025-A/20	Holds TURKAK Accreditation with No: AB-1252-T
3	GCNTR – Global Technology Laboratory	Dated 28.07.2020 # GTL-TLM-025/20	Holds TURKAK Accreditation with No: AB-1252-T
4	GCNTR – Global Technology Laboratory	Dated 21.12.2020 # GTL-TLM-097-A/20	Holds TURKAK Accreditation with No: AB-1252-T
5	GCNTR – Global Technology Laboratory	Dated 21.12.2020 # GTL-TLM-097/20	Holds TURKAK Accreditation with No: AB-1252-T
6	Çevre Endüstriyel Analiz Laboratuarı	Dated 08.07.2020 Number: 2013885E	Holds TURKAK Accreditation with No: AB-0363-T
The laboratories are contracted bodies with UNIVERSAL and the technical competence of the laboratories is also under supervision assessment of UNIVERSAL based on the provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and services standard.			

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ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING to Annex ZA of EN ISO 13688:2013 STANDARD

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

1.2. Innocuousness of PPE

1.2.1. Absence of inherent risks and other nuisance factors

PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.

1.4. Manufacturer's instructions and information

In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:

a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;
b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;
c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;
d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
f) where applicable, the type of packaging suitable for transport;
g) the significance of any markings (see point 2.12);
h) the risk against which the PPE is designed to protect;
i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;
j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;
k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;
l) the internet address where the EU declaration of conformity can be accessed.

The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

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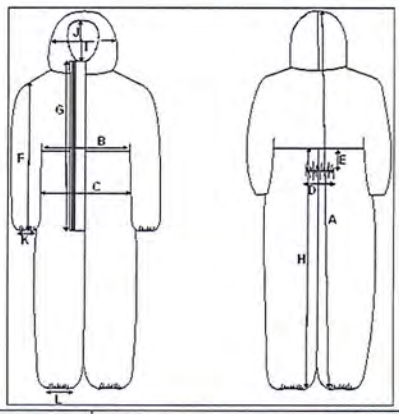
Technical Assessment of EN ISO 13688: 2013 Standard and other Standards it refers to, Clauses Corresponding to the Essential Health and Safety Requirements given above

EN ISO 13688 Standard Requirements Evaluation	
Article 4.2	EHSR Ref 1.2.1.1; The manufacturer declares in his technical file that the materials used in the manufacturing process of this specific PPE do not adversely affect the health or hygiene of the user. The manufacturer claims that the materials do not, in the foreseeable conditions of normal use, release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, toxic to reproduction or otherwise harmful. These declarations are supported with Material Safety Data Sheets belonging to the materials used in the manufacturing of the PPE. These datasheets claims that the materials are not toxic and do not have risks under normal conditions. The claim of the manufacturer includes non existence of heavy metals including Chromium VI, nonexistence of carcinogenic amines and the pH value of the material is between the allowed range by the standard (3,5 to 8,5). Ref: Technical File Material Identification section.
Article 4.4	EHSR Ref 1.2.1.2; The comfort of the PPE was subject to visual inspection by our experts for rough, sharp or hard surfaces that irritate or injure the user and found to be appropriate for use. In addition such properties of the PPE was subject to evaluation during the practical exercise testing as defined in the EN ISO 17491-4 testing standard and the PPE is reported as to be comfortable enough to allow the wearer to complete the excercises. Ref: Test Reports.
Article 5.3	EHSR Ref 1.2.1; The samples received from the manufacturer are claimed to be single use. No further evaluation is conducted on the dimensional change due to cleaning Ref: Technical File Material Identification section.
Article 6	EHSR Ref 2.12; The coverall is available in 6 nominal sizes. The nominal sizes are defined in the technical file of the manufacturer. The given dimensions in chest or bust girth and height are found in the limits defined in Annex D of the standard.



Measurement Points		SIZES						
		S	M	L	XL	XXL	XXXL	Tolerance
A	Length from top of hood	186	192	198	204	210	216	± 1,5 cm
B	Chest width	60	64	64	68	72	76	± 1 cm

Ref: Technical File Sizes section.

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EN ISO 13688 Standard Requirements Evaluation	
Article 7	EHSR Ref 2.12; Each piece of coverall have marking with the following information; • Name / trademark of the manufacturer, type of product • Size of the coverall • Applied product standards (Type defining product standards) • Applied protection pictograms with standard references The markings on the coverall / label are found to be easily visible and enough big to read. The marking rules are explained in the marking section of the technical file. For further clarifications for the marking requirements of applied product standards are available in the relevant standard section of this report.
Article 8	EHSR Ref 1.4; The information supplied by the manufacturer is defined in the relevant section of the technical file. This information includes explanation required by all applied product standard requirements. The defined user information text in the technical file includes the following data; • Name / trademark of the manufacturer, its address, • Applied standards and relevant classification, marking, size information • Pictograms and explanations • Coverall constituent materials used • Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary PPEs, re-usability, instructions for disposal The above user information text is available in Turkish

UNIVERSAL CERTIFICATION CE 2163 Notified Body

ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING to Annex ZA of EN 14605:2005 + A1:2009 STANDARD

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

1.1. Design principles

1.1.1. Ergonomics

PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.

1.2. Innocuousness of PPE

1.2.1. Absence of inherent risks and other nuisance factors

PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the use

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.

1.3. Comfort and effectiveness

1.3.2. Lightness and strength

PPE must be as light as possible without prejudicing its strength and effectiveness. PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

1.3.3. Compatibility of different types of PPE intended for simultaneous use

If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.

1.4. Manufacturer's instructions and information

In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:

a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;
b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;
c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;
d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
f) where applicable, the type of packaging suitable for transport;
g) the significance of any markings (see point 2.12);
h) the risk against which the PPE is designed to protect;
i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;
j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;
k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;
l) the internet address where the EU declaration of conformity can be accessed.

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2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user. If necessary, such PPE must be treated or provided with means to prevent misting-up. Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

CE 2163 Notified Body

UNIVERSAL UYGUNLUK DEĞERLENDİRME HİZM. ve TİC. A.Ş. Tatlısu Mh. Arif Ay Sk. No: 15/3 Ümraniye / İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

Technical Assessment of EN 14605:2005 + A1:2009 Standard and other Standards it refers to, Clauses Corresponding to the Essential Health and Safety Requirements given above

EN 14605:2005 + A1:2009 Standard Requirements Evaluation	
Article 4.1	EHSR Ref 1.2.1.1, 1.3.2, 3.10.2; The coverall material performance are tested according to EN 14325:2018 standard for the following properties, since the coverall is claimed to be for single use no cleaning cycle is applied;

Property of Material EN 14325:2018	Result Classification		Requirement of EN 14605	Evaluation
4.4 Abrasion Resistance	No Abrasion @2000 revs	Class 6	Class 1 or above	Success
4.5 Flex cracking resistance	> 40,000 Cycles	Class 5	Class 1 or above	Success
4.7 Trapezoidal tear resistance	Width 23.0 N Length 10.6 N	Class 1	Class 1 or above	Success
4.9 Tensile Strength	W 77.5 N L 38.5 N	Class 1	Class 1 or above	Success
4.10 Puncture Resistance	17.3 N	Class 2	Class 1 or above	Success
4.11 Resistance to penetration by liquids	Sulfuric Acid (H_2SO_4 %30 concentration) Sudium Hydroxide (NaOH %10 concentration) o-Xylene (Undiluted) I_P < 1 %	Class 3	Class 1 or above	Success

The above results are derived from the test report, in the reference below. In the evaluation of the test report it was stated that all the tests are conducted with the completion of conditioning requirements as (20 ± 2) C° and (65 ± 5) % relative humidity for 24 hours. Since the PPE are single use no cleaning or disinfection process is applied. The results fulfils the minimum requirements of the standard.
The manufacturer do not claim a performance for the resistance to ignition or flammability of the product, in the user information sheet it is explained that the coveralls must be kept away of fire.
Other requirements refered for skin compatibility, no irritation or adverse effects are evaluated in EN ISO 13688 section of this report.

Ref: Laboratory Test Report 1, Technical File

Article 4.2

EHSR Ref 1.3.2, 3.10.2;
The affects of seams to the performance of the coverall in penetration of liquids through sealed stitch holes are evaluated in the jet and spray tests of whole suit and evaluated in Article 4.3 of this section. In addition the seam strength and permeation of chemicals through the seams are tested and the results are given in the below table.
The seam strength is evaluated based on the test report as shown below;

Property of Material EN 14325:2018	Result Classification		Requirement of EN 14605	Evaluation
4.11 Resistance to permeation by chemicals	Sulfuric Acid (H_2SO_4 %30 concentration) Sudium Hydroxide (NaOH %10 concentration) o-Xylene (Undiluted) I_P < 1 %	Class 3	Class 1 or above	Success
5.5 Seam Strength	Refer to the strength values for seams at different parts of coverall. The lowest Class is given among all kinds of seams	Class 1	Class 1 or above	Success

Ref: Laboratory Test Report 1

UNIVERSAL UYGUNLUK DEĞERLENDİRME HİZM. ve TİC. A.Ş. Tatlısu Mh. Arif Ay Sk. No: 15/3 Ümraniye / İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

EN 14605:2005 + A1:2009 Standard Requirements Evaluation	
Article 4.3	EHSR Ref 1.1.1, 1.1.2.1, 1.2.1.2, 1.2.1.3, 1.3.1, 1.3.3, 3.10.2; The requirements of the coverall with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report. The coverall under evaluation is a one piece full body clothing, without a visor and foot protection. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested as a part of the Jet and spray tests (Seven Movements) and found to be appropriate. According to the test results reported; The test report claims the jet test that it is conducted according to EN ISO 17491-3 and the spary test that is conducted according to EN ISO 17491-4 Method B which is given in Clause 4.3.4.2 and 4.3.4.3 of this standard. • The subjects were able to complete the excercises described comfortably. The inspection on the tested samples states that there was no damage, tears or rips in fabrics, seams and connection points to the additionaly worn PPEs like gloves, boots etc. • For spray test, the calibrated stain area is calculated for the undergarment is 4.56 cm^2. The laboratory reports that for the 3 samples tested the total stain are of undergarments are smaller then three times the calibrated stain area, values are (0 cm^2, 0 cm^2, 0 cm^2). For more details please refer to the test report. • For jet test, the calibrated stain area is calculated for the undergarment is 4.56 cm^2. The laboratory reports that for the 3 samples tested the total stain are of undergarments are smaller then three times the calibrated stain area, values are (2 cm^2, 1.5 cm^2, 0 cm^2). For more details please refer to the test report. The above results indicates that the tested coveralls complies with the resistance to penetration by liquids in the form of spray test and jet test requirement of this standard. Which is based on a test report conducted according to EN ISO 17491-4:2008+A1:2016 and EN ISO 17491-3:2008. Ref: Laboratory Test Report 2, Laboratory Test Report 3
Article 4.4	EHSR Ref 1.1.1, 1.1.2.1, 1.2.1.2, 1.2.1.3, 1.3.1, 1.3.3, 3.10.2; The coverall do not have visor.
Article 5	EHSR Ref 2.12; Each piece of coverall have marking with the following information on the single PPE package / PPE itself; • Name / trademark of the manufacturer, type and model of PPE • Size of the coverall • Applied product standards (EN ISO 14605:2005 +A1:2019) • Pictograms for protection against chemicals, invitation to read manufacturer's instructions • Shelf life and date of manufacturing, and non reusable marking The above mentioned marking requirements are stated in the technical file of the manufacturer. The evaluated samples did not have all these marking and information on the PPE. The manufacturer shall follow the instructions in the technical file in case of serial manufacturing of the PPE and verify before putting the PPE on the market. The PPE coverall is for single use, the markings for re-use cleaning or disinfection is discarded. Ref: Technical File PPE Marking section.

