PB0060 -Copriscarpe – lunghi laminati

- I copriscarpe sono un' aggiunta alla nostra Linea DPI
- Lo scopo è di limitare la trasmissione delle infezioni

- Dotati di soletta antiscivolo, sono forniti di un elastico nella parte superiore per maggiore protezione.
- Struttura ergonomica.

MATERIALE	COLORE	PACKAGING
57 gr PP+PE	bianco	Imbustate singolarmente

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PB0060 -Copriscarpe – lunghi laminati

EN 13034:2005+A1:2009
Indumenti protettivi contro prodotti chimici liquidi
EN 14126:2003+AC:2004
Indumenti protettivi contro agenti infettivi
ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

CARATTERISTICHE DEL PRODOTTO
- Tessuto laminato PP + PE
- Non sterile.
- Suola antiscivolo.
- Fornisce protezione avvolgendo completamente i copriscarpe.
- È realizzato in tessuto leggero e facile da indossare

COME INDOSSARLO?
- I copriscarpe vengono aperti con entrambe le mani per consentire alle scarpe di entrare facilmente nel copriscarpe.
- Lacci arte legati in modo che il piede non si stringa troppo.
- I lacci impediscono alla scarpa di scivolare verso il basso.

COME RIMUOVERE?
- Dovrebbe essere rimosso sedendosi.
- Nella rimozione, dovrebbe fare attenzione a rimuovere la scarpa capovolta.
- Si aprono i lacci, si allargano le gomme per togliere il lato posteriore della scarpa e poi il lato anteriore.
- Le mani vengono lavate con sapone dopo questa procedura. Il disinfettante deve essere utilizzato quando non ci sono acqua e sapone.

Conservazione/Uso finale
Si consiglia di conservarlo in cartone o scatola di cartone, al riparo dalla luce solare, a una temperatura compresa tra 15 e 25 ° C. Si consiglia di utilizzarlo entro 3 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.
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 Eschericihia coli batteriofase".

CLASSI DI RESISTENZA MECCANICA

Resistenza all'abrasione Classe 6
Forza lacerante Classe 1
Resistenza alla trazione Classe 1
Resistenza alla perforazione Classe 2
Forza della cucitura Classe 1

Resistenza alla rottura da flessione
Classe 5
Repellenza ai liquidi
• Concentrazione di idrossido di sodio (NaOH) al 10%,
Classe 3
• Concentrazione di acido solforico (H2S04) al 30%,
Classe 3

Fabbricante: *YELKENCI HAZIR GIYIM SANAYI VE TICARET A.S. Selimpasa Merkez Mh. SK. N. 6 / A Silivri Istanbul*

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.
ATTENZIONE:
Questa borsa non è un giocattolo. Può causare soffocamento. Si prega di tenerlo lontano da bambini e neonati.
INDUMENTO MONOUSO
Si prega di leggere il manuale utente
Non lavare.
Non lavare a secco
Non stirare
Non usare la candeggina
Non utilizzare due volte. È usa e getta

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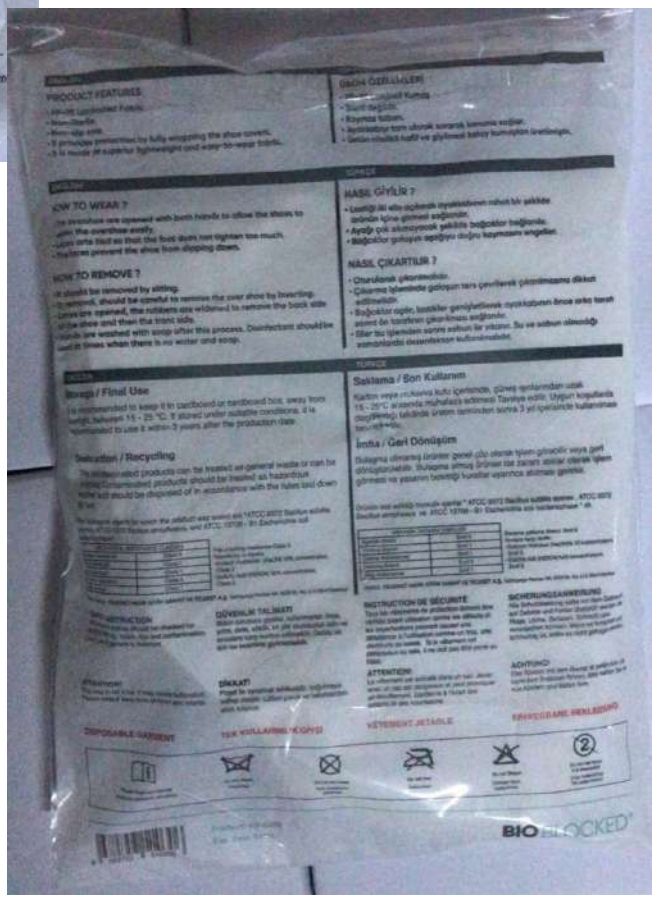
CE 2163 Notified Body www.universalcert.com
UNIVERSAL CERTIFICATION EN 14126 / AC EN ISO 13034 + A1 EN 13688

PB0060 -Copriscarpe – lunghi laminati



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EN 13688

PB0060 -Copriscarpe – lunghi laminati

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CERTIFICATION
NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1390

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 31.08.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment
Brand Name: BIOBLOCKED, **Model:** PB 0060
Protective OverShoe, as a protective clothing for the part of body Type PB [6]-B, manufactured from white laminated polypropylene non-woven fabric, inside over lock seams, with shoelace and anti-slip layer. The OverShoe is available in 1 size fit all.

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing,
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **31/08/2020** and will be valid for 5 years from the issue date.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

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UNIVERSAL CERTIFICATION
EN 14126 / AC
EN ISO 13034 + A1
EN 13688

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TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 31.08.2020 / 2163-KKD-1390/R1

This report is re-issued on 10.09.2020 with addition of 2 models (PB 0065 OverShoe Taped and SC 0065 OverSleeve seamless). The details of the report for PB 0060 and SC 0060 remains same.

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

Introduction

This report is prepared based on the evaluations on the technical file of the manufacturer dated 05.09.2020 version 1, 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 manufacturer have different PPE products made of same fabrics (Type 5, 6 Coveralls) and the common fabric tests are not repeated for each PPE or PPE model which are manufactured from the same fabric, which is guaranteed by the manufacturer in the technical file, the use of same fabric. The fabric mechanical strength tests were conducted for the BIOBLOCKED PS 5657 coverall model and used as a reference for PB 0060 model OverShoe / Boot Cover and SC 0060 Over Sleeve as well. The fabrics and seam technology are claimed to be identically same by the manufacturer. The seams on the OverShoe and OverSleeve products re-evaluated by the laboratory for their strength. The manufacturer also have models PB 0065 OverShoe Taped (same model of PB 0060 OverShoe where seams are covered with hotmelt tape) and SC 0065 OverSleeve (same model of SC 0060 OverSleeve where ultrasonic welding is used instead over lock sewing). The evaluated design and other properties remains same of the OverShoes and OverSleeves. These products considered as complementary PPEs for use with other clothing PPE products. 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 OverShoes and OverSleeves, as a protective clothing for the part of body Type PB-[6]-B, manufactured from white laminated polypropylene non-woven fabric, inside over lock seams (OverShoe taped models have hotmelt tape on seams, and sealmless OverSleeve models have ultrasonic sewing on side instead) and elastic under knee, wrist, shoulder parts. The The PPEs are available in 1 size.

The PPE fabric is 57gsm, breathable PE film (35gsm) + 2 gsm glue + SS (20gsm) white PP. Belt is same fabric.
Protective Clothing Type: Type PB [6]-B
Brand Name: BIOBLOCKED
Models: OverShoe - PB 0060, OverSleeve - SC 0060, OverShoe Taped - PB 0065, OverSleeve Seamless - SC 0065.
Sizes Available: Available only one size (to fit all)

Applied Harmonised Standards

EN ISO 13688:2013, (General requirements for protective clothing)
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing.
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB[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 18.08.2020 Number: 20018044-Add-RER	Holds TURKAK Accreditation with No: AB-0583-T
2	Ekoteks Laboratuar ve Gözetim Hizmetleri A.Ş.	Dated 24.08.2020 Number: 20028903-Ing	Holds TURKAK Accreditation with No: AB-0583-T
3	Ekoteks Laboratuar ve Gözetim Hizmetleri A.Ş.	Dated 25.08.2020 Number: 20030503-Ing	Holds TURKAK Accreditation with No: AB-0583-T
4	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. 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 in practical examination.
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 OverShoe (BootCover) is available only one sizes. The given sizes are expected to fit all sizes depending on the shoe worn by the user. Under normal conditions the product is expected to fit on regular shoes or safety shoes available on the market. Ref: Technical File Sizes section.
Article 7	EHSR Ref 2.12: Each piece of OverShoe and OverSleeve have marking with the following information: • Name / trademark of the manufacturer, type of product • Applied product standards (Type defining product standards) • Applied protection pictograms with standard references The markings on the product / 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 • OverShoe 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.

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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.

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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.

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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 OverShoe and OverSleeve material performance are tested according to EN 14325:2018 standard for the following properties, since OverShoe and OverSleeve 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 %30 concentration) I_R > 90 %	Class 3	Class 3 at least for 1 chemical	Success
4.10 Resistance to penetration by liquids	Sulfuric Acid (H2SO4 %30 concentration) Sudium Hydroxide (NaOH %10 concentration) o-Xylene (Non diluted) I_P < 1 %	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 OverShoe and OverSleeve 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 OverShoe and OverSleeve in penetration of liquid through stitch holes or through other components of a seam are evaluated in the seam strength and resistance to penetration by chemicals.

The seam strength is evaluated based on the test report as shown below; Hence the seam strength value is selected among the smallest strength among constructive seams as stated corresponding clause of this standard.