UNIVERSAL CERTIFICATION CE 2163 Notified Body

EN 14605:2005 + A1:2009 Standard Requirements Evaluation	
Article 6	EHSR Ref 1.4; The information supplied by the manufacturer is defined in the relevant section of the technical file. This information includes explanation required by all applied product standard requirements. The defined user information text in the technical file includes the following data; • Name / trademark of the manufacturer, its address, or the authorised representative for EU community • Type of protection against chemicals (Type-3, Type-4, Type-5, Type-6). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, mask and visor / face shield). • Size of the coverall • Material test performance classifications (Based on EN 14325:2018 classification) • The statement that the coverall is tested against the chemical names (tested for) and performance levels for mechanical strengths including repellency and resistance to penetration of liquids (Based on EN 14325:2018 classification) • Pictogram and information that the PPE is non-reusable also the shelf life is mentioned • Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary, instructions for disposal. • Statement for warning the user on flammability, to keep away of fire The above user information text is available in Turkish Ref Technical File, User Information Sheet

UNIVERSAL CERTIFICATION CE 2163 Notified Body

UNIVERSAL UYGUNLUK DEĞERLENDİRME HİZM. ve TİC. A.Ş. Tatlısu Mh. Arif Ay Sk. No: 15/3 Ümraniye / İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING to Annex ZA of EN ISO 13982-1:2004 + A1:2010 STANDARD

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

1.1. Design principles

1.1.1. Ergonomics

PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.

1.1.2 Levels and classes of protection

1.1.2.1 Optimum level of protection

The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.

1.2. Innocuousness of PPE

1.2.1. Absence of inherent risks and other nuisance factors

PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.

1.3. Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and strength

PPE must be as light as possible without prejudicing its strength and effectiveness. PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

1.3.3. Compatibility of different types of PPE intended for simultaneous use

If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.

1.4. Manufacturer's instructions and information

In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:

m) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;

n) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;

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o) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;
p) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
q) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
r) where applicable, the type of packaging suitable for transport;
s) the significance of any markings (see point 2.12);
t) the risk against which the PPE is designed to protect;
u) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;
v) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;
w) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;
x) the internet address where the EU declaration of conformity can be accessed.

The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

UNIVERSAL CERTIFICATION CE 2163 Notified Body

UNIVERSAL UYGUNLUK DEĞERLENDİRME HİZM. ve TİC. A.Ş. Tatlısu Mh. Arif Ay Sk. No: 15/3 Ümraniye / İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

Technical Assessment of EN ISO 13982-1:2004 + A1:2010 Standard and other Standards it refers to, Clauses Corresponding to the Essential Health and Safety Requirements given above

EN ISO 13982-1:2004 + A1:2010 Standard Requirements Evaluation

Article 4.1

EHSR Ref 1.2.1, 1.3.2;

The coverall material performance are tested according to EN 14325:2018 standard for the following properties, since the coverall is claimed to be for single use no cleaning cycle is applied;

Property of Material EN 14325:2018	Result Classification		Requirement of EN ISO 13982-1	Evaluation
4.4 Abrasion Resistance	No Abrasion @2000 revs	Class 6	Class 1 or above	Success
4.5 Flex cracking resistance	> 40,000 Cycles	Class 5	Class 1 or above	Success
4.7 Trapezoidal tear resistance	Width 23.0 N Length 10.6 N	Class 1	Class 1 or above	Success
4.10 Puncture Resistance	17.3 N	Class 2	Class 1 or above	Success

The above results are derived from the test report, in the reference below. In the evaluation of the test report it was stated that all the tests are conducted with the completion of conditioning requirements as (20 ± 2) C° and (65 ± 5) % relative humidity for 24 hours.
The manufacturer do not claim a performance for the resistance to ignition or flammability of the product, in the user information sheet it is explained that the coveralls must be kept away of fire.
Other requirements refered for skin compatibility, no irritation or adverse effects are evaluated in EN ISO 13688 section of this report.

Ref: Laboratory Test Report 1, Technical File

Article 4.2

EHSR Ref 1.3.2, 3.10.2;

The affects of seams to the performance of the coverall in penetration of solid particles through stitch holes are evaluated in the whole suit test and evaluated in Article 4.3 of this section.

The seam strength is evaluated based on the test report as shown below;

Property of Material EN 14325:2018	Result Classification		Requirement of EN ISO 13982-1	Evaluation
5.5 Seam Strength	Refer to the strength values for seams at different parts of coverall. The lowest Class is given among all kinds of seams	Class 1	Class 1 or above	Success

Ref: Laboratory Test Report 1

Article 4.3

EHSR Ref 1.1.1, 1.1.2.1, 1.2.1.2, 1.2.1.3, 1.3.1, 1.3.3, 3.10.2;

The requirements of the coverall with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.

The coverall under evaluation is a one piece full body clothing, without a visor and foot protection. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested as a part of the Total Inward Lekage test and found to be appropriate.

According to the test results reported;

- The subjects were able to complete the excercises described comfortably. The inspection on the tested samples states that there was no damage, tears or rips in fabrics, seams and connection points to the additionaly worn PPEs like gloves, boots etc.

UNIVERSAL CERTIFICATION CE 2163 Notified Body

UNIVERSAL UYGUNLUK DEĞERLENDİRME HİZM. ve TİC. A.Ş. Tatlısu Mh. Arif Ay Sk. No: 15/3 Ümraniye / İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

EN ISO 13982-1:2004 + A1:2010 Standard Requirements Evaluation	
	• The results of percentages of inward lekage values reported claims that all 90 measurements are smaller and equal to 30. Which means 90 of the total lekage measurement among all excercises for all positions and all samples are smaller than 30%. • All 10 of the average total inward lekage per tested suit are smaller or equal to 15%. The above results indicates that the tested coveralls complies with the total inward leakage of aeroslols of solid particles requirement of this standard. Which is based on a test report conducted according to EN ISO 13982-2:2005 Ref: Laboratory Test Report 4
Article 5	EHSR Ref 2.12; Each piece of coverall have marking with the following information on the single PPE package / PPE itself; • Name / trademark of the manufacturer, type and model of PPE • Size of the coverall • Applied product standards (EN ISO 13982-1+A1:2010) • Pictograms for protection against chemicals, invitation to read manufacturer's instructions • Shelf life and date of manufacturing The above mentioned marking requirements are stated in the technical file of the manufacturer. The evaluated samples did not have all these marking and information on the PPE. The manufacturer shall follow the instructions in the technical file in case of serial manufacturing of the PPE and verify before putting the PPE on the market. The PPE coverall is for single use, the markings for re-use cleaning or disinfection is discarded. Ref: Technical File PPE Marking section.
Article 6	EHSR Ref 1.4; The information supplied by the manufacturer is defined in the relevant section of the technical file. This information includes explanation required by all applied product standard requirements. The defined user information text in the technical file includes the following data; • Name / trademark of the manufacturer, its address, or the authorised representative for EU community • Type of protection against chemicals (Type-5). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, mask and visor / face shield). • Size of the coverall • The statement that the coverall provides a total inward lekage $L_{jmn,82/90} \leq 30$ % and $L_{S,8/10} \leq 15$ % • Material test performance classifications (Based on EN 14325:2018 classification) • Pictogram and information that the PPE is non-reusable also the shelf life is mentioned • Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary, instructions for disposal The above user information text is available in Turkish Ref Technical File, User Information Sheet

UNIVERSAL UYGUNLUK DEĞERLENDİRME HİZM. ve TİC. A.Ş. Tatlısu Mh. Arif Ay Sk. No: 15/3 Ümraniye / İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING to Annex ZA of EN ISO 13034:2005 + A1:2009 STANDARD

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

1.1. Design principles

1.1.1. Ergonomics

PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.

1.2. Innocuousness of PPE

1.2.1. Absence of inherent risks and other nuisance factors

PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.

1.3. Comfort and effectiveness

1.3.2. Lightness and strength

PPE must be as light as possible without prejudicing its strength and effectiveness. PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

1.3.3. Compatibility of different types of PPE intended for simultaneous use

If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.

1.4. Manufacturer's instructions and information

In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:

a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;
b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;
c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;
d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
f) where applicable, the type of packaging suitable for transport;
g) the significance of any markings (see point 2.12);
h) the risk against which the PPE is designed to protect;
i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;
j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;
k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;
l) the internet address where the EU declaration of conformity can be accessed.

UNIVERSAL CERTIFICATION CE 2163 Notified Body

UNIVERSAL UYGUNLUK DEĞERLENDİRME HİZM. ve TİC. A.Ş. Tatlısu Mh. Arif Ay Sk. No: 15/3 Ümraniye / İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

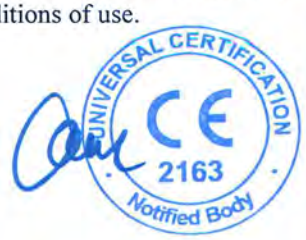
3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.



Technical Assessment of EN ISO 13034:2005 + A1:2009 Standard and other Standards it refers to, Clauses Corresponding to the Essential Health and Safety Requirements given above

EN ISO 13034:2005 + A1:2009 Standard Requirements Evaluation	
Article 4.1	EHSR Ref 1.2.1, 1.2.1.1, 1.3.2, 3.10.2; The coverall material performance are tested according to EN 14325:2018 standard for the following properties, since the coverall is claimed to be for single use no cleaning cycle is applied;

Property of Material EN 14325:2018	Result Classification		Requirement of EN ISO 13034	Evaluation
4.4 Abrasion Resistance	No Abrasion @2000 revs	Class 6	Class 1 or above	Success
4.7 Trapezoidal tear resistance	Width 23.0 N Length 10.6 N	Class 1	Class 1 or above	Success
4.9 Tensile Strength	W 77.5 N L 38.5 N	Class 1	Class 1 or above	Success
4.10 Puncture Resistance	17.3 N	Class 2	Class 1 or above	Success
4.12 Liquid repellency	Sulfuric Acid (H_2SO_4) I_R is 93.0 %	Class 3	Class 3 at least for 1 chemical	Success
4.10 Resistance to penetration by liquids	Sulfuric Acid (H_2SO_4) I_P is 0 % Sudium Hydroxide (NaOH) I_P is 0 % o-Xylene (Undiluted) I_P is 0 %	Class 3	Class 2 at least for 1 chemical	Success

The above results are derived from the test report in the reference below. In the evaluation of the test report it was stated that all the tests are conducted with the completion of conditioning requirements as (20 ± 2) C° and (65 ± 5) % relative humidity for 24 hours.
The manufacturer do not claim a performance for the resistance to ignition or flammability of the product, in the user information sheet it is explained that the coveralls must be kept away of fire.
Other requirements refered for skin compatibility, no irritation or adverse effects are evaluated in EN ISO 13688 section of this report.