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 the OverShoe and OverSleeve. The lowest Class is given among constructive kinds of seams	Class 2 Class 3	Class 1 or above	Success
4.10 Resistance to penetration by liquids	Sulfuric Acid (H2SO4 %30 concentration) I_P < 1 %	Class 3	Class 3 at least for 1 chemical	Success

Ref: Laboratory Test Report 2 and 3

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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 for the OverShoe and OverSleeve with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report. The OverShoe and OverSleeve under evaluation is a one piece part of body clothing. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested with subjects and found to be appropriate. Since the PPE is part of body clothing, the mist test is not conducted according to Clause 5.2. The results of tested same fabric indicates that the tested OverShoe and OverSleeve, made of same fabric, complies with the resistance to penetration by liquids. Ref: Laboratory Test Report 1
Article 6	EHSR Ref 2.12: Each piece of OverShoe and OverSleeve have marking with the following information on the single PPE package / PPE itself: • Name / trademark of the manufacturer, type and model of PPE • 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, OverShoe and OverSleeve, 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 (Type PB [6]). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e coveralls, boots, gloves, mask and visor / face shield etc.). • The standard code / name with the published year • The statement that the OverShoe and OverSleeve 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 and English Ref Technical File, User Information Sheet

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UNIVERSAL
CERTIFICATION

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	
	EHSR Ref 1.3.2;
Article 4.1.2	The OverShoe and OverSleeve material performance are tested according to EN 14325:2018 standard for the relevant properties required by the Type defining standards for protective clothing. The OverShoe and OverSleeve under evaluation claims compliance with Type PB [6]. The required mechanical and flammability performance levels are evaluated in the corresponding clauses of EN ISO 13034 standard within this report. No further evaluation is necessary for this standard.
	EHSR Ref 1.1.2.2, 3.10.2;
	Evaluation of the performance requirements against penetration by infactive agents; The OverShoe and OverSleeve 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 OverShoe and OverSleeve 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 OverShoe and OverSleeve 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 OverShoe and OverSleeve 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.
Article 4.1.4	The OverShoe and OverSleeve 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 is 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 2

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EN 14126:2003 + AC:2004 Standard Requirements Evaluation

EHSR Ref 1.3.2:

The seam strength is evaluated and classified based on the test report as shown below:

Article 4.2

Property of Material EN 14325:2018	Result Classification		Requirement of EN EN 14126
5.5 Seam Strength	Refer to the strength values for seams at different parts of OverShoe and OverSleeve. The lowest Class is given among all kinds of seams	Class 2 Class 3	To be Classified

Ref: Laboratory Test Report 2 and 3

EHSR Ref 1.3.1, 3.10.2:

Article 4.3

The PPE under evaluation conforms the relevant requirements of EN ISO 13688 standard. The requirements of the OverShoe and OverSleeve with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.

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 OverShoe and OverSleeve have marking with the following information on the single PPE package / PPE itself:

Article 5

- Applied product standards (EN 14126:2003+AC:2004)
- Type marking of the PPE as Type PB [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.

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:

Article 6

- Name / trademark of the manufacturer, its address, or the authorised representative for EU community
- Type of protection against chemicals (Type PB [6]-B). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e coveralls, boots, gloves, mask and visor / face shield).
- The standard number (EN 14126)

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- 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 and English
Ref Technical File, User Information Sheet

PPE Experts contributed to this report:

Arzu ŞEREMETLİ

Osman CAMCI

Approval
Suat KAÇMAZ
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 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-06**), 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".

PREPARED BY		APPROVED BY
Production Control Representative SABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Mah. 5001 Sokak No 6/A Silivri / İST. Tel : (0 212) 723 86 00 Fax : (0212) 723 86 15 Silivri Vergi Dairesi : 547 017 7579 Ticaret Sicil No : 4[illegible]834

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; is prepared as a part of the system used to evaluate the conformity of standards

- EN 14126/AC:2004 Protective Clothing - Against Pathogenic Organisms
- EN 13034: 2005 + A1: 2009 Protective Clothing Against Liquid Chemical Substances - Performance Rules for Protective Clothing Providing Limited Protection Against Liquid Chemical Substances (Type PB [6] - B 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.

Basic Requirements of the European Union Directive 2016/425 / EU:

8.1. Medical devices and manufacturing processes should be designed in such a way that the infection risk of the patient, practitioner and third parties is eliminated or reduced as much as possible. The design should be easy to implement and, if necessary, minimize contamination of the patient from the medical device or from the patient during use.

- **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
EN ISO 13688	Protective Clothing - General Features
EN 14126	Protective Clothing - Against Pathogenic Organisms - Performance Properties and Test Methods
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)
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

3. Product Information

3.1 Product Description

Protective Clothing (Overshoes, Oversleeves, Bones) that we manufacture have a suitable microbial barrier, which aims to limit the transmission of infective agents between personnel and patients during surgical procedures and in other medical environments with similar requirements. It can be effective in reducing the spread of infective agents in asymptomatic carrier or patient with clinical symptoms, our company produces Protective Clothing with these features in a high quality and hygienic environment.

2 Brand Name: BIOBLOCKED

3.3 Product Model No:

PB 0060 Overshoe Long - Laminated
SC 0060 Protective Oversleeve - Laminated
CP 0045 Bouffant Cap - Laminated
PB 0065 Overshoe Taped - Long
SC 0065 Protective Oversleeve - Seamless

3.4 Product Dimension: Tek Beden

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	FABRIC	Laminated Fabric 57 gr	Pelsan Tekstil
2	SEWING THREAD		COATS
3	PACKING MATERIAL - BAG	Coast 120 Number Yarn	DEKA PLASTİK
4	PARCEL		MERCAN AMBALAJ
5	RUBBER	PRINTED BAG	SANCAK ÖRME
6	Wigan Non-Slip Fabric	KSSK QUALITY	Mahmut Tekstil
7	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 Essential Health and Safety Requirements Fulfilled by the Product (Annex E)
3.12 Machinery and equipment used in the production of the product;

- Flat Machine
- Overlock Machine
- Cutting Engine
- Marker Table

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- Modelroom Mold Drawing Machine
- Cutter Cutting Machine (for narrow fabrics)
- Tape Welding Machine
- Ultrasonic Sewing Machine

3.13 Stitch Joining Section

PB 0060 & SC 0060 & CP 0045 = All stitches are made with 5 thread overlock stitch. A single needle sewing machine is used for sewing elastics, laces, labels and non-slip tapes.

PB 0065 = All stitches are made with 5 threads overlock stitch. A single needle sewing machine used for sewing elastics , laces, labels and non-slip tapes. Welding tape is welded on all seams from the outer surface.

SC 0065 = The whole pieces are performed with ultrasonic sewing. A single needle sewing machine is used for sewing elastics , laces, labels and non-slip tapes.

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 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

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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.

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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)

f) Label user manual and packaging control

5.4 Transport, Storage and Distribution

It includes the procedures that will ensure the hygiene rules during the transportation and storage of Surgical Garments and Covers.

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

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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 (Overalls) 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

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 5001 Sokak No:5/A Silivri / İST.
Tel: (0 212) 723 88 00 Fax: (0212) 723 88 15
Silivri Vergi Dairesi 947 017 7578
Ticaret Sicil No: 457834

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

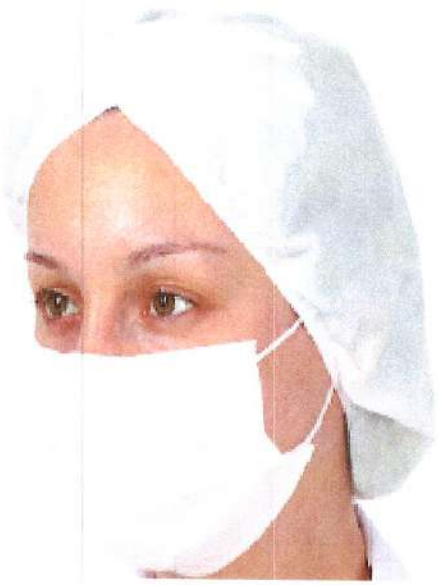
Training records
Training plan

Annex A

PRODUCT PHOTOS

Disposable Protective Sleeve

Product: SC 0060



Product: CP 0045

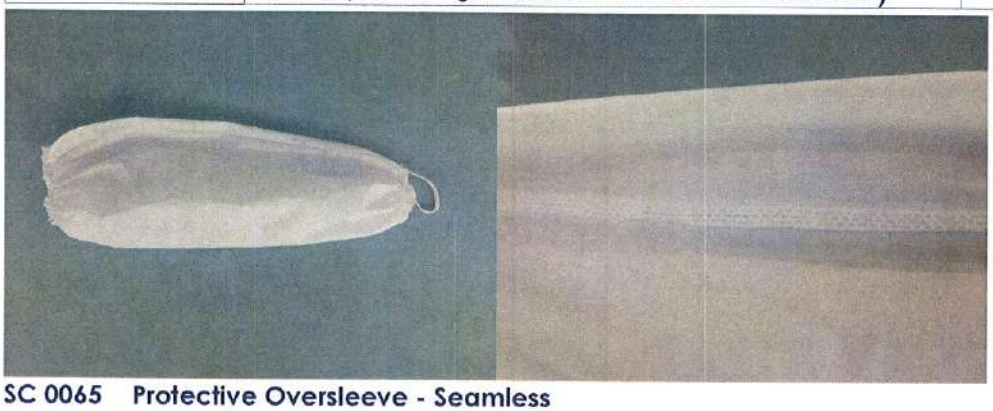
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

PB 0060 Uzun Galoş (Overshoe Long - Laminated)

PB 0065 Overshoe Taped - Long

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.



SC 0065 Protective Oversleeve - Seamless

Labels;

BIOBLOCKED®

Protective Oversleeve - Seamless

PRODUCT: SC 0065

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58767
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

EN 14126:2003+AC:2004 Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Overshoe Taped - Long

PRODUCT: PB 0065

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58765
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

EN 14126:2003+AC:2004 Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Overshoe - Long

PRODUCT: PB 0060

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58764
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

EN 14126:2003+AC:2004 Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

PREPARED BY		APPROVED BY
Production Control Representative SABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 5001 Sok. No:6/A Silivri / İST.
Tel: (0 212) 728 68 00 Fax: (0212) 723 85 15
Silivri Vergi Dairesi: 347 017 7579
Ticaret Sicil No: 457834

BIOBLOCKED®

Protective Oversleeve

PRODUCT: SC 0060

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58763
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

EN 14126:2003+AC:2004 Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Bouffant Cap - Laminated

PRODUCT: CP 0045

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58765
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

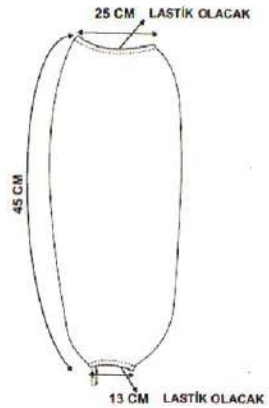
EN 14126:2003+AC:2004 Protective clothing against infective agents

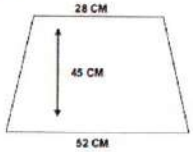
READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

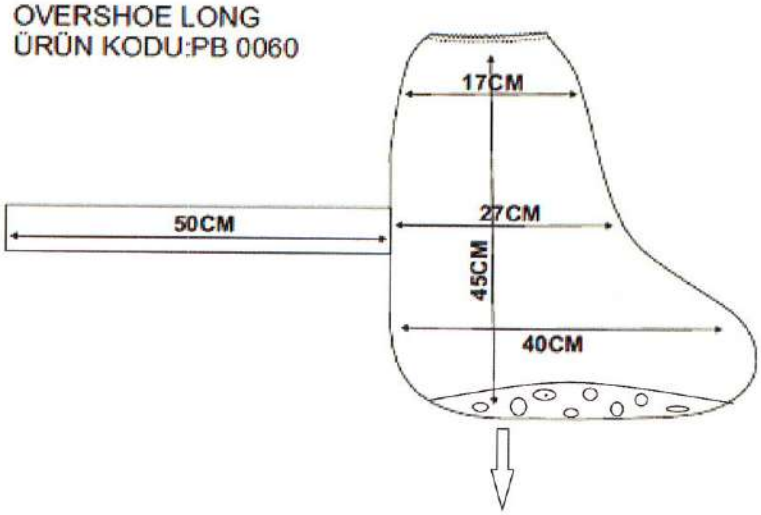
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

PROTECTIVE OVERSLEEVE
ÜRÜN KODU:SC 0060





OVERSHOE LONG
ÜRÜN KODU:PB 0060

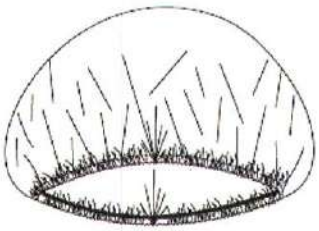


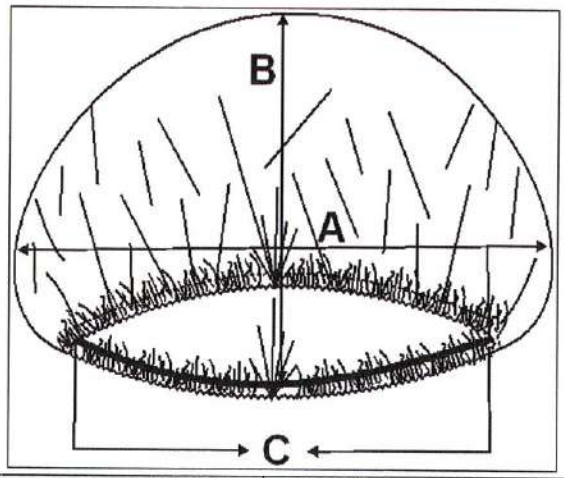
KAYMAZ BANT

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

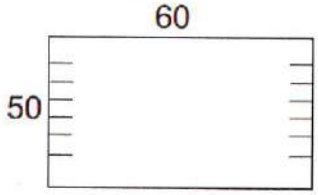
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Sefaköşkü Mah. 9001 Sok. No:6/A Silivri / İST.
Tel: (0 212) 723 88 00 Fax: (0212) 723 88 15
Silivri Vergi Dairesi: 917 017 7579
Ticaret Sicil No: 457834

BOUFFONT CAP
ÜRÜN KODU:CP 0045



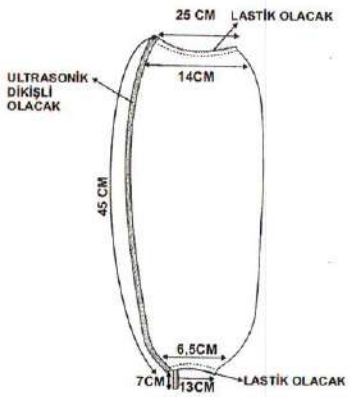


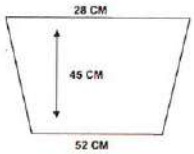
BONE PİLELİ KALIBI



	ÖLÇÜM NOKTALARI	BEDENLER	
		TEK BEDEN	Tolerans
A	Bone eni (bitmiş)	19	-/+1 cm
B	Bone boyu (bitmiş)	32	-/+1 cm
C	Lastik(bitmiş)	19	

PROTECTIVE OVERSLEEVE - SEAMLESS
ÜRÜN KODU:SC 0065

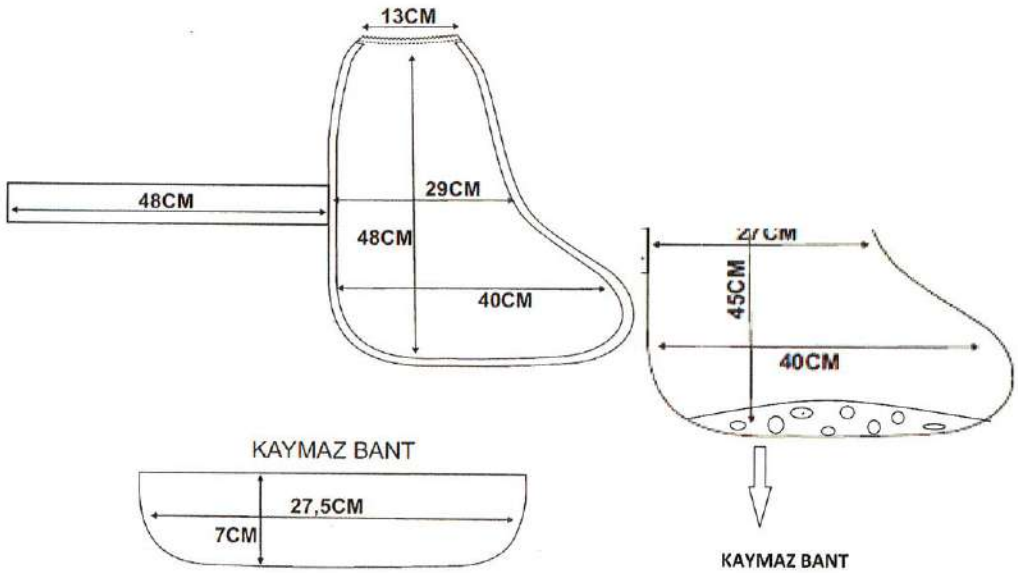




PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 1421 Sokak No:6/A Silivri / İST.
Tel: (0 212) 723 88 00 Fax: (0 212) 723 88 15
Silivri Vergi Dairesi 947 017 7579
Ticaret Sicil No: 457034

OVERSHOE TAPED-LONG
ÜRÜN KODU:PB 0065



Annex B

MARKING

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET AŞ

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

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif püskürtülen sıvılara karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

13.3. Information that should be included on the label:

a) The name or commercial name and address of the manufacturer, for imported medical devices, as well as the name or commercial name and address of the authorized representative and / or importer must be included on the label or in the sales package or in the user manual.

PREPARED BY		APPROVED BY
Production Control Representative SABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 5001 Sokak No:6 Silivri/İST.
Tel: (0 212) 723 66 00 Fax: (0212) 723 86 15
Silivri Vergi Dairesi 007 011 0579
Ticaret Sicil No: 457634

b) Detailed information that defines the contents of the packaging and the medical device and especially for the user,
c) When necessary, the phrase "STERILE",
ç) When necessary, batch code or serial number with the expression "LOT",
d) If necessary, the expiry date in month and year,
e) When necessary, the phrase "for single use",
f) If the medical device is made on order, the phrase "It is a custom-made device",
g) The phrase "For Clinical Research" in clinical research devices,
ğ) Special storage and / or usage conditions,
h) Special user manual,
ı) Warnings and / or measures to be taken,
i) For active medical devices, the date of manufacture to be specified in the batch / lot or serial number, apart from sub-paragraph (d),
j) When required, the method of sterilization,
k) With regard to container and medical devices containing radioactive substances, information on Turkey Atomic Energy Agency permit to be obtained from,
l) If the medical device contains a human blood derivative, the statement stating this is sought.

Annex C

USAGE INSTRUCTIONS

PB 0060

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif püskürtülen partüküllere karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE
2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

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YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Sefaköy Mah. 5001 Sokak No: 4 A Silivri / İST.
Tel: (0 212) 723 86 00 Faks: (0 212) 723 86 15
Silivri Vergi Dairesi: 947 017 [illegible]
Ticaret Sicil No: 457834

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- Non-slip sole.
- It provides protection by fully wrapping the shoe covers.
- It is made of superior lightweight and easy-to-wear fabric.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Lamineli Kumaş
- Steril değildir.
- Kaymaz taban.
- Ayakkabıyı tam olarak sararak koruma sağlar.
- Üstün nitelikli hafif ve giyilmesi kolay kumaştan üretilmiştir.