Ref: Laboratory Test Report 1, Technical File

Article 4.2

EHSR Ref 1.3.2, 3.10.2;

The affects of seams to the performance of the coverall in penetration of liquid through stitch holes or through other components of a seam are evaluated in the whole suit mist test and evaluated in Article 5.2 of this section.

The seam strength is evaluated based on the test report as shown below;

Property of Material EN 14325:2018	Result Classification		Requirement of EN ISO 13034	Evaluation
5.5 Seam Strength	Refer to the strength values for seams at different parts of coverall. The lowest Class is given among all kinds of seams	Class 1	Class 1 or above	Success

Ref: Laboratory Test Report 1

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EN ISO 13034:2005 + A1:2009 Standard Requirements Evaluation	
Article 5.1,5.2	EHSR Ref 1.2.1.3, 2.4, 3.10.2; The requirements of the coverall with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report. The coverall under evaluation is a one piece full body clothing, without a visor and foot protection. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested as a part of the light spray (mist) test (Seven Movements) and found to be appropriate. The test report claims the light spray test that it is conducted according to Method A of EN ISO 17491-4 which corresponds the test setup defined in Clause 5.2 of this standard. According to the test results reported; • The subjects were able to complete the excercises (seven movements) described comfortably. The inspection on the tested samples states that there was no damage, tears or rips in fabrics, seams and connection points to the additionaly worn PPEs like gloves, boots etc. • The calibrated stain area is calculated for the undergarment is 4.56 cm^2. The laboratory reports that for the 3 samples tested the total stain are of undergarments are smaller then three times the calibrated stain area, values are (0 cm^2, 0 cm^2, 0 cm^2). For more details please refer to the test report. The above results indicates that the tested coveralls complies with the resistance to penetration by liquids in the form of a light spray (mist) test requirement of this standard. Which is based on a test report conducted according to EN ISO 17491-4:2008+A1:2016. Ref: Laboratory Test Report 3
Article 6	EHSR Ref 2.12; Each piece of coverall have marking with the following information on the single PPE package / PPE itself; • Name / trademark of the manufacturer, type and model of PPE • Size of the coverall • Applied product standards (EN ISO 13034:2005+A1:2009) • Pictograms for protection against chemicals, invitation to read manufacturer's instructions • Shelf life and date of manufacturing The above mentioned marking requirements are stated in the technical file of the manufacturer. The evaluated samples did not have all these marking and information on the PPE. The manufacturer shall follow the instructions in the technical file in case of serial manufacturing of the PPE and verify before putting the PPE on the market. The PPE coverall is for single use, the markings for re-use cleaning or disinfection is discarded. Ref: Technical File PPE Marking section.
Article 7	EHSR Ref 1.3.3, 2.4, 2.12; The information supplied by the manufacturer is defined in the relevant section of the technical file. This information includes explanation required by all applied product standard requirements. The defined user information text in the technical file includes the following data; • Name / trademark of the manufacturer, its address, or the authorised representative for EU community • Type of protection against chemicals (i.e Type-6). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, mask and visor / face shield). • Size of the coverall and model name • The standard code / name with the published year • The statement that the coverall is tested against the chemical names (tested for) and performance levels for mechanical strengths including repellency and resistance to penetration of liquids (Based on EN 14325:2018 classification) • Pictogram and information that the PPE is non-reusable also the shelf life is mentioned

EN ISO 13034:2005 + A1:2009 Standard Requirements Evaluation	
	• Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary, instructions for disposal • The statement on the light spray test results • Statement for warning the user on flammability, to keep away of fire The above user information text is available in Turkish Ref Technical File, User Information Sheet

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ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING to Annex ZA of EN ISO 14126:2003 + AC:2004 STANDARD

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

1.1. Design principles

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.3. Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and strength

PPE must be as light as possible without prejudicing its strength and effectiveness.

PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

1.4. Manufacturer's instructions and information

In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:

a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;
b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;
c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;
d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
f) where applicable, the type of packaging suitable for transport;
g) the significance of any markings (see point 2.12);
h) the risk against which the PPE is designed to protect;
i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;
j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;
k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;
l) the internet address where the EU declaration of conformity can be accessed.

The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

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Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

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Technical Assessment of EN 14126:2003 + AC:2004 Standard and other Standards it refers to, Clauses Corresponding to the Essential Health and Safety Requirements given above

EN 14126:2003 + AC:2004 Standard Requirements Evaluation	
Article 4.1.2	EHSR Ref 1.3.2; The coverall material performance are tested according to EN 14325:2018 standard for the relevant properties required by the Type defining standards for protective clothing. The coverall under evaluation claims compliance with Type 3, Type 4, Type 5 and Type 6. The required mechanical and flammability performance levels are evaluated in the corresponding clauses of EN 14605, EN ISO 13982-1 and EN ISO 13034 standards within this report. No further evaluation is necessary for this standard.
Article 4.1.4	EHSR Ref 1.1.2.2, 3.10.2; Evaluation of the performance requirements against penetration by infactive agents; The coverall is subjected to the tests according to ISO 16603 and ISO 16604 standards for its resistance to penetration by contaminated liquids under hydrostatic pressure. According to the obtained results of the corresponding test report; • The coverall material withstands and do not allow any penetration of bacteria under 20kPa hydrostatic pressure and is classified as **Class 6** according to Table 1 given in 4.1.4.1 Clause of this standard, • The coverall material was also subjected to evaluation of the bacteriophage test and passes the test according to ISO 16604 at 20kPa, and is classified as **Class 6** according to Table 1 given in 4.1.4.1 Clause of this standard, The coverall is tested for its resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids according to ISO 22610:2018 testing standard. The laboratory environmental conditions and the test setup parameters were inline with the standard requirements. The laboratory results indicates that the tested specimens withstands the 2 turns with no penetration for total 30 minutes and classified as **Class 3** according to Table 2 of Clause 4.1.4.2 of EN 14126 standard Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids. The coverall is tested for its resistance to penetration by contaminated solid particles according to ISO 22612:2005 testing standard. The laboratory environmental conditions and the test setup parameters were inline with the standard requirements. The laboratory results indicates that the tested 10 specimens the arithmetic mean of penetration results are smaller than 1 log cfu. The tested sample is classified as **Class 3** according to Table 4 of Clause 4.1.4.4 of EN 14126 standard Classification of resistance to penetration by contaminated solid particles. The results of evaluation for clause 4.1.4 is summarised below;

Resistance to Penetration Propery	Result Classification		Requirement of EN 14126
ISO 16604 - Resistance to penetration by contaminated liquids under hydrostatic pressure	Successful Hydrostatic pressure > 20 kPa	Class 6	To be Classified
EN ISO 22610 - Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.	Breakthrough time t > 30 min	Class 3	To be Classified
EN ISO 22612 - Resistance to penetration by contaminated solid particles	Penetration log cfu < 1	Class 3	To be Classified

Ref: Laboratory Test Report 6

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EN 14126:2003 + AC:2004 Standard Requirements Evaluation	
Article 4.2	EHSR Ref 1.3.2; The seam strength is evaluated and classified based on the test report as shown below; **Property of Material EN 14325:2018** / **Result Classification** / **Requirement of EN 14126** 5.5 Seam Strength — Refer to the strength values for seams at different parts of coverall. The lowest Class is given among all kinds of seams — Class 1 — To be Classified Ref: Laboratory Test Report 1
Article 4.3	EHSR Ref 1.3.1, 3.10.2; The PPE under evaluation conforms the relevant requirements of EN ISO 13688 standard. The requirements of the coverall with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.
Article 5	EHSR Ref 2.12; The marking requiremnts for protective clothing against chemicals are evaluated in the relevant section of this report. Aditionally; Each piece of coverall have marking with the following information on the single PPE package / PPE itself; • Applied product standards (EN 14126:2003+AC:2004) • Type marking of the PPE as Type 3-B and / or Type 4-B and /or Type 5-B and / or Type 6-B • the pictogram "protection against biological hazard" The above mentioned marking requirements are stated in the technical file of the manufacturer. The evaluated samples did not have all these marking and information on the PPE. The manufacturer shall follow the instructions in the technical file in case of serial manufacturing of the PPE and verify before putting the PPE on the market. Ref: Technical File PPE Marking section.
Article 6	EHSR Ref 1.4; The information supplied by the manufacturer is defined in the relevant section of the technical file. This information includes explanation required by all applied product standard requirements. The defined user information text in the technical file includes the following data; • Name / trademark of the manufacturer, its address, or the authorised representative for EU community • Type of protection against chemicals (i.e Type-6). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, mask and visor / face shield). • The standard number (EN 14126) • The performance levels identified with the tests against infactive agents • Pictogram and information that the PPE is non-reusable also the shelf life is mentioned • Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary, instructions for disposal The above user information text is available in Turkish Ref Technical File, User Information Sheet

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Product Sample Photos:

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Approval
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UNIVERSAL CERTIFICATION – Director

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TABLE OF CONTENTS-ABOUT THE GUIDE

Technical File - Manufacturing Control Guide has been prepared in accordance with EN 14126, EN 14605, EN ISO 13982-1 and EN 13034 Standards in order to introduce the production facility control system and explain the basic elements of the system. Control Guide is used not only to guide the establishment of the system and the preparation of the system documentation, and also to introduce the system to customers and third parties. Manufacturing Control Guide; is prepared by Production Control Representative, Quality Management Representative, controlled, approved and published by the Company Manager.

On the pages of the Control Manual, "**YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ**" logo, "Technical File - Manufacturing Control Guide" phrase, Department Name, Document No (TD-02), Publication Date, Revision Date, Revision No, Page No. (Title and Signature) Person Controlled (Title and Signature) and Person Approved (Title and Signature) information are found. Page No; is given as showing "page number/total page number".

The revision made in the Technical File - Manufacturing Control Guide is made in the whole document, the guide revision number is increased by 1, the revision date is updated and the revision reason is entered in the revision reason section on each page and republished.

Other issues regarding the revision and distribution of the manual are applied according to the "PR.01 Document Control Procedure".

0. INTRODUCTION

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ *Technical File - Manufacturing Control Guide*; has been prepared as a part of the system used to evaluate the conformity of the following standards.