ENGLISH

HOW TO WEAR ?

- The overshoe are opened with both hands to allow the shoes to enter the overshoe easily.
- Laces arte tied so that the foot does not tighten too much.
- The laces prevent the shoe from slipping down.

HOW TO REMOVE ?

- It should be removed by sitting.
- In removal, should be careful to remove the over shoe by inverting.
- Laces are opened, the rubbers are widened to remove the back side of the shoe and then the front side.
- Hands are washed with soap after this process. Disinfectant should be used at times when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Lastiği iki elle açılarak ayakkabının rahat bir şekilde ürünün içine girmesi sağlanılır.
- Ayağı çok sıkmayacak şekilde bağcıklar bağlanılır.
- Bağcıklar galoşun aşağıya doğru kaymasını engeller.

NASIL ÇIKARTILIR ?

- Oturularak çıkarılmalıdır.
- Çıkarma işleminde galoşun ters çevrilerek çıkarılmasına dikkat edilmelidir.
- Bağcıklar açılır, lastikler genişletilerek ayakkabının önce arka tarafı sonra ön tarafının çıkarılması sağlanılır.
- Eller bu işlemden sonra sabun ile yıkanır. Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

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

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 bacteriophase".

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

Flex cracking resistance Class 6
Repellency to liquids:
- Sodium Hydroxide (NaOH) 10% concentration, Class 3
- Sulfuric Acid (H2SO4) 30% concentration Class 3

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No: 6/A Silivri İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis spores , ATCC 9372 Bacillus atrophaeus ve ATCC 13706 - B1 Escherichia coli bacteriophase " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Esneme çatlama direnci Sınıf 6
Sıvılara karşı dirençlik:
- Sodyum Hidroksit (NaOH)% 10 konsantrasyon, Sınıf 3
- Sülfürik Asit (H2SO4)%30 konsantrasyon, Sınıf 3

Üretici: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No: 6/A Silivri İstanbul

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 5001 Sokak No:6/A Silivri/İST.
Tel: (0 212) 723 86 00 Fax: (0 212) 723 86 15
Silivri Vergi Dairesi 94 011 1579
Ticaret Sicil No: 457834

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

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

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

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

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DİSPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 510306

Product: PB 0060
Exp. Date: 07/23

BIOBLOCKED®

SC 0060

TYPE PB [6] – B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif püskürtülen sıvılara karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE 2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

BioBlocked.com

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. Eski Sokak No: [illegible] Silivri/İST.
Tel: (0 212) 723 [illegible] Fax: (0 212) 723 88 15
Silivri Vergi Dairesi [illegible]
Ticaret Sicil No: [illegible]

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- It can be used in all environments that require hygiene.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Lamineli Kumaş
- Steril değildir.
- Hijyen gerektiren tüm ortamlarda kullanılabilir.

ENGLISH

HOW TO WEAR ?

- The disposable protective oversleeve cuff is wear on the wide side of the arm.
- To prevent the cuff from sliding towards the elbow, a finger is attached to the thumb.

HOW TO REMOVE ?

- The cuff is removed from the elbow by turning it upside down.
- Hands are washed with soap after this procedure. Disinfectant should be used when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Koruyucu kolluğun geniş tarafından kola giydirilir.
- Kolluğun dirseğe doğru kaymasını engellemek için baş parmağa parmaklık takılır.

NASIL ÇIKARTILIR ?

- Kolluk dirsek kısmından başlanarak ters çevrilerek çıkarılır.
- Eller bu işlemden sonra sabun ile yıkanır.Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

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

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",

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Class 6
Tearing strength	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

Manufacturer: **YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.** Selimpaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis spores , ATCC 9372 Bacillus atrophaeus ve ATCC 13706 - B1 Eschericihia coli bacteriophase " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Esneme çatlama direnci: Sınıf 5
Sıvılara karşı itici lik:
•Sodyum Hidroksit (NaOH)% 10 konsantrasyon, Sınıf 3
•Sülfürik Asit (H2SO4)%30 konsantrasyon, Sınıf 3

Üretici: **YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.** Selimpaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 5001 Sokak. No:6/A Silivri / İST.
Tel : (0 212) 723 88 00 Fax : (0 212) 723 88 15
Silivri Vergi Dairesi : 547 017 4579
Ticaret Sicil No : 459834

YELKENCİ GROUP	**TECHNICAL FILE** MANUFACTURING CONTROL GUIDE Protective Clothing (Long Overshoes, Protective Oversleeve, Bouffant Cap, Overshoe Taped - Long, Protective Oversleeve - Seamless)	DOCUMENT NO	TD-06
		ISSUE DATE	01.05.2020
		REV DATE	----
		REV NO	00
		PAGE NO	18/29

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

GÜVENLİK TALİMATI
Bütün koruyucu giysiler, kullanmadan önce, yırtık, delik, söküK, kir gibi olumsuzluk defo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli ise kesinlikle giyilmemelidir.

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft worden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

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

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 510405

Product: SC 0060
Exp. Date: 07/23

BIOBLOCKED®

CP 0045

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif püskürtülen sıvılara karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE 2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

BioBlocked.com

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 901 Sokak No:6/A Silivri / İST.
Tel : (0 212) 723 88 00 Fax : (0212) 723 88 15
Silivri Vergi Dairesi : 940 017 7579
Ticaret Sicil No : 457834

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- It can be used in all environments that require hygiene.

ENGLISH

HOW TO WEAR ?

- The bonnet is opened with two hands by its rubbery part.
- The rubber part of the bonnet is placed on the forehead.
- The bonnet is placed on the head, completely covering the hair.

HOW TO REMOVE ?

- The rubber of the bonnet is gripped from the back of the head.
- The rubber is folded in front and the bone is removed.
- Hands are washed with soap after this procedure. Disinfectant should be used when there is no water and soap.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date,

Destruction / Recycling

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

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",

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Class 6
Tearing strength	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

Manufacturer: **YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.** Selimpaşa Merkez Mh. 5001 Sk. No: 6/A Silivri İstanbul

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Lamineli Kumaş
- Steril değildir.
- Hijyen gerektiren tüm ortamlarda kullanılabilir.

TÜRKÇE

NASIL GİYİLİR ?

- Bone, lastikli kısmından iki elle tulup açılır.
- Bonenin lastikli kısmı alına yerleştirilir.
- Bone, saçları tamamen içine alacak şekilde başa yerleştirilir.

NASIL ÇIKARTILIR ?

- Kafanın arka tarafından bonenin lastiği kavranır.
- Lastik ön tarafa doğru içe katlanarak bone çıkarılır.
- Eller bu işlemden sonra sabun ile yıkanır.Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis spores , ATCC 9372 Bacillus atrophaeus ve ATCC 13706 - B1 Eschericihia coli bacteriophase " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Esneme çatlama direnci Sınıf 5
Sıvılara karşı itici lik.
-Sodyum Hidroksit (NaOH)% 10 konsantrasyon, Sınıf 3
-Sülfürik Asit (H2SO4)%30 konsantrasyon, Sınıf 3

Üretici: **YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.** Selimpaşa Merkez Mh. 5001 Sk. No: 6/A Silivri İstanbul

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

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

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

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

DİKKAT!
Poşet ile oynamak tehlikeldir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT **TEK KULLANIMLIK GİYSİ** **VÊTEMENT JETABLE** **EINWEGBARE BEKLEIDUNG**

Please read user manual / Kullanma talimatını okuyunuz.	Do Not Wash. / Yıkanmaz	Do not dry clean / Kuru temizleme yapılmaz	Do not iron / Ütülenmez	Do not Bleach / Çamaşır suyu kullanılmaz	Do not use twice / It is disposable / Zarar kullanılmaz / Tek kullanımlıktır

8 682753 510504

Product: CP 0045
Exp. Date: 07/23

BIOBLOCKED®

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

YELKENCİ GROUP	**TECHNICAL FILE** MANUFACTURING CONTROL GUIDE Protective Clothing (Long Overshoes, Protective Oversleeve, Bouffant Cap, Overshoe Taped - Long, Protective Oversleeve - Seamless)	DOCUMENT NO	TD-06
		ISSUE DATE	01.05.2020
		REV DATE	----
		REV NO	00
		PAGE NO	20/29

SC 0065

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif püskürtülen sıvılara karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE 2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

BioBlocked.com

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- It can be used in all environments that require hygiene.
- Ultrasonically stitched.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Laminell Kumaş
- Steril değildir.
- Hijyen gerektiren tüm ortamlarda kullanılabilir.
- Ultrasonik dikişli.

ENGLISH

HOW TO WEAR ?

- The disposable protective oversleeve cuff is wear on the wide side of the arm.
- To prevent the cuff from sliding towards the elbow, a finger is attached to the thumb.

HOW TO REMOVE ?

- The cuff is removed from the elbow by turning it upside down.
- Hands are washed with soap after this procedure. Disinfectant should be used when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Koruyucu kolluğun geniş tarafından kola giydirilir.
- Kolluğun dirseğe doğru kaymasını engellemek için baş parmağa parmaklık takılır.

NASIL ÇIKARTILIR ?

- Kolluk dirsek kısmından başlanarak ters çevrilerek çıkarılır.
- Eller bu işlemden sonra sabun ile yıkanır.Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

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

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 bacteriophase".

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Class 6
Tearing strength	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

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis spores , ATCC 9372 Bacillus atrophaeus ve ATCC 13706 - B1 Escherichia coli bacteriophase " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Esneme çatlama direnci Sınıf 5
Sıvılara karşı iticilik:
- Sodyum Hidroksit (NaOH)%10 konsantrasyon, Sınıf 3
- Sülfürik Asit (H2SO4)%30 konsantrasyon, Sınıf 3

Üretici: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 5001 Sokak No:6/A Silivri / İST.
Tel: (0 212) 725 66 00 Fax: (0 212) 723 86 15
Silivri Vergi Dairesi 647 027 7579
Ticaret Sicil No: 457[illegible]

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

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

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiée avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

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

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babye fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 513406

Product: SC 0065
Exp. Date: 07/23

BIOBLOCKED®

PB 0065

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif püskürtülen partüküllere karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE 2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

BioBlocked.com

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 5001 Sokak No:4A Silivri/İST.
Tel: (0 212) 723 86 00 Fax: (0 212) 723 86 15
Silivri Vergi Dairesi: 947 017 7579
Ticaret Sicil No: 457834

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- Non-slip sole.
- It provides protection by fully wrapping the shoe covers.
- It is made of superior lightweight and easy-to-wear fabric.
- Welding tape is welded on all seams.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Lamineli Kumaş
- Steril değildir.
- Kaymaz taban.
- Ayakkabıyı tam olarak sararak koruma sağlar.
- Üstün nitelikli hafif ve giyilmesi kolay kumaştan üretilmiştir.
- Tüm dikiş yerlerinin üzerine kaynak bant yapıştırılır.

ENGLISH

HOW TO WEAR ?

- The overshoe are opened with both hands to allow the shoes to enter the overshoe easily.
- Laces arte tied so that the foot does not tighten too much.
- The laces prevent the shoe from slipping down.

HOW TO REMOVE ?

- It should be removed by sitting.
- In removal, should be careful to remove the over shoe by inverting.
- Laces are opened, the rubbers are widened to remove the back side of the shoe and then the front side.
- Hands are washed with soap after this process. Disinfectant should be used at times when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Lastiği iki elle açılarak ayakkabının rahat bir şekilde ürünün içine girmesi sağlanılır.
- Ayağı çok sıkmayacak şekilde bağcıklar bağlanılır.
- Bağcıklar galoşun aşağıya doğru kaymasını engeller.

NASIL ÇIKARTILIR ?

- Oturularak çıkarılmalıdır.
- Çıkarma işleminde galoşun ters çevrilerek çıkarılmasına dikkat edilmelidir.
- Bağcıklar açılır, lastikler genişletilerek ayakkabının önce arka tarafı sonra ön tarafının çıkarılması sağlanılır.
- Eller bu işlemden sonra sabun ile yıkanır. Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

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

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 bacteriophase".

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Class 6
Tearing strength	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

Manufacturer: **YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.** Sefinepaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

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Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis spores , ATCC 9372 Bacillus atrophaeus ve ATCC 13706 - B1 Escherichia coli bacteriophase " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Esneme çatlama direnci Sınıf 5
Sıvılara karşı iticilik;
- Sodyum Hidroksit (NaOH)% 10 konsantrasyon, Sınıf 3
- Sülfürik Asit (H2SO4)%30 konsantrasyon, Sınıf 3

Üretici: **YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.** Sefinepaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Sefinepaşa Mah. 5001 Sokak No:6/A Silivri/İST.
Tel: (0 212) 723 86 00 Fax: (0 212) 723 86 15
Silivri Vergi Dairesi 947 047 7579
Ticaret Sicil No.: 457344

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

GÜVENLİK TALİMATI
Bütün koruyucu giysiler, kullanmadan önce, yırtık, delik, söküK, kir gibi olumsuzluk defo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli ise kesinlikle giyilmemelidir.

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou salete. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

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

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 513307

Product: PB 0065
Exp. Date: 07/23

BIOBLOCKED®

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.

STORAGE/USE BY: It is recommended to keep it in a cardboard or cardboard box, away from sunlight at 15 -25 °C. If stored under appropriate conditions, it should be used within 3 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.

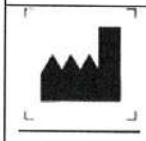
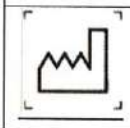
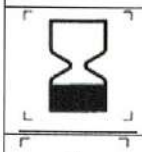
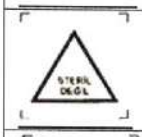
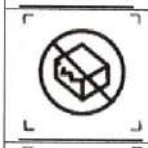
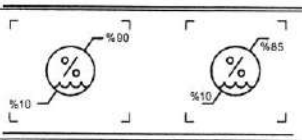
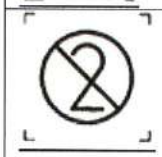
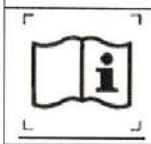
"In case of long-term use in temperate climates and environments, it may cause overheating "

"Flammable material. Keep away from fire."

Disposable, "Do not reuse!"

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Mah. 502. Sokak [illegible] Silivri/İST. Tel : (0 212) 723 86 00 Fax : (0 212) 723 86 15 Silivri Vergi Dairesi : 541 017 4579 Ticaret Sicil No : 427834

Meaning of the Symbols on the Product Package

SYMBOL	TITLE OF THE SYMBOL	DESCRIPTION OF THE SYMBOL	SAMPLE
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385 / EEC, 93/42 / EEC and 98/79 / EC.	 **Name Address**
	Production date	Indicates the date the medical device was manufactured.	 **2020 - 06**
	Used by	Shows the expiration date of the medical device.	 **2021 - 06**
	(Non Sterile)	Indicates that a medical device has not been subjected to sterilization.	
	Do not use if the package is damaged.	Indicates that the medical device should not be used if the packaging is damaged or opened.	
	Keep dry	Indicates that the medical device must be protected from moisture.	
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed.	
	Humidity limitation	Indicates the humidity range to which the medical device can be safely exposed.	
	Do not reuse	Indicates that the medical device is intended for single use or for use on a single patient during a single procedure.	Disposable PPE, "Do not reuse!"
	See instructions for use	It shows that I have to look at the user's instructions for use.	

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

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Ticaret Sicil No.: 457[illegible]

- General principles effective in biological evaluation of medical devices within a risk management process,
- General classification based on the structure of the devices in contact with the body and the duration of contact,
- Evaluation of relevant available data obtained from all kinds of sources,
- Identification of gaps in existing data sets based on a risk analysis,
- Identification of additional data groups required to analyze the biological safety of the medical device,
- Determining the biological safety of the medical device

processes and the risk management plan have identified and assigned biological assessment issues that require specific technical competences and the person (s) responsible for biological safety assessment. Hazardous Material Safety Data Sheets (MSDS) are obtained and evaluated from all of our suppliers. (ISO 10993)

EK - E

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

EN 14126/AC:2004 Standardının Karşıladığı Temel Sağlık ve Güvenlik Gerekleri/ Basic Health and Safety Requirements Meets EN 14126 / AC: 2004 Standard

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

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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 referansları/ *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 ; in particular, whwn such marks incorporate 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.*

PRODUCT PERFORMANCE VALUES

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Abrasion resistance
Tear resistance	Tear resistance
Tensile strength	Tensile strength
Puncture resistance	Puncture resistance
Seam strength	Seam strength

Flex cracking resistance Class 3

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

EN 14126:2003+AC:2004
Biological agents for which the product is tested are "ATCC 9372 Bacillus subtilis spores, ATCC 9372 Bacillus atrophaeus and ATCC 13706 - B1 Escherichia coli bacteriophase".

EN 13034:2005+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 dâhil olmak üzere, kullanıcının sağlık ve güvenliğini olumsuz yönde etkilememelidir. / *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.*

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Ticaret Sicil No: 457834

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*

1.3.2.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.*

1.3.3. Aynı Anda Kullanılmak Üzere Tasarlanmış Farklı KKD Tipleri veya Sınıflarının Uyumu / *Compatibility of different types of PPE intended 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 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.*

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

2.4. KKD'nin Kullanım Ömrü ve Kullanımdan Dolayı Özelliğini Kaybetmesi / *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 KKD'nin ambalajı üzerinde de bulunmalıdır. / *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.*

KKD'nin kullanımından dolayı özelliğini ne sürede kaybedeceğinin öngörülemediği durumda imalatçı, tüketici ve nihai kullanıcıya kullanım kılavuzunda KKD modelinin kalite seviyesi ve depolanması, kullanımı, temizlenmesi, hizmete sunumu ve bakımına ilişkin etken koşulları da dikkate alarak makul bir kullanım ömrünü ay ve yıl olarak belirtmelidir. / *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.*

KKD'nin temizlenmesinde periyodik olarak kullanılan ve imalatçının tavsiye ettiği bir temizleme işlemi sonucunda oluşan yıpranmalardan kaynaklanan, KKD'nin performansında hızlı şekilde azalmaya sebep olan koşullar; mümkün olduğu durumda, piyasaya arz edilen her bir KKD'nin üzerine kullanım ömrünün tamamlanmasından önce yapılabilecek azami temizleme sayısını içerecek şekilde gerekli işaretleme iliştirilmelidir. Bunun mümkün olmadığı durumda bu bilgiler kullanım kılavuzunda verilmelidir. / *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. 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 ; in particular, whwn such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.*

YELKENCİ DEĞİRMİ GİYİM SANAYİ VE TİCARET A.Ş.
Sefapaşa Mah. 5101 Sokak No:6/A Silivri/İST.
Tel: (0 212) 723 88 00 Fax: (0 212) 723 88 15
Silivri Vergi Dairesi: 947 017 4579
Ticaret Sicil No: 457654

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.*

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

KİŞİSEL KORUYUCU EKİPMANLAR PERSONAL PROTECTIVE EQUIPMENTS (14126)

Ürün Kodu : Overshoe - Long - PB 0060

Ürün Kodu : Overshoe Taped - Long - PB 0065

Ürün Kodu : Protective Oversleeve - SC 0060

Ürün Kodu : Protective Oversleeve - Seamless - SC 0065

Ürün Kodu : Bouffant Cap - Laminated - CP 0045

Belgeler :

- Teknik Föy ve Ölçü Tablosu
- EU TYPE EXAMINATION CERTIFICATE
- EU DECLARATION OF CONFORMITY
- FDA Belgesi
- Test Raporu
- Teknik Değerlendirme Raporu
- Teknik Dosya

Standartlar :

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

Preparation date: 14.06.2020

T.006.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
PRODUCT	OVERSHOE - LONG (NON-STERILE)
PRODUCT CODE	PB 0060

BIOBLOCKED®

Overshoe - Long

PRODUCT: PB 0060

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58764
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

EN 14126:2003+AC:2004 Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

PRODUCT INFORMATION	
Model Description	Long overshoes with anti-slip sole, straps and rubber.
Fabric	57 gr PP+PE fabric.
Material	Number 120 white polyester yarn.
	3 mm rubber.
	Anti-slip sole.