- EN 14126/AC:2004 Protective Clothing - Against Pathogenic Organisms
- EN 14605 : 2005 + A1 : 2009 Protection Against Liquid Chemical Substances Liquid Proof (Type 3-B) And Protection Against Liquid Chemical Substances Spray Proof (Type 4-B)
- EN ISO 13982-1: 2004 / A1: 2010 Protective Clothing for Use Against Solid Particles - Part 1: Performance Rules for Chemical Protective Clothing Providing Whole Body Protection against Airborne Solid Particles (Type 5 Clothing)
- EN 13034: 2005 + A1: 2009 Protective Clothing Against Liquid Chemical Substances - Performance Rules for Protective Clothing Providing Limited Protection Against Liquid Chemical Materials (Type 6 and Type pb [6] Equipment)

The Technical File - Manufacturing Control Guide process is designed to apply harmonized European standards for Protective Clothing, regardless of whether marking is applied pursuant to legislation or not.

1.SCOPE

Technical File - Manufacturing Control Guide covers the quality and factory manufacturing control requirements used during the manufacture of Protective Clothing, conformity with the Basic Health and Safety Requirements Associated with the European Union Directive 2016/425/EU Provisions.

- **Company Name:** *YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ*
- **Production Place Address:** E5 Karayolu Üzeri 5001. Sokak No:6 Selimpaşa Silivri İSTANBUL

2. REFERENCED STANDARD AND/OR DOCUMENTS

In this manual, reference is made to other standards and / or other documents, with or without a date. These references are indicated at appropriate places in the text and are listed below.

EN,ISO,IEC etc.NO	NAME IN TURKISH
EN ISO 13688	Protective Clothing - General Features
EN 14126	Protective Clothing - Against Pathogenic Organisms - Performance Properties and Test Methods
EN 14605	Protection Against Liquid Chemical Substances Liquid Proof (Type 3-B) And Protection Against Liquid Chemical Substances Spray Proof (Type 4-B)
EN ISO 13982-1	Protective Clothing for Use Against Solid Particles - Part 1: Performance Rules for Chemical Protective Clothing Providing Whole Body Protection Against Airborne Solid Particles (Type 5 Clothing)
EN 13034:2005+A1	Protective Clothing Against Liquid Chemical Substances - Performance Rules for Protective Clothing Providing Limited Protection Against Liquid Chemical Substances (Type 6 and Type pb [6] equipment)

3. Product Information

3.1 Product Description

Protective Clothing (Overalls) that we produce are reusable and limited use protective clothing that provides protection against pathogenic organisms, comply with minimum rules for chemical protective clothing resistant to the penetration of airborne solid particles, minimum requirements for the limited use and limited reusability performance of protective clothing against chemicals, protective clothing against chemicals of limited performance, light sprays where a full liquid permeability barrier (at the molecular level) is not required, produced in a high quality and hygienic environment with, intended for use in situations where exposure to liquid aerosols or low pressure, low volume splashes.

3.2 Brand Name: BIOBLOCKED
3.3 Product Model No: PS 3455 (Royal Shield Coverall - Type 3-B / 4-B / 5-B / 6-B)
3.4 Product Dimension: S - M – L – XL – 2XL – 3XL
3.5 Factory Production Control:
The documentation of the manufacturing control system is designed to ensure that the quality assurance is widely understood, to ensure that the required product properties are provided and to control the effective operation of the manufacturing control system.

3.6 Materials and Intermediates Used

NO	MATERIAL USED	SPECIFICATION	MANUFACTURER INFORMATION
1	Non Woven Fabric	(20 g / m2 nonwoven, 35 g / m2 PE film, 2 g / m2 hotmelt) total 57 g / m2 laminated nonwoven	PELSAN TEKSTİL
2	Zipper	Polyester Woven Ribbon Zipper White	BİR FERMUAR
3	Sewing thread	COATS 120 white	COATS
4	Adhesive tape	DOUBLE SIDED ADHESIVE TAPE	YILMAZ OFİS KIRTASİYE
5	Rubber	3 mm Tire	SANCAK ÖRME
6	Packaging material	PE QUALITY PRINTED BAGS	DEKA PLASTİK
7	PACKAGE	KSSK QUALITY	MERCAN AMBALAJ
8	Stİcker and Promotion Card Materials	CELLOPHANE COATED PAPER	NİRAY MATBAACILIK
9	Welding tape	16 mm tape	İNANÇ BANT

3.7 Product Photos (Appendix A)
3.8 Marking (Annex B)
3.9 Instructions for Use (Annex C)
3.10 Essential Health and Safety Requirements Fulfilled by the Product (Annex D)
3.11. Stitch Combine Points :
All combining stitches are made with 5 thread overlock stitch. Welding tape is adhered on all seams from the outer surface.
Zipper stitch and elastic stitches are made with single needle machine .
3.12. EQUIPMENT USED IN THE PRODUCTION OF TYPE 3-B / 4-B / 5-B / 6-B PPE OVERALLS

- *Flat Machine*
- *Overlock Machine*
- *Tape Welding Machine*
- *Cutting Engine*
- *Marker Table*
- *Modelroom Mold Drawing Machine*

- *Cutter Cutting Machine (for narrow fabrics)*

4. REQUIREMENTS

4.1 MANUFACTURING CONTROL

Technical File - Manufacturing Control Guide is the continuous internal control of manufacturing processes. This system includes the requirements for the controls performed to ensure the above-defined Protective Clothing (Coveralls) with the performance declared in the EU Type Approval Certificate.
Our company operates the Technical File - Manufacturing Control system in accordance with the requirements of these standards.
Our company has established a Manufacturing Control system to guarantee that the product supplied to the market is in accordance with the specified specifications, has started certification studies and maintains this system. The Manufacturing Control system includes operations, regular inspections, tests and/or evaluations, and the use of results for the control of raw and other input materials or components, the manufacturing processes of equipment and the product.

4.2 QUALITY PLAN

Our company has determined and continues its policy and procedures for Manufacturing Control in the quality plan. The quality plan includes the identification and specification of specific processes that directly affect product quality and conformity. The quality plan includes the following features.

-The organizational structure of the manufacturer regarding suitability and quality
Document control
- Control procedures regarding the components and the product supplied
-Process control
- Conditions in the transportation and storage of the product,
- Requirements for inspection and testing of processes and products
-Methods to be applied in case of non-conformity

4.3 ORGANIZATION

4.3.1 Responsibility and Authority

The responsibility, authority and relationship between all personnel who manage, do and approve the works affecting conformity and quality are defined in the quality plan. While making the definition, the personnel authorized for the following issues are specified.
- Starting a process to prevent the production of non-conforming products,
-Defining and recording any quality problems in the product.

4.3.2 Management Representative

Our company has determined an authorized representative with appropriate knowledge and experience to ensure the implementation and maintenance of the Manufacturing Control inspection and Quality Plan requirements. This representative can perform supervision and surveillance work alone.

REFERENCE
Management Representative Appointment Letter

4.3.3 Internal audits

Our company conducts internal audits to verify that the works are in accordance with the planned regulations and to determine the effectiveness of Manufacturing Control. The audits are scheduled according to the importance and condition of the work performed. Audits and subsequent activities are carried out according to written documents. The results of the audits are reported and presented to the attention of the personnel who have responsibility in the field of audit. The personnel responsible for this area keeps records of the measures taken by taking timely measures when there is a non-conformity during the inspections.

REFERENCE
Internal Audit Procedure
Non-conforming Product Control Procedure
Corrective and Preventive Actions Procedure

4.3.4 Management Review

The Manufacturing Control system is reviewed **annually** by the management to ensure its continuity and effectiveness, and relevant records are kept.

REFERENCE
MR Meeting Minutes

4.3.5 Subcontractor Services

Our company does not supply any subcontracting services other than its own resources, and in case of such a situation, a control method will be established and this application will be a part of our company's quality control procedures.

4.4 Document Control

Our company has determined and continues the written procedures to be implemented in order to control all documents and data related to the requirements specified in these standards.

REFERENCE
Document Control Procedure

Records Control Procedure

5 CONTROL METHODS

5.1 Component Materials

Sufficient component materials are kept ready to ensure that manufacturing and distribution are carried out at the planned speeds, so as not to adversely affect the conformity of the product.

In order to ensure compliance of Protective Clothing (Overalls), specifications and tolerances have been created for the necessary component materials used in production and these are notified to the supplier in writing.

These checks verify that input material suppliers are able to ensure the required quality of materials and conform to the EU Type Approval Certificate.

Production approval is not given without checking whether the materials supplied from different suppliers can affect the quality and conformity of the product.

5.2 Customer supplied product

No component material to be used in Protective Clothing supplied by the customer is not used, and in such a case, the necessary conditions will be provided by our company.

5.3 Operations control

The quality plan includes the following issues.

a) Conformity with all inputs used with the type-approved protype

b) The suitability of the cutting process (coming together of the same pieces from the same lot)

c) Stitch control, stitch step density control, stitch type control, sealing tape control used in seams, if any

d) Size control

e) Final product control (seams, sewing thread cleaning, checking the tires used in waist-arm-head and wrists)

f) Zipper control, touch and close fastener control and placket band control

g) Label user manual and packaging control

5.4 Transport, Storage and Distribution

It covers the procedures that will ensure the hygiene rules during the transportation and storage of Protective Clothing (Overalls).

REFERENCE
Transport, Storage, Storage and Shipping instruction

6 INSPECTION AND TESTS

6.1 General

All necessary tools, equipment and personnel are available to carry out the necessary inspections and tests.

All inspections performed by quality control personnel are recorded, and if non-conforming products can be separated, the shipment of products that are eliminated by reprocessing is approved.

6.2 Input Component Material

Input component materials are inspected and tested using the detailed procedures specified in the input quality plans. If the quality plan of the supplier is also included in the quality plan of our company, the results of the tests carried out by the supplier can be used.
In order to prevent any deterioration in storage, the necessary inspections of the materials continue.

7 NON-CONFORMITY STATUS

7.1 General

Provided that it is reasonably applicable, our company has documented and ensures its continuity in order to prevent the use and application of the product that does not comply with the specified requirements. This control is necessary for identification evaluation and segregation (where practical) and elimination of non-compliant product. All of the procedures to be carried out are documented and a system has been established to inform the user if the shipment of the inappropriate product cannot be prevented.

Nonconformity may occur in the following stages;
a) In component materials in the warehouse,
b) If the product is processed,
c) In the transportation, storage and distribution of the product.

In these cases, when non-conforming materials, products or processes are identified, investigations are initiated to determine the causes of non-conformity and effective corrective measures are applied according to the methods specified in the quality plan to prevent recurrence of the non-conformity.

REFERENCE
Non-conforming product control procedure

7.2 Non-conformity of component materials

In case of non-conforming component materials, corrective measures may be the following;

a) Reprocessing of component materials
b) Adjusting manufacturing control to separate non-conforming components
c) Rejection and elimination of unsuitable material.