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 inter face operations will be used with 5 thread overlock.
	By combining the overshoes sizes, the overalls are made with 2 strapping straps from top to bottom 10 cm and 5 thread overlock.
	Anti-slip insoles are sewn.
	Overall is turned inside out. Stitches are turned inside out with a finger from the inside by stroking.
	From 1 cm below the upper throttle, the rubber is sewn with a firm tension.
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
Labels and Washing Instructions	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 where it will be shipped 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.
	24x32+5cm printed bags will be used.
Package	The amount in the package should be the same as the 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.

T.032.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
NAME OF THE PRODUCT	OVERSHOE TAPED - LONG (NON-STERILE)
PRODUCT CODE	PB 0065

PRODUCT INFORMATION	
Model Description	Long overshoes with anti-slip sole, straps, welded seams and rubber.
Fabric	57 gr PP + PE fabric.
Material	Number 120 white polyester yarn.
	3 mm rubber.
	Anti-slip sole.
	16 mm wide welding tape.

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.
	By combining the overshoes sizes, the overalls are made with 2 strapping straps from top to bottom 10 cm and 5 thread overlock.
	Anti-slip insoles are sewn.
	Jumpsuit is turned upside down. Stitches are translated with a finger from the inside stroke.
	From 1 cm below the upper throttle, the rubber is sewn with a firm tension.
	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 interlace seams and the welding strip is welded onto the seams by means of heat. The binding strap is divided into two and a band is welded in the middle of the seam. There should not be additions on tapes and make sure that they adhere well.
Labels and Washing Instructions	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 where it will be shipped 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.
	24x32+5cm printed bags will be used.
Package	The amount in the package should be the same as the 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.

T.007.01	TEKNİK FÖY
BRAND	BIOBLOCKED
PRODUCT	Protective Oversleeve (NON-STERILE)
PRODUCT CODE	SC 0060

BIOBLOCKED®

Protective Oversleeve

PRODUCT: SC 0060

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58763
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals

EN 14126:2003+AC:2004
Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

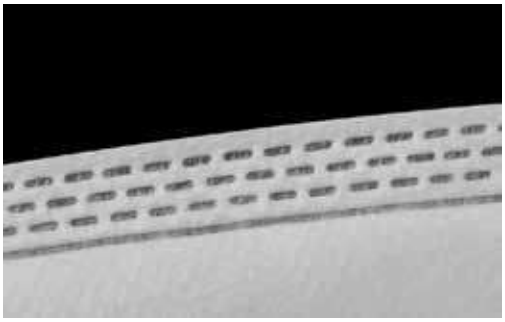
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

PRODUCT INFORMATION	
Model Description	Arm protector with two ends of rubber and finger cot.
Fabric	57 gr PP+PE
Material	Number 120 white polyester yarn.
	3 mm rubber
	16 cm spunbound piping. The cut tpiping width will be 2.8 cm. The finished version will be 1 cm.

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)
	The product is interlaced with 5 thread overlock by folding in two.
	The product is turned to its flat face. A set of rubber is made on the wrist and biceps parts.
	The 16 cm piping is folded in two and sewn by zigzagging the inside seam on the wristband side.
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
Labels and Washing Instructions	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, the name of the manufacturer, the chart number and the production batch number. The label must be in the language the product where it will be shipped 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 it complies with the product code specified on the chart.
	Make sure the bag is closed properly and that there are no tears or holes.
Package	The amount inside the box should be the same as the ones specified on the 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.

T.033.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
PRODUCT	Protective Oversleeve - Seamless (NON-STERILE)
PRODUCT CODE	SC 0065



PRODUCT INFORMATION	
Model Description	Arm protector with two ends of rubber, ultrasonic stitching and finger cot.
Fabric	57 gr PP+PE
Material	Number 120 white polyester yarn.
	3 mm rubber
	16 cm spunbound piping. The cut tpiping width will be 2.8 cm. The finished version will be 1 cm.

SEWING INSTRUCTIONS, LABEL AND IMPORTANT DETAILS	
General Sewing Instructions	A yellow Groz Beckert needle with a ball tip numbered 9 or 10 will be used. (Gold needle)
	The product is interlaced with ultrasonic stitch by folding in two.
	The product is turned to its flat face. A set of rubber is made on the wrist and biceps parts.
	The 16 cm piping is folded in two and sewn by zigzagging the inside seam on the wristband side.
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
Labels and Washing Instructions	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, the name of the manufacturer, the chart number and the production batch number. The label must be in the language the product where it 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 it complies with the product code specified on the chart.
	Make sure the bag is closed properly and that there are no tears or holes.
Package	The amount inside the box should be the same as the ones specified on the 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.

T.008.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
PRODUCT	Bouffant Cap - Laminated (NON-STERILE)
PRODUCT CODE	CP 0045

PRODUCT INFORMATION	
Model Description	Head protector with rubber around.
Fabric	57 gr PP+PE fabric.
Material	Number 120 white polyester yarn.
	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)
	The product is one piece and folded from 3 cm notches and placed on top of each other and the first edge is sewn from 1 cm.
	The second side is folded from 3 cm notches and placed on top of each other and sewn, while 1 cm gap is left from the open side and sewn.
	Starting from the side we left open, the rubber is sewn all around at maximum tension and exit from the other open side.
	Both caps are folded together and sewn again. The excess is regulated with scissors.
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
Labels and Washing Instructions	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 where the product will be shipped 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.
	15x15+5 cm printed bags will be used.
Package	The pieces inside the box should be the same as the ones specified in the 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-1390

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 31.08.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment
Brand Name: BIOBLOCKED, **Model:** PB 0060
Protective OverShoe, as a protective clothing for the part of body Type PB [6]-B, manufactured from white laminated polypropylene non-woven fabric, inside over lock seams, with shoelace and anti-slip layer. The OverShoe is available in 1 size fit all.

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing,
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **31/08/2020** and will be valid for 5 years from the issue date.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1390/01

Protective clothing – (coveralls) manufactured by

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

continues to fulfil the requirements of

Personal Protective Equipment Regulation (EU) 2016/425 and applied standards EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14126:2003 /AC:2004 based on the evaluation of test reports and internal quality control audit reports according to Module C2 (Annex VII) of PPE Regulation.

This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Brand Name and Model		EU Type Examination Certificate		
		Serial No.	Date	Issuing NB No.
BIOBLOCKED	PB 0060	2163-PPE-1390	31.08.2020	2163

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **03/11/2020** and will be valid for one year, until **02/11/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1431

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 05.09.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment
Brand Name: BIOBLOCKED, **Model:** PB 0065
Protective OverShoe, as a protective clothing for the part of body Type PB [6]-B, manufactured from white laminated polypropylene non-woven fabric, inside over lock seams covered with hotmelt tape, with shoelace and anti-slip layer. The OverShoe is available in 1 size fit all.

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing.
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **10/09/2020** and will be valid for 5 years from the issue date.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1431/01

Protective clothing – (coveralls) manufactured by

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

continues to fulfil the requirements of

Personal Protective Equipment Regulation (EU) 2016/425 and applied standards EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14126:2003 /AC:2004 based on the evaluation of test reports and internal quality control audit reports according to Module C2 (Annex VII) of PPE Regulation.

This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Brand Name and Model		EU Type Examination Certificate		
		Serial No.	Date	Issuing NB No.
BIOBLOCKED	PB 0065	2163-PPE-1431	10.09.2020	2163

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **03/11/2020** and will be valid for one year, until **02/11/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1391

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 31.08.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment
Brand Name: BIOBLOCKED, **Model:** SC 0060
Protective OverSleeve, as a protective clothing for the part of body Type PB [6]-B, manufactured from white laminated polypropylene non-woven fabric, inside over lock seams, elastic wrist and shoulder. The OverSleeve is available in 1 size fit all.

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing,
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **31/08/2020** and will be valid for 5 years from the issue date.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1391/01

Protective clothing – (coveralls) manufactured by

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

continues to fulfil the requirements of

Personal Protective Equipment Regulation (EU) 2016/425 and applied standards EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14126:2003 /AC:2004 based on the evaluation of test reports and internal quality control audit reports according to Module C2 (Annex VII) of PPE Regulation.

This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Brand Name and Model		EU Type Examination Certificate		
		Serial No.	Date	Issuing NB No.
BIOBLOCKED	SC 0060	2163-PPE-1391	31.08.2020	2163

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **03/11/2020** and will be valid for one year, until **02/11/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1432

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 05.09.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment
Brand Name: BIOBLOCKED, **Model:** SC 0065
Protective OverSleeve, as a protective clothing for the part of body Type PB [6]-B, manufactured from white laminated polypropylene non-woven fabric, with sides ultrasonic sewing, elastic wrist and shoulder. The OverSleeve is available in 1 size fit all.