REFERENCE
Non-conforming product control procedure

7.3 Non-conformity of the final, finished product (from the result of the examination of the operations performed)

Non-conforming Protective Clothing (Coveralls) are evaluated and necessary methods are followed to take corrective measures. Some measures consist of the following:

a) If the non-conforming product is applicable, re-processing and acceptance of its shipment,
b) If reprocessing is not applicable, directing to alternative use,
c) Rejection of the product,

REFERENCE
Non-conforming product control procedure
Quality plan

8 Records

Manufacturing control results are recorded. Along with the details of the constituent materials subjected to inspection, the place, date and time of the sample taken, and other relevant information are recorded.

In cases where the component material or Protective Clothing that is being worked on does not meet the specification requirements, the corrective measures taken to ensure the product quality of the materials are recorded.

Records are archived and retained for a period of at least 5 years in a reproducible form or for a longer period as required by country legislation.

REFERENCE
Sample Label
Analysis Reports
Quality Records Control Procedure

9 Training

Our company has established and implemented methods for the training of all personnel involved in the work that affects the quality. Personnel taking on specific tasks have appropriate quality and expertise based on appropriate education, training or experience as required. Training records are kept.

Note- Although a demonstrable training may be needed for the implementation of the quality mark, as per the legislation, marking is related to the compliance of the product with the performance characteristics using only written procedures. Therefore, although it may be necessary to use "expert" personnel in marking as required by the legislation, a training requirement that needs to be proven especially for expertise is not sought.

REFERENCE

Training records
Training plan

Annex A

PRODUCT PHOTOS

ANNEX B

MARKING

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET AŞ

E5 Karayolu üzeri 5001 sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY

Protection Against Chemicals

Protection Against Pathogenic Organisms

EN 14126:2003+AC:2004

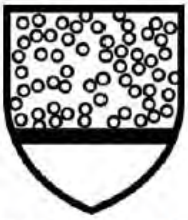
Protection Against Liquid Chemical Substances
Liquid Proof
Tip 3-B

EN 14605:2005+A1:2009

Protection Against Liquid Chemical Substances
Spray Proof
Tip 4-B

EN 14605:2005+A1:2009

Type 5 B



EN ISO 13982-1:2004+A1:2010
Teklikeli Kuru Partiküllere
Karşı Koruma

Type 6 B

EN 13034:2005+A1:2009
Hafif Püskürtülen Partiküllere
Karşı Koruma

ANNEX C

USAGE INSTRUCTIONS

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET AŞ
E5 Karayolu üzeri 5001 sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY
Brief indication of product type, trade name and code:

SAFETY INSTRUCTIONS: All protective clothing should be checked against defects and malfunctions that may cause adverse effects such as tears, holes, and loose dirt. It should never be worn if it is faulty and dirty.

Caution! It is dangerous to play with the bag, it can cause suffocation. Please keep away from children and babies.

"In case of long-term use in temperate climates and environments, it may cause overheating"

"Flammable material. Keep away from fire."

Disposable PPE, "Do not reuse!"

Production date: 2020 – 07

2020 - 06: Indicates that it was produced in the first 6 months of 2020.
2020 - 12: Indicates that it was produced in the second 6 months of 2020.

INSTRUCTIONS FOR USE: Type 3-B / 4-B / 5-B / 6-B Model Protective overalls, Protection of Workers Against Liquid Chemicals Liquid Proof (Type 3-B) , Protection Against Liquid Chemicals Spray Proof (Type 4-B) , from hazardous material particles (Type 5) and chemical liquid splashes (Type 6).

USE LIMITATIONS: Care should be taken while removing the dirty or liquid exposed overalls and contact with hazardous materials should be avoided. It is designed for extremely dangerous conditions and toxic chemicals. Coverall seams may not provide protection against infectious agents. The final decision and responsibility for any application protection of the type 3-B / 4-B / 5-B / 6-B coverall is with the user. In case the overalls are used with other Personal Protection; cuffs should be attached to gloves, ankles to boots and a respirator (mask) to the head beforehand. The suitability of this combination is at the discretion of the user. The person wearing the overalls must be properly grounded for the static electricity generated in the body. When grounding, the resistance on the person should be less than 10^8 ohms. These conditions can be easily created by wearing suitable shoes. The duration of use of the product and the effect of the working environment on the comfort of use should be planned in advance.

HOW TO WEAR: While wearing overalls, make sure that the area you are in is clean. Open the package properly without damaging the product. Open the zipper of the jumpsuit and put it on the overalls, with your feet first. Do not wrinkle the overalls too much while doing this. After putting your torso and arms on the overalls, put the hood on your head and close the zipper. Remove the paper of the adhesive tape in the zipper area and attach it to the overalls, taking care that it is not folded. In this way, the permeability of the zipper will be prevented.

STORAGE/USE BY: It is recommended to keep it in a cardboard or cardboard box, away from sunlight at +50 -10 ˚C. If stored under appropriate conditions, it should be used within 5 years after the production date.

DISPOSAL AND RECYCLING: Uncontaminated products can be treated as general waste or recycled. Contaminated products, on the other hand, must be treated as hazardous wastes and disposed of in accordance with the rules specified by law.


Do not wash


Do not dry in washing machine


No dry cleanining


Do not iron


Do not use bleach

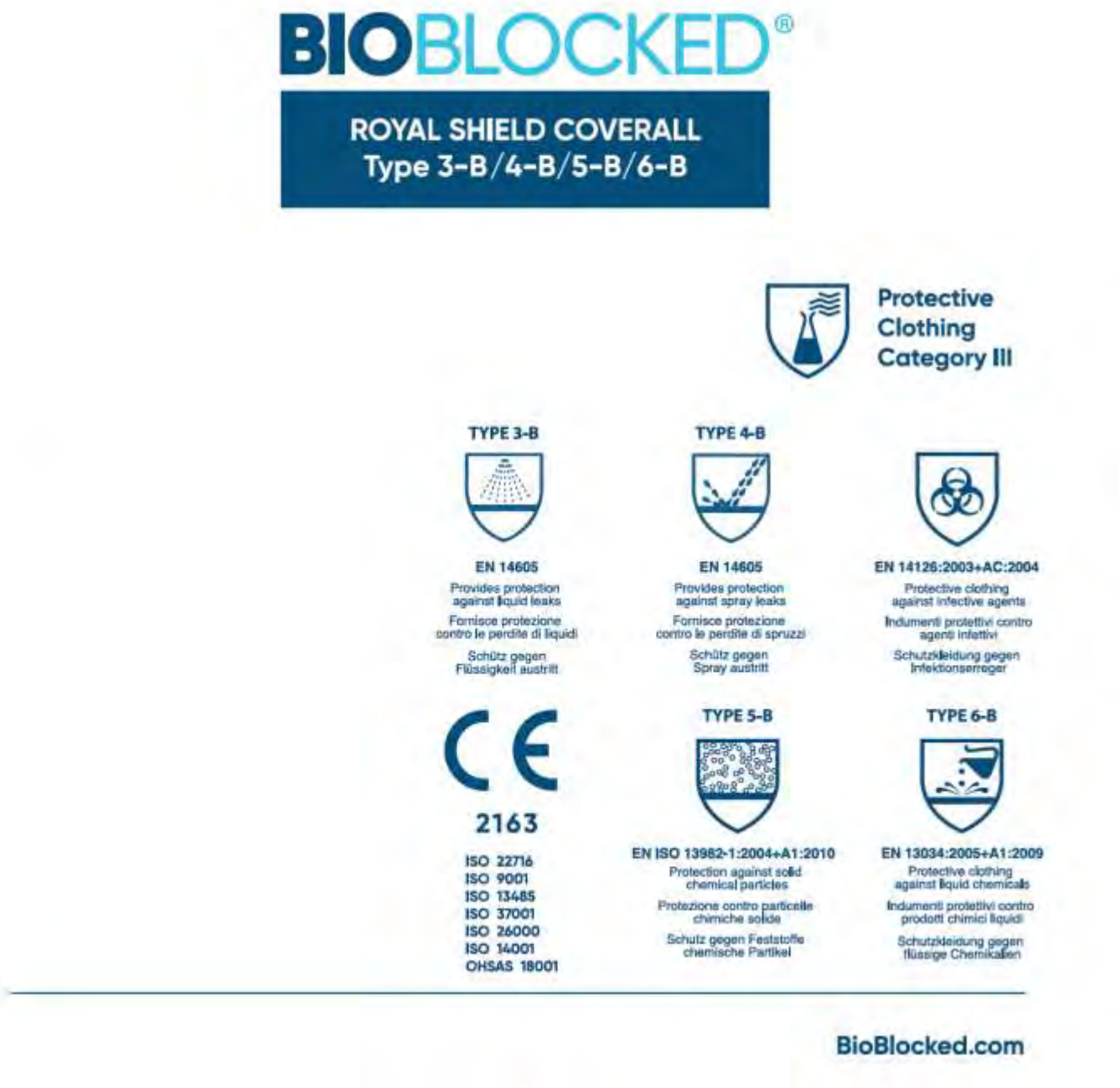
Label and sticker on the nylon bag,

PREPARED BY		APPROVED BY
Production Control Representative OKAN ÖZTELLİ	Quality Control Representative GÜRSEL ÖZCANLI	Plant Manager ÖZGÜR ÖZENİR


BIOBLOCKED
Royal Shield Coverall
Type 3-B / 4-B / 5-B / 6-B
PRODUCT : PS 3455
PRODUCTION DATE: 08.11.2020
PRODUCTION NO : 58762
EXP DATE : 08.11.2025
XL
CE 2163
Protective Clothing Category III
TYPE 3-B
TYPE 4-B
TYPE 5-B
TYPE 6-B
READ THE INSTRUCTION MANUAL!
Keep away from fire and heat!
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.


Size
S
PRODUCT NO: PS 3455
LOT NO : 10044
EXP. DATE : 01.2026
8 682753 510276
Size
M
PRODUCT NO: PS 3455
LOT NO : 10044
EXP. DATE : 01.2026
8 682753 510283
Size
L
PRODUCT NO: PS 3455
LOT NO : 10044
EXP. DATE : 01.2026
8 682753 510290
Size
XL
PRODUCT NO: PS 3455
LOT NO : 10044
EXP. DATE : 01.2026
8 682753 510245

Size
2XL
PRODUCT NO: PS 3455
LOT NO : 10044
EXP. DATE : 01.2026
8 682753 510252
Size
3XL
PRODUCT NO: PS 3455
LOT NO : 10044
EXP. DATE : 01.2026
8 682753 510269


BIOBLOCKED®
ROYAL SHIELD COVERALL
Type 3-B/4-B/5-B/6-B
Protective Clothing Category III
TYPE 3-B
EN 14605
Provides protection against liquid leaks
Fornisce protezione contro le perdite di liquidi
Schütz gegen Flüssigkeit austritt
TYPE 4-B
EN 14605
Provides protection against spray leaks
Fornisce protezione contro le perdite di spruzzi
Schütz gegen Spray austritt
EN 14126:2003+AC:2004
Protective clothing against infective agents
Indumenti protettivi contro agenti infettivi
Schutzkleidung gegen Infektionserreger
CE
2163
ISO 22716
ISO 9001
ISO 13485
ISO 37001
ISO 26000
ISO 14001
OHSAS 18001
TYPE 5-B
EN ISO 13982-1:2004+A1:2010
Protection against solid chemical particles
Protezione contro particelle chimiche solide
Schutz gegen Feststoffe chemische Partikel
TYPE 6-B
EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Indumenti protettivi contro prodotti chimici liquidi
Schutzkleidung gegen flüssige Chemikalien
BioBlocked.com

EN - DIRECTIONS FOR USE — DISPOSABLE GARMENT

Main Use Areas

Type 3-B / 4-B / 5-B / 6-B Model Protective overalls, Protection of Workers Against Liquid Chemicals Liquid Proof (Type 3-B) , Protection Against Liquid Chemicals Spray Proof (Type 4-B) , from hazardous material particles (Type 5-B) and chemical liquid splashes (Type 6-B).

Restrictions Of Use

Attention should be paid when removing the coveralls exposed to liquid or dirt 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 Bioblocked 3-B/4-B/5-B/6-B model Protective coverall. In case 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. The resistance between the person and the ground should be less than 108 ohm. These conditions can easily be created by wearing the appropriate shoes. In case the characteristics of the clothing are not taken into consideration, wearing the chemical protective clothing can create a heat stress. The effect of the working environment and work duration have to be planned in advance for maximum comfort. Appropriate clothing wear under the coverall will help to reduce the heat stress. It can cause overheating in case of prolonged use. Attention is flammable, keep away from fire. The biological agents for which the product was tested are "ATCC 9372 Bacillus subtilis spores, ATCC 9372 Bacillus atrophaeus, and ATCC 13706 - B1 Escherichia coli bacteriophage".

MECHANICAL RESISTANCE CLASSES							
Abrasion resistance	Class 6	Tearing strength	Class 1	Tensile strength	Class 1	Puncture resistance	Class 1	Seam strength	Class 3

Flex cracking resistance Class 5 Repellency to liquids: - Sodium Hydroxide (NaOH) 10% concentration, Class 3 -Sulfuric Acid (H2SO4) 30% concentration, Class 3

The Statement

This product has undergone a resistance test for the passage of liquids in the form of light spray.For the part of the body (PB), the product was not subjected to a pass resistance test of liquids in the form of light spray. Ljmn, 82/90 ^ 30%, Ls, 8/10 ^ 15% , declared to be.

How To Wear It?

When putting on the coverall, be sure that the surrounding area is clean. Open the packaging carefully without damaging the product. Open the zipper of the product and then, pass firstly your feet through the coverall paying attention not to crumple and break the coverall. When the coverall is completely wear, put on the hood and close the zipper. Remove the adhesive tape on the zipper side and paste it to the coverall carefully. Do not fold it. In this way the permeability of the zipper will be secured.

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between -10 +50 °C. If stored under suitable conditions, it is recommended to use it within 5 years after the production date.

Destruction / Recycling

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

SAFETY INSTRUCTION

All protective clothes should be checked for defects like cuts, holes, rips and contamination.Don't use if garment is defected.

ATTENTION!

This bag is not a toy. It may cause suffocation. Please keep it away from children and infants.

IT - ISTRUZIONI PER L'USO — INDUMENTO MONOUSO

Principali aree di utilizzo

Tipo 3-B / 4-B / 5-B / 6-B Tuta protettiva modello, protezione dei lavoratori contro sostanze chimiche liquide a prova di liquido (tipo 3-B), protezione contro sostanze chimiche liquide a prova di spruzzo (tipo 4-B), da sostanze pericolose particelle di materiale (Tipo 5-B) e schizzi di liquidi chimici (Tipo 6-B).

Restrizioni d'uso

Prestare attenzione quando si rimuovono le tute che sono state esposte a liquidi o sporco ed evitare il contatto con materiali pericolosi. Non è progettato per essere utilizzato in condizioni estremamente pericolose o per la protezione dalle sostanze chimiche tossiche. I nastri saldati sulle cuciture generali forniscono protezione contro la permeabilità del materiale infettivo. L'utente è l'unico responsabile e dovrà prendere la decisione finale in merito all'usabilità per qualsiasi applicazione della Tuta Protettiva modello Bioblocked 3-B/4-B/5-B/6-B. Nel caso in cui la tuta sia utilizzata in combinazione con altri prodotti per la protezione personale, è necessario legare i polsini ai guanti, il cinturino agli stivali e il dispositivo respiratorio al cappuccio. L'utente è l'unico responsabile delle decisioni in merito alla conformità della combinazione. È assolutamente necessario che la persona che indossa la tuta sia correttamente messa a terra. La resistenza tra la persona e il suolo dovrebbe essere inferiore a 10 ^ohm. Queste condizioni possono essere facilmente create indossando le scarpe appropriate. Se le caratteristiche dell'abbigliamento non vengono prese in considerazione, l'uso dell'abbigliamento protettivo chimico può creare stress termico. L'effetto dell'ambiente di lavoro e la durata del lavoro devono essere pianificati in anticipo per il massimo comfort. Un abbigliamento adeguato sotto la tuta contribuirà a ridurre lo stress da calore. Può provocare surriscaldamento in caso di utilizzo prolungato. Attenzione è infiammabile, tenere lontano dal fuoco. Gli agenti biologici per i quali il prodotto è stato testato sono "ATCC 9372 Bacillus subtilis spore, ATCC 9372 Bacillus atrophaeus e ATCC 13706 - B1 Escherichia coli batteriofase"

CLASSI DI RESISTENZA MECCANICA							
Resistenza all'abrasione	Classe 6	Forza lacerante	Classe 1	Resistenza alla trazione	Classe 1	Resistenza alla perforazione	Classe 1	Forza della cucitura	Classe 3

Resistenza alla rottura da flessione Classe 5 Repellenza ai liquidi: - Concentrazione di idrossido di sodio (NaOH) al 10%, Classe 3 - Concentrazione di acido solforico (H2SO4) al 30%, Classe 3

La dichiarazione

Questo prodotto ha subito una prova di resistenza al passaggio di liquidi sotto forma di leggero spruzzo. Per la parte del corpo (PB), il prodotto non è stato sottoposto a prova di superamento di liquidi sotto forma di leggero spruzzo. Ljmn, 82/90 ^ 30%, Ls, 8/10 ^ 15% ha dichiarato di essere.

Come indossarlo?

Quando si indossa la tuta, assicurarsi che l'area circostante sia pulita. Aprire con cura la confezione senza danneggiare il prodotto. Aprire la cerniera del prodotto e poi passare prima i piedi attraverso la tuta facendo attenzione a non accartocciare e rompere la tuta. Quando la tuta è completamente indossata, indossare il cappuccio e chiudere la cerniera. Rimuovere il nastro adesivo sul lato della cerniera e incollarlo con cura sulla tuta. Non piegarlo. In questo modo, sarà evitata la permeabilità della cerniera.

Conservazione/Uso finale

Si consiglia di conservarlo in cartone o scatola di cartone, al riparo dalla luce solare, a una temperatura compresa tra -10 e +50 ° C. Si consiglia di utilizzarlo entro 5 anni dalla data di produzione se conservato in condizioni adeguate.

Distruzione / Riciclaggio

I prodotti non contaminati possono essere trattati come rifiuti generici o possono essere riciclati. E i prodotti contaminati devono essere trattati come rifiuti pericolosi e devono essere smaltiti in conformità con le norme stabilite dalla legge.

ISTRUZIONI DI SICUREZZA

Tutti gli indumenti protettivi dovrebbero essere controllati per difetti come tagli, buchi, strappi e contaminazioni. Non utilizzare se l'indumento è difettoso.

ATTENTION!

This bag is not a toy. It may cause suffocation. Please keep it away from children and infants.

DE - GEBRAUCHSANWEISUNGEN — **EINWEGBARE BEKLEIDUNG**

Hauptnutzungsbereiche

Modell 3-B / 4-B / 5-B / 6-B Modell Schutzoveralls, Schutz der Arbeitnehmer vor flüssigen Chemikalien Flüssigkeitsschutz (Typ 3-B), Schutz gegen flüssige Chemikalien Sprühschutz (Typ 4-B) vor Gefahren Materialpartikel (Typ 5-B) und chemische Flüssigkeitsspritzer (Typ 6-B).

Nutzungsbeschränkungen

Beim Entfernen schmutziger oder flüssigkeitsexponierter Overalls sollte darauf geachtet werden, dass der Kontakt mit gefährlichen Stoffen verhindert wird. Entwickelt für extreme gefährliche Bedingungen und giftige Chemikalien. Die an der Gesamtnaht angeschweißten Bänder bieten Schutz gegen die Durchlässigkeit von infektiösem Material. Die endgültige Entscheidung und Verantwortung für den Anwendungsschutz des Overalls mit bioblockiertem Typ 3-B / 4-B / 5-B / 6-B liegt beim Benutzer. Wenn der Overall mit anderen persönlichen Schutzvorrichtungen verwendet wird, sollten die Manschetten an den Handschuhen, die Armbänder an den Stiefeln und die Kapuze der Atemschutzmaske befestigt werden. Der einzige Entscheidungsträger für die Eignung der Kombination ist der Benutzer. Die Person, die den Overall trägt, muss ordnungsgemäß geerdet sein. Der Widerstand zwischen Person und Masse sollte weniger als 108 Ohm betragen. Diese Bedingungen können leicht durch das Tragen geeigneter Schuhe geschaffen werden. Das Tragen chemischer Schutzkleidung kann zu Hitzestress führen, wenn die Eigenschaften der Kleidung nicht berücksichtigt werden. Die Verwendungsdauer des Produkts und die Auswirkung der Arbeitsumgebung auf den Nutzungskomfort sollten im Voraus geplant werden. Durch geeignete Kleidungsmaßnahmen wird der Hitzestress verringert. Bei längerem Gebrauch kann es zu Überhitzung kommen. Vorsicht ist brennbar, vom Feuer fernhalten. Die biologischen Mittel, auf die das Produkt getestet wurde, sind "ATCC 9372 Bacillus subtilis-Sporen, ATCC 9372 Bacillus atrophaeus und ATCC 13706 - B1 Escherichia coli-Bakteriophase".