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing,
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **10/09/2020** and will be valid for 5 years from the issue date.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1432/01

Protective clothing – (coveralls) manufactured by

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

continues to fulfil the requirements of

Personal Protective Equipment Regulation (EU) 2016/425 and applied standards EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14126:2003 /AC:2004 based on the evaluation of test reports and internal quality control audit reports according to Module C2 (Annex VII) of PPE Regulation.

This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Brand Name and Model		EU Type Examination Certificate		
		Serial No.	Date	Issuing NB No.
BIOBLOCKED	SC 0065	2163-PPE-1432	10.09.2020	2163

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **03/11/2020** and will be valid for one year, until **02/11/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1445

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 05.09.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment
Brand Name: BIOBLOCKED, **Model:** CP 0045
Protective Bouffant Cap, as a protective clothing for the part of body Type PB [6]-B, manufactured from white laminated polypropylene non-woven fabric, inside over lock seams, around head with latex free. The Bouffant Cap is available in 1 size.

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing,
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **14/09/2020** and will be valid for 5 years from the issue date.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

EU DECLARATION OF CONFORMITY

MANUFACTURER

YELKENCİ HAZIR GİYİMSANAYİ VE TİCARET ANONİM ŞİRKETİ
E5 Karayolu üzeri 5001 Sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name: BIOBLOCKED
Model: PB 0060
Overshoe - Long

Protective Equipment with high performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as EU 2016/425Personal Protective Equipment Regulation.

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

The Conformity is assessed especially with the following provisions:

- Complies with EU 2016/425Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards EN 14126/AC:2004, EN 13034:2005+A1:2009, EN ISO 13688: 2013
- 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, after all technical evaluations for conformity to the regulation and harmonised standards conducted, by;
    - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as Notified Body number 2163
- The product is under surveillance of same Notified Body, NB 2163 according to the Annex III (Module C2) of the PPE Regulation (EU) 2016/425, for quality assurance.

MARKING, LABELLING

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

MEASURES TO ENSURE CONFORMITY

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

Eren YELKENCİ
General Manager
04/11/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

CE
2163

EU DECLARATION OF CONFORMITY

MANUFACTURER

YELKENCİ HAZIR GİYİMSANAYİ VE TİCARET ANONİM ŞİRKETİ
E5 Karayolu üzeri 5001 Sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name: BIOBLOCKED
Model: PB 0065
Overshoe Taped - Long

Protective Equipment with high performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as EU 2016/425Personal Protective Equipment Regulation.

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

The Conformity is assessed especially with the following provisions:

- Complies with EU 2016/425Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards EN 14126/AC:2004, EN 13034:2005+A1:2009, EN ISO 13688: 2013
- 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, after all technical evaluations for conformity to the regulation and harmonised standards conducted, by;
    - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as Notified Body number 2163
- The product is under surveillance of same Notified Body, NB 2163 according to the Annex III (Module C2) of the PPE Regulation (EU) 2016/425, for quality assurance.

MARKING, LABELLING

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

MEASURES TO ENSURE CONFORMITY

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

Eren YELKENCİ
General Manager
04/11/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

CE
2163

EU DECLARATION OF CONFORMITY

MANUFACTURER

YELKENCİ HAZIR GİYİMSANAYİ VE TİCARET ANONİM ŞİRKETİ
E5 Karayolu üzeri 5001 Sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name: BIOBLOCKED
Model: SC 0060
Protective Oversleeve

Protective Equipment with high performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as EU 2016/425 Personal Protective Equipment Regulation.

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

The Conformity is assessed especially with the following provisions:

- Complies with EU 2016/425Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards EN 14126/AC:2004, EN 13034:2005+A1:2009, EN ISO 13688: 2013
- 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, after all technical evaluations for conformity to the regulation and harmonised standards conducted, by;
    - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as Notified Body number 2163
- The product is under surveillance of same Notified Body, NB 2163 according to the Annex III (Module C2) of the PPE Regulation (EU) 2016/425, for quality assurance.

MARKING, LABELLING

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

MEASURES TO ENSURE CONFORMITY

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

Eren YELKENCİ
General Manager
04/11/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

CE
2163

EU DECLARATION OF CONFORMITY

MANUFACTURER

YELKENCİ HAZIR GİYİMSANAYİ VE TİCARET ANONİM ŞİRKETİ
E5 Karayolu üzeri 5001 Sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name: BIOBLOCKED
Model: SC 0065
Protective Oversleeve - Seamless

Protective Equipment with high performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as EU 2016/425 Personal Protective Equipment Regulation.

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

The Conformity is assessed especially with the following provisions:

- Complies with EU 2016/425Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards EN 14126/AC:2004, EN 13034:2005+A1:2009, EN ISO 13688: 2013
- 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, after all technical evaluations for conformity to the regulation and harmonised standards conducted, by;
    - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as Notified Body number 2163
- The product is under surveillance of same Notified Body, NB 2163 according to the Annex III (Module C2) of the PPE Regulation (EU) 2016/425, for quality assurance.

MARKING, LABELLING

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

MEASURES TO ENSURE CONFORMITY

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

Eren YELKENCİ
General Manager
04/11/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

CE
2163

EU DECLARATION OF CONFORMITY

MANUFACTURER

YELKENCİ HAZIR GİYİMSANAYİ VE TİCARET ANONİM ŞİRKETİ
E5 Karayolu üzeri 5001 Sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name: BIOBLOCKED
Model: CP 0045
Bouffant Cap - Laminated

Protective Equipment with high performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as EU 2016/425 Personal Protective Equipment Regulation.

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

The Conformity is assessed especially with the following provisions:

- Complies with EU 2016/425Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards EN 14126/AC:2004, EN 13034:2005+A1:2009, EN ISO 13688: 2013
- 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, after all technical evaluations for conformity to the regulation and harmonised standards conducted, by;
    - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as Notified Body number 2163
- The product is under surveillance of same Notified Body, NB 2163 according to the Annex III (Module B) of the PPE Regulation (EU) 2016/425, for quality assurance.

MARKING, LABELLING

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

MEASURES TO ENSURE CONFORMITY

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

Eren YELKENCİ
General Manager
31/08/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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 Registration:	**3016879381**
DUNS No.:	**35-497-3328**
Device Classification Name:	**COVER, SHOE, OPERATING-ROOM**
Product Code:	**FXP**
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.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: August 10, 2020

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 Registration:	**3016879381**
DUNS No.:	**35-497-3328**
Device Classification Name:	**ACCESSORY, SURGICAL APPAREL**
Product Code:	**LYU**
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.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

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info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: August 10, 2020

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 Registration:	**3016879381**
DUNS No.:	**35-497-3328**
Device Classification Name:	**CAP, SURGICAL**
Product Code:	**FYF**
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.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
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info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: August 10, 2020

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

TEST REPORT
DENEY RAPORU

AB-0583-T
20018044-Add- RER
08-20

Müşterinin adı:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Adresi:	15 Temmuz Mah. Gülbahar Cad. No:96 Bağcılar/İSTANBUL
Alıcı firma:	YELKENCİ HAZIR GİYİM
İlgili kişi:	SUAT KAÇMAZ
İstek numarası:	-
Model numarası:	-
Numunenin adı ve tarifi:	Beyaz koruyucu tulum.
Numunenin kabul tarihi:	08.06.2020
İlave numune ve/veya ilave bilgi geliş tarihi:	-
Deneyin yapıldığı tarih:	08.06.20230-03.07.2020
Açıklamalar:	-
Numune alımı:	Bu raporda verilen sonuçlar müşteri tarafından gönderilen numuneye aittir.
Numunenin son kullanımı:	-
Yıkama talimatı:	Belirtilmedi.
Raporun sayfa sayısı:	9

Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınması konusunda Avrupa Akreditasyon Birliği (EA) ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı tanınma antlaşmasını imzalamıştır. Deney laboratuvarı olarak faaliyet gösteren EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. TÜRKAK'tan AB-0583-T akreditasyon dosya numarası ile ISO 17025:2017 standardına göre akredite edilmiştir.

Deney ve/ veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri (olması halinde) ve deney metodları bu sertifikanın tamamlayıcı kısmı olan takip eden sayfalarda verilmiştir

Mühür	***Tarih***	***Müşteri Temsilcisi***	***Laboratuvar Müdürü***
TESTED BY EKOTEKS TEST EDİLMİŞTİR	18.08.2020	Servet KURTSEVEN	Sevim A. RAZAK

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İSTENEN TESTLER	SONUÇ	AÇIKLAMA
FİZİKSEL TESTLER		
Aşınma	-	Sınıf 6
Su Geçirgenliği	-	Sınıf 6
Yırtılma Mukavemeti	-	Sınıf 1
Kopma Mukavemeti	-	Sınıf 1
Sıvılara Karşı İticilik	-	Test sonucuna bakınız
Sıvıların Nüfus Etmesine Karşı Direnci	-	Sınıf 3
Dikiş Mukavemeti	-	Sınıf 1
Antistatik(1)	F	
Delinme Dayanımı	-	Sınıf 2
Gramaj	-	-
Esnetme ile oluşan hasara karşı direncin Tayini(3)		Sınıf 5
MİKROBİYOLOJİ TESTLERİ		
Islak Mikrobiyal Geçirgenlik	-	Sınıf 3

P:Geçer
F:Kalır
R:Alıcı firmanın teknik kişisine başvurunuz.
Test sonuçları BS EN 14325:2018'e göre sınıflandırılmıştır.
(1)İstenen değerler müşteri tarafından belirtilmiştir.
(2).İstenen değerler belirtilmemiştir.
(3) Bu test sonucu eklendiği için rapor tekrardan basılmıştır

NOT: Aksi belirtilmediği taktirde testler ile ilgili kayıtlar 5 yıl, orjinal numuneler 3 ay saklanır. Müşteri tarafından talep edildiğinde, testlere ait ölçüm belirsizliği raporlanır fakat "Geçer/Kalır" değerlendirmesinde ölçüm belirsizliği değeri dikkate alınmaz. Raporlanan belirsizlik, genişletilmiş belirsizlik olup standart belirsizlik kapsam faktörü k=2 kullanılarak elde edilmiştir. Güvenilirlik düzeyi % 95'tir. Bu raporda (*) işaretli deneyler akreditasyon kapsamına dahil değildir.

Not: 03.07.2020 tarihli 20018044-Addnumaralı rapor müşteri isteği üzerine Sıvılara Karşı İticilik ve Sıvıların Nüfus Etmesine Karşı Direnci test sonucunun tekrar değerlendirilmesi nedeni ile 20018044-Add-RER numaralı 18.08.2020 tarihli raporla değiştirilmiştir.

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TEST SONUÇLARI

Test Metodu: BS EN 14325:2018 (KIMYASALLARA KARŞI KORUYUCU GİYSİLER- KIMYASAL KORUYUCU GİYSİ MALZEMELERİNİN, DİKİŞLERIN VE BIRLEŞTIRICI MALZEMELERİN PERFORMANS SINIFLANDIRILMASI VE TEST METOTLARI)

AŞINMA DAYANIMI ve SIZDIRMAZLIK

Madde 4.4.Aşınma Dayanımı (EN ISO 12947-2) EK-B

Lissajous deseni oluşturan Martindale Test Cihazı (47.5±2 rpm)
9 kPa basınç, (595±7) g kütle.
Kondüsyon şartlarında test edilmiştir.(20±2°C-65%±4)

SONUÇ	SINIF
Aşınmadı @ 2.000 devir	6 Tablo-1 'e gore yapılır

Malzemeye zarar vermeyen en yüksek aşınma devri Tablo-1 e göre tayin edilir.
Aşınma Dayanımının Sınıflandırılması (Tablo-1)

Sınıf	*Devir Sayısı*
6	>2000
5	>1000
4	>400
3	>100
2	>40
1	>10

Madde 4.4.2.3 Su geçirmezlik tayini hidrostatik basınç metodu (EN 20811)
Orijinal numune (aşındırılmamış) test sonucu > 200 mmSS olmalıdır.Bunu sağlarsa madde 4.4'e göre en yüksek devirde bulunan numuneye EN 20811 uygulanır.

SU GEÇİRGENLİĞİ; EN ISO 811:2018

Hidrostatik Başlık Cihazı, Textest marka Fx 3000 model
Su sıcaklığı 10 .°C. Basınç artış oranı 10 mbar/dk.
Kondüsyonlu ortamda test edilmiştir. (20±2°C-65%±4).

	SONUÇ	İSTENEN
Numune 1	519.2 mm SS	>200 mmSS
Numune 2	466.1 mm SS	
Numune 3	755.8 mm SS	
Numune 4	575.3 mm SS	
Numune 5	883.3 mm SS	
Ortalama	639.9 mm SS	

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TEST SONUÇLARI

YIRTILMA MUKAVEMETİ;
Madde 4.7.Trapezoidal Yırtılma Dayanımı TS EN ISO 9073-4:2002
Instron 5969 Hız: 100 mm/dk±10, Çene mesafesi 5 cm.
En boy yönlerinde 4 adet sonucun ortalaması verilmiştir.
2N Ön gerilim uygulanmıştır.
Kondüsyon şartlarında test edilmiştir. (20±2°C - %65±4)

	SONUÇ	SINIF
EN	23.0N	1
BOY	10.6 N	Tablo-4 'e gore yapılır

Yırtılma Dayanımının Sınıflandırılması (Tablo-4)

Sınıf	*Yırtılma Mukavemeti*
6	>150 N
5	>100 N
4	>60 N
3	>40 N
2	>20 N
1	>10 N

KOPMA MUKAVEMETİ;
Madde 4.9.Kopma Mukavemeti EN ISO 13934-1:2013
Hız: 100 mm/dk±10, Çene mesafesi 200 mm.
Ön gerilme uygulanmamıştır. Islatma işlemi yapılmamıştır.
Atkı ve Çözgü yönlerinde 4 adet sonucun ortalaması verilmiştir.
Kondüsyon şartlarında test edilmiştir. (20±2°C - %65±4)

	SONUÇ	SINIF
Atkı	77.5 N	1
Çözgü	38.5 N	Tablo-5 'e gore yapılır

Kopma Mukavemeti Sınıflandırılması (Tablo-5)

Sınıf	Kopma Mukavemeti
6	>1000 N
5	>500 N
4	>250 N
3	>100 N
2	>60 N
1	>30N

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TEST SONUÇLARI
SIVILARA KARŞI İTİCİLİK ÖZELLİĞİ

Madde 4.12 Sıvılara Karşı İticilik (EN ISO 6530:2005)

Sıvı dayanımı Tablo-9 da verilen sıvı kimyasallar yada genel amaçlı bir izlenimi görmek için test sıvısı olarak su da kullanılabilir.
Kondüsyon şartlarında test edilmiştir. (20±2°C - %65±4)
Test edilecek herbir kimyasal sıvıya dayanımı ölçmek için 3 en, 3 boy numune (360±2)mm x (235±5)mm alınmıştır.
Analitik saflıkta kimyaal kullanılmıştır.Test sıvısı (10cm ^{3}) , (10±1)s de numune yüzeyinden geçirilmiştir. Bkz Tablo-9
Sonuç Değerlendirmesi Tablo-10 ve tbalo-11'e göre yapılmıştır.

Absorbsiyon,Penetrasyon (nüfuz etme) ve iticilik testlerinde kullanılan kimyasallar (Tablo-9)

Kimyasal	*Kimyasal Marka*	*% Konsantrasyon*	*Sıcaklık (±2°C)*
Sülfürik Asit (H2SO4)		*30*	*20*
Sodyum Hidroksit(NaOH)		*10*	*20*
o-Xylene		*Seyreltik değil*	*20*

Sıvı İticiliğinin Sınıflandırılması (Tablo-10)

Sınıf	*İticilik Indeksi (IR)*
3	*> 90 %*
2	*>80 %*
1	*>70 %*

Madde 4.13 Sıvıların Nüfus Etmesine Karşı Direnci (EN ISO 6530)

Sıvılara Karşı Nüfus Etme Direncinin Sınıflandırılması (Tablo-11)

Sınıf	***Nüfus Etme Indeksi (Ip)***
3	< 1 %
2	< 5 %
1	<10 %

SONUÇ

Kimyasal	*%Konsantrasyon*	I_P	*Sınıf*	I_R	*Sınıf*
Sülfürik Asit (H2SO4)	30	% 0	3	% 93.0	3
Sodyum Hidroksit (NaOH)	10	% 0	3	%30.6	-
o-Xylene	Seyreltik değil	% 0	3	%69.3	-

I_P *:Penetrasyon İndeksi*
I_R *:* İticilik Indeksi

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TEST SONUÇLARI

DİKİŞ MUKAVEMETİ-GRAB METOT ;

Madde 5.5 Dikiş Mukavemeti ISO 13935-2: 2014

NSTRON 5969

Hız: 50±5 mm/dk, Çene Aralığı: 100 ±1 mm

5kN yük uygulanmıştır.

Kondüsyon şartlarında test edilmiştir.(20±2°C-65%±4)

	Dikiş Mukavemeti (N)	Hata	SINIFLANDIRMA
Ağ	88.2 N	FTJ	1 Tablo-13 'e gore yapılır
İç yan dikiş	75.3 N	FTS	
Ön orta dikiş	68.1 N	FTS	
Arka orta dikiş	74.2 N	FTS	
Bel	47.7 N	FTJ	
Kol dikişi	53.0 N	FTS	
Kapüşon	48.1 N	FTS	
Fermuar elcik	132.2N	-	

FTJ : Çenede Kumaş Yırtılması
FTS: Dikişte Kumaş Yırtılması

Dikiş Mukavemeti Sınıflandırılması (Tablo-13)

SINIF	*Dikiş Mukavemeti*
6	*>500 N*
5	*>300 N*
4	*>125 N*
3	*>75 N*
2	*>50 N*
1	*>30 N*

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TEST SONUÇLARI

YÜZEY ÖZ DİRENCİ ÖLÇÜMÜ; EN 1149-1:2006

Ohm metre (METRISO 3000) ve halka prob kullanılmıştır.

Müşteri isteği ile, numune alındığı hali ile test edilmiştir.

Ön İşlem	-
Kondüsyonlama ve test koşulları	(23± 1)°C, (25± 5)%RH
Kondüsyonlama süresi	≥ 24 saat
Uygulanan Voltaj	10 Volt / 100 Volt
Test edilen numune sayısı	5

	SONUÇ	
Ölçüm	**Yüzey Öz Direnci**	**İSTENEN**
Geometrik Ortalama	$1.20 \times 10^{12}\ \Omega$	$<2,5 \times 10^{9}\ \Omega$

KUMAŞ GRAMAJI; ISO 3801:1977 Metot 5

5 adet sonucun ortalaması verilmiştir.
Kondüsyon şartlarında test edilmiştir (20±2°C-65%±4).

SONUÇ	İSTENEN
$62.1\ g/m^2$	-

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TEST SONUÇLARI

DELİNME DAYANIMI

Madde 4.10.Delinme Dayanımı EN 863

SONUÇ

17.3 N

SINIF

2
Tablo-6 'ya göre yapılır

Delinme Dayanımının Sınıflandırılması (Tablo-6)

Sınıf	*Delinme Dayanımı*
6	>250 N
5	>150 N
4	>100 N
3	>50 N
2	>10 N
1	>5N

ESNETME İLE OLUŞAN HASARA KARŞI DİRENCİN TAYİNİ METOT C (BÜKÜLME /ESNEKLİK TESTİ) Madde 4.5

Test Metodu : ISO 7854 :1995 Kauçuk