MECHANISCHE WIDERSTANDSKLASSEN									
Abriebfestigkeit	Klasse 6	Reißfestigkeit	Klasse 1	Zugfestigkeit	Klasse 1	Durchstoßfestigkeit	Klasse 1	Nahtfestigkeit	Klasse 2

Biegerissbeständigkeit Klasse 5 Abweisung gegen Flüssigkeiten: •Natriumhydroxid (NaOH) 10% ige Konzentration, Klasse 3 • 30% ige Schwefelsäure (H2SO4) -Konzentration, Klasse 3

Die Aussage

Dieses Produkt wurde einem Beständigkeitstest für den Durchgang von Flüssigkeiten in Form eines leichten Sprühnebels unterzogen. Für den Körperteil (PB) wurde das Produkt keinem Durchgangstest für Flüssigkeiten in Form eines leichten Sprühnebels unterzogen. deklariert als Ljmn, 82/90 <= 30%, Ls. 8/10 <= 15%.

Wie trage ich es?

Stellen Sie beim Anziehen des Overalls sicher, dass die Umgebung sauber ist. Öffnen Sie die Verpackung vorsichtig, ohne das Produkt zu beschädigen. Öffnen Sie den Reißverschluss des Produkts und führen Sie dann zuerst Ihre Füße durch den Overall, wobei Sie darauf achten, dass der Overall nicht zerknittert und zerbrochen wird. Wenn der Overall vollständig abgenutzt ist, setzen Sie die Kapuze auf und schließen Sie den Reißverschluss. Entfernen Sie das Klebeband auf der Reißverschlussseite und kleben Sie es vorsichtig in den Overall. Falten Sie es nicht. Auf diese Weise wird die Durchlässigkeit des Reißverschlusses sichergestellt.

Lagerung / Endverbrauch

Es wird empfohlen, es zwischen -10 und +50 ° C in Pappe oder Pappkarton vor Sonnenlicht zu schützen. Bei Lagerung unter geeigneten Bedingungen wird empfohlen, es innerhalb von 5 Jahren nach dem Produktionsdatum zu verwenden.

Vernichtung / Recycling

Die nicht kontaminierten Produkte können als allgemeiner Abfall behandelt oder recycelt werden. Kontaminierte Produkte sollten als gefährliche Abfälle behandelt und gemäß den gesetzlich festgelegten Vorschriften entsorgt werden.

SICHERHEITSANLEITUNG

Alle Schutzkleidung sollte auf Mängel wie Schnitte, Löcher, Risse und Verunreinigungen überprüft werden. Nicht verwenden, wenn das Kleidungsstück defekt ist.

ACHTUNG!

Diese Tasche ist kein Spielzeug. Dies kann zum Ersticken führen. Bitte halten Sie es von Kindern und Kleinkindern fern.

Please read user manual / Si prega di leggere il manuale utente / Bitte lesen Sie die Bedienungsanleitung

Do Not Wash / Non Lavare / Nicht waschen

Do not dry clean / Non Lavare a secco / Keine chemische Reinigung

Do not iron / Non stirare / Nicht bügeln

Do not Bleach / Non usare la candeggina / Nicht bleichen

Do not use twice. It is disposable / Non utilizzare due volte. È usa e getta / Nicht zweimal verwenden. Nur zum einmal tragen

Manufacturer / Fabricante / Hersteller :
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 3001 Sk. No. 6/A Silivri İstanbul

EC REP FINITURA FELICE S.R.L LARGO FRATELLI CERVI, 8 20099 VIMODRONE (MI) Tel: +390245370500 info@finiturafelice.com

Product: PS 3455

BIOBLOCKED®

PRODUCT PERFORMANCE VALUES

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Class 6
Tear resistance	Class 1
Tensile strength	Class 1
Puncture resistance	Class 2
Seam strength	Class 1

Flex cracking resistance Class 5
Repellency to liquids:

- Sodium Hydroxide (NaOH) 10% concentration, Class 3,
- Sulfuric Acid (H2SO4) 30% concentration, Class 3

EN 14126:2003+AC:2004

The biological agents for which the product was tested are "ATCC 9372 Bacillus subtilis spores, ATCC 9372 Bacillus atrophaeus, and ATCC 13706 - B1 Eschericihia coli bacteriophase".

EK D/ ANNEX D

Ürünün Karşıladığı Temel Sağlık ve Güvenlik Gerekleri/ Basic Health and Safety Requirements that the Product Meets.

EN 14126/AC:2004 Standardının Karşıladığı Temel Sağlık ve Güvenlik Gerekleri

1.1. Tasarım Prensipleri / *Design principles*

1.1.2. Koruma Düzeyleri ve Sınıfları / *Levels and classes of protection*

1.1.2.2. Farklı Risk Düzeyleri İçin Uygun Koruma Sınıfları

KKD'nin tasarımında, aynı risk faktörünün farklı düzeylerinin ayırt edilebilmesi gibi öngörülebilir kullanım koşullarının farklılık gösterdiği durumlarda uygun koruma sınıflandırmaları dikkate alınmalıdır. / *Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.*

1.3 Rahatlık ve Etkinlik / *Comfort and efficiency*

1.3.2 **Hafiflik ve Dayanıklılık** / *Lightness and design strength*

KKD, dayanıklılık ve işlevselliğini azaltmayacak şekilde olabildiğince hafif imal edilmelidir. /*PPE must be as light as possible without prejudicing design strength and efficiency.*

KKD, bu Ek'in 3. maddesinde belirtilen risklere karşı yeterli korunma sağlayabilmek için yerine getirilmesi şart olan ve belirli riskler için ilave gereksinimlerden ayrı olarak, öngörülen kullanım koşulları altındaki ortam koşullarının etkisine dayanabilmelidir. / *Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use*

1.4. İmalatçı Tarafından Verilecek Bilgiler / *Information supplied by the manufacturer*

İmalatçı, piyasaya sunduğu KKD ile birlikte aşağıdaki hususları içeren kullanım kılavuzunu da vermelidir: / *The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:*

- **a)** İmalatçının veya yetkili temsilcisinin isim ve adresi/ *In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community*
- **b)** Depolama, kullanım, temizlik, bakım, onarım ve dezenfekte etmeye ilişkin bilgiler (imalatçı tarafından önerilen temizlik, bakım ve enfeksiyondan arındırma maddeleri, kullanım kılavuzunda verilen talimata uygun olarak kullanıldığında kullanıcı veya KKD'ye zarar vermemelidir) / *storage, use, cleaning, maintenance,servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;*
- **c)** Söz konusu KKD'nin sağladığı korumanın sınıfını ya da seviyesini ölçmek için uygulanan teknik testlerde kaydedilen performans sonuçları/ *performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;*
- **d)** Söz konusu KKD'ye uygun aksesuarların ve yedek parçaların özellikleri /*suitable PPE accessories and the characteristics of appropriate spare parts;*
- **e)** Farklı risk seviyeleri için uygun koruma sınıfları ve bunlara karşılık gelen kullanım limitleri/ *the classes of protection appropriate to different levels of risk and the corresponding limits of use;*
- **f)** KKD veya belirli parçalarının kullanma ömrü veya son kullanma tarihi / *the obsolescence deadlineor period of obsolescence of PPEor certain of its components;*
- **g)** Taşımaya uygun paketleme şekli / *the type of packaging suitable for transport;*
- **h)** İşaretlerin anlamı (2.12)/ *the significance of any markings(see 2.12)*
- **i)** Eğer varsa, bu Yönetmeliğin 6. maddesinin son fıkrasında belirtilen düzenlemelerin REFERENCEları/ *where appropriate the references of the Directives applied inaccordance with Article5(6) (b);*
- **j)** KKD'lerin tasarımını yapan onaylanmış kuruluşun unvanı, adresi ve kimlik numarası / *the name , address and identification number of the notified body involved in the design stage of the PPE*

Bu bilgiler, anlaşılır, kesin ve Türkçe olmalı veya diğer bir üye ülkede piyasaya arz ediliyorsa o üye ülkenin resmi dil veya dillerinde olmalıdır. / *These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination*

2. BAZI KKD TİPLERİ VEYA SINIFLARI İÇİN ORTAK İLAVE GEREKLİLİKLER /*ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE*

2.12. Üzerinde Dolaylı veya Doğrudan Sağlık ve Güvenlikle İlgili Bir veya Birden Fazla Tanımlayıcı İşaret Taşıyan KKD'ler

/ *PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety*

KKD üzerine yapıştırılmış, dolaylı ya da doğrudan sağlık ve güvenlik ile ilgili tanımlayıcı işaretler, vermek istediği mesaja uygun ikaz işaretleri (piktogramlar veya ideogramlar) şeklinde olmalı ve KKD' nin öngörülen kullanma ömrü boyunca anlaşılabilir halini tam olarak korumalıdır. Ayrıca, herhangi bir yanlış anlamaya meydan vermeyecek şekilde bu işaretler anlaşılır, kesin ve tam olmalıdır. Özellikle, bu işaretler üzerinde yazılı bir ifade veya kelime bulunuyorsa, bunların cihazın kullanılacağı ülkenin resmi dil veya dillerinde olmalıdır./*The identification or recognition marks directly or indirectly relating to*

health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation ; ın particular, whwn such marks ıncorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.

KKD veya bir KKD elemanı gerekli işaretlerin tamamının veya bir kısmının konulamayacağı kadar küçükse, o zaman buna ait açıklayıcı bilgi, ambalaj üzerinde ve kullanım kılavuzunda bulunmalıdır. / *If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.*

3. BELİRLİ RİSKLER İÇİN İLAVE GEREKSİNİMLER /*ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS*

3.10.2. Tehlikeli maddeler ve patojen organizmalara karşı koruma / *Protection against cutaneous and ocular contact*

Vücut yüzeyinin tamamını veya bir bölümünü tehlikeli maddeler ve karışımlar veya zararlı biyolojik ajanlarla temastan korumak amacıyla üretilen KKD'lerin koruyucu yüzeyleri öngörülen kullanım şartlarında, bu tür maddelerin kullanıcıya geçmesini veya sızmasını önleyebilecek özellikte olmalıdır. / *PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.*

Bu amaçla, bu sınıf KKD'lerin yapıldığı malzemeler ve diğer elemanlar, gerektiğinde gün boyunca kullanılabilmesi için, mümkün olduğu kadar tam bir sızdırmazlık sağlayacak şekilde seçilmeli veya tasarlanmalı ve birleştirilmelidir. Sızdırmazlığın tam olarak sağlanamadığı durumlarda giyme süresi kısıtlanmalıdır. / *To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.*

Yapılarından ve öngörülen kullanım koşullarından dolayı, yüksek sızma gücüne sahip belirli tehlikeli maddeler ve karışımlar veya zararlı biyolojik ajanların söz konusu olduğu ve bunların KKD'lerin sağladığı koruma süresini sınırladığı durumlarda, KKD'ler sınıflandırma amacıyla etkinlik esasına dayalı standart testlere tabi tutulmalıdır. Testlerde belirtilen özelliklere uygun olduğu kabul edilen KKD'lerde, özellikle testlerde kullanılan maddelerin isimlerini veya bunun yapılamaması halinde, kodlarını ve bunlara karşılık gelen standart koruma sürelerini gösteren bilgiler bulunmalıdır. Kullanım kılavuzunda, özellikle, kodların bir açıklaması, gerekiyorsa standart testlerin detaylı bir tanımlaması ve öngörülen değişik kullanım koşullarında müsaade edilen maksimum kullanma süresini belirlemek için gerekli bütün bilgiler de bulunmalıdır. / *Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.*

EN 14605:2005+A1:2009 Standardının Karşıladığı Temel Sağlık ve Güvenlik Gerekleri

1.1. Tasarım Prensipleri /*Design principles*

1.1.1. Ergonomi /*Ergonomics*

KKD, tehlike içeren iş yapılırken, öngörülebilen koşullarda ve amaçlanan doğrultuda kullanımı sırasında kullanıcıyı mümkün olan en yüksek düzeyde koruyacak şekilde tasarlanarak imal edilmelidir./ *PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level.*

1.2. KKD'nin Kendisinin Tehlikeye Yol Açmaması / *Innocuousness of PPE*

1.2.1. KKD'nin Yapısından Kaynaklanan ve Rahatsızlık Veren Faktörlerin ve Diğer Risklerin Bulunmaması /*Absence of risks and other inherent nuisance factors*

KKD, öngörülebilir koşullarda kullanımı sırasında tehlikelere ve yapısından kaynaklanabilen rahatsızlık verici diğer faktörlere neden olmayacak şekilde tasarlanarak imal edilmelidir./*PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.*

1.2.1.1. Uygun Malzemeden İmali / *Suitable constituent materials*

KKD malzemesi ve parçaları, bozulma sonucu ortaya çıkan maddeler de dahil olmak üzere, kullanıcının sağlık ve hijyenini olumsuz yönde etkilememelidir./*PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health.*

1.2.1.3. KKD'nin Kullanıcıyı Engellememesi / *Maximum permessible user impediment*

KKD'nin vücudun duruş şekline ve hareket etmesine neden olduğu kısıtlamalar ile duyu organlarında yol açabileceği hassasiyet kaybı en aza indirilmeli ve KKD, kullanıcı veya diğer kişiler için tehlikeli olabilecek hareketlere neden olmamalıdır. /*Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.*

1.3 Rahatlık ve Etkinlik/ *Comfort and efficiency*

1.3.3 Hafiflik ve Dayanıklılık /*Lightness and design strength*

KKD, dayanıklılık ve işlevselliğini azaltmayacak şekilde olabildiğince hafif imal edilmelidir. /*PPE must be as light as possible without prejudicing design strength and efficiency.*

KKD, bu Ek'in 3. maddesinde belirtilen risklere karşı yeterli korunma sağlayabilmek için yerine getirilmesi şart olan ve belirli riskler için ilave gereksinimlerden ayrı olarak, öngörülen kullanım koşulları altındaki ortam koşullarının etkisine dayanabilmelidir. /*Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use.*

1.3.3. Aynı Anda Kullanılmak Üzere Tasarlanmış Farklı KKD Tipleri veya Sınıflarının Uyumu /*Compatibility of different classes or types of PPE designed for simultaneous use*

Aynı imalatçı, aynı anda birden fazla risk söz konusu olduğunda bu risklere karşı vücudun birbirine yakın kısımlarının eş zamanlı korunmasını sağlamak için farklı tip ve sınıflarda KKD modellerini piyasaya sunarsa, bunlar birbiriyle uyumlu olmalıdır./*If the same manufacturer markets several PPE models of different classes or types in order to ensure the simultaneous protection of adjacent parts of the body against combined risks , these must be compatible.*

2. BAZI KKD TİPLERİ VEYA SINIFLARI İÇİN ORTAK İLAVE GEREKLİLİKLER /*ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE*

2.3. Yüz, gözler ve solunum yollarında kullanılacak KKD'ler / *PPE to be used on face, eyes and respiratory tract*

Yüz, gözler veya solunum yollarında kullanılacak KKD, kullanıcının görüş alanına veya görüşüne asgari kısıtlama getirmelidir. / *PPE to be used on the face, eyes or respiratory tract should bring a minimum restriction to the user's field of view or view.*

Bu KKD sınıflarının görüş sistemlerinin optik nötrlüğü, kullanıcının nispeten özenli ve/veya uzun süreli tipteki faaliyetleriyle uyumlu olmalıdır.

Gerekirse, nem oluşumunu önlemek için işlem görmeli veya parçalarla birlikte satılmalıdır. / *The optical neutrality of the vision systems of these PPE classes should be compatible with the user's relatively careful and / or long-term activities.*

Görüşün düzeltilmesi gereken kullanıcıları hedef alan KKD modellerinin gözlükle veya kontak lensle birlikte kullanılmaya uygun olması gerekir. / *The PPE models targeted at users who need to be addressed should be suitable for use with glasses or contact lenses.*

2.4. KKD'nin Kullanma Ömrü /*PPE subject to ageing*

Yeni bir KKD' nin işlevinin zamana bağlı olarak önemli oranda azaldığı biliniyorsa, üretim tarihi ve mümkünse son kullanma tarihi her bir KKD parçasının ve değişebilen bölümlerinin üzerine, hiçbir yanlış anlamaya meydan vermeyecek şekilde, açıkça belirtilmeli ve bu bilgiler ambalaj üzerine de yazılmalıdır./*If it is known that the design performances of new PPE may be significantly affected by ageing , the date of manufacture and/or, if possible, the date of obsolescence, must be indelibly inscribed on every PPE ite mor interchangeable component placed on the market in such a way as to preclude any misinterpretation; this information must also be indelibly inscribed on the packaging.*

İmalatçı, KKD' nin kullanma ömrü ile ilgili bir taahhütte bulunamıyorsa, hazırlanan kullanım kılavuzunda, kullanıcı veya satın alan kişinin makul bir son kullanma tarihi tespit etmesine yarayacak bakım, onarım, temizlik, uygun saklama koşulları, modelin kalitesi vb. konularla ilgili tüm bilgiler bulunmalıdır. İmalatçı tarafından önerilen temizleme işleminin periyodik olarak uygulanması sonucu, KKD' nin performansında fark edilir hızlı bir azalma olasılığı varsa, kullanma ömrü boyunca en fazla kaç kez temizlik işleminin uygulanacağı, mümkünse her bir KKD parçası üzerine yapıştırılır, bu olmazsa kullanım kılavuzunda belirtilmelidir./*If a manufacturer is unable to give an undertaking with regard to the useful life of PPE, his notes must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence date, bearing in mind the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer , the latter must, if possible, affix a mark to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded; failing that, the manufacturer must give this information in hisd notes.*

2.12. Üzerinde Dolaylı veya Doğrudan Sağlık ve Güvenlikle İlgili Bir veya Birden Fazla Tanımlayıcı İşaret Taşıyan KKD'ler
/*PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety*

KKD üzerine yapıştırılmış, dolaylı ya da doğrudan sağlık ve güvenlik ile ilgili tanımlayıcı işaretler, vermek istediği mesaja uygun ikaz işaretleri (piktogramlar veya ideogramlar) şeklinde olmalı ve KKD' nin öngörülen kullanma ömrü boyunca anlaşılabilir halini tam olarak korumalıdır. Ayrıca, herhangi bir yanlış anlamaya meydan vermeyecek şekilde bu işaretler anlaşılır, kesin ve tam olmalıdır. Özellikle, bu işaretler üzerinde yazılı bir ifade veya kelime bulunuyorsa, bunların cihazın kullanılacağı ülkenin resmi dil veya dillerinde olmalıdır./*The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must remain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation ; ın particular, whwn such marks ıncorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.*

KKD veya bir KKD elemanı gerekli işaretlerin tamamının veya bir kısmının konulamayacağı kadar küçükse, o zaman buna ait açıklayıcı bilgi, ambalaj üzerinde ve kullanım kılavuzunda bulunmalıdır./*If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.*

3. BELİRLİ RİSKLER İÇİN İLAVE GEREKSİNİMLER /*ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS*

3.10.2. Kütanöz ve oküler temasa karşı koruma / *Protection against cutaneous and ocular skin*

Vücudun tamamının veya bir kısmının tehlikeli maddelerle ve enfeksiyöz ajanlarla yüzey temasının önlenmesine yönelik KKD'lerin, KKD'nin piyasaya sürüldüğü öngörülebilir kullanım koşullarında söz konusu maddelerin koruyucu dış katmandan girmesi veya nüfuz etmesini önleyebilmelidir. Bu amaçla söz konusu KKD sınıfını oluşturan malzemeler ve diğer bileşenlerin, gerekli hallerde uzun süreli günlük kullanıma olanak tanıyan tam sızdırmazlığı mümkün olduğunca sağlayacak, bunun olmadığı hallerde giyme süresiyle sınırlandırılmasını gerektirecek şekilde sınırlı sızdırmazlık sağlayacak şekilde seçilmiş veya tasarlanmış ve birleştirilmiş olmalıdır. */ PPE for preventing surface contact with all or some of the body's surface with hazardous substances and infectious agents should prevent PPE from penetrating or penetrating the protective outer layer in the foreseeable conditions of use in which the PPE is marketed. For this purpose, it must be selected or designed and assembled so that the materials and other components making up the PPE class provide limited tightness, where necessary, to ensure full waterproofing, where possible, for long periods of daily use,*

Nitelikleri gereği ve öngörülebilir kullanım koşulları nedeniyle bazı tehlikeli maddelerin veya enfeksiyöz ajanların, söz konusu KKD'nin sağladığı korumanın süresini sınırlandıracak şekilde yüksek derecede nüfuz etme gücünün olduğu hallerde, verimlilik tabanlı sınıflandırmaları göz önünde bulundurularak KKD'nin standart testlerine tabi olması gerekir. Testin teknik özelliklene uygun olduğu düşünülen KKD'nin özellikle testlerde kullanılan maddelerin adlarını, adlarının bulunmadığı hallerde kodlarını ve karşılık gelen standart koruma süresini gösteren işaretler taşıması gerekir. / *Where hazardous substances or infectious agents are vulnerable due to their nature and foreseeable conditions of use, they should be subjected to PPE's standard tests, taking into account productivity-based classifications, where there is the power to penetrate at a high level to limit the duration of the protection provided by the PPE. The PPE considered to be suitable for the test specification should bear the names of the substances used in the tests, the codes where the names are not available and the corresponding standard protection period.*

İmalatçı notlarında ayrıca, özellikle kodların açıklaması (gerekiyorsa), standart testlerin ayrıntılı bir açıklaması ve farklı öngörülebilir kullanım koşullarında izin verilen azami yıpranma süresinin belirlenebilmesi için tüm uygun bilgiler bulunmalıdır. / *The manufacturer notes should also contain all appropriate information, in particular for the description of the codes (if necessary), a detailed description of the standard tests and for determining the maximum allowable wear time under different foreseeable conditions of use.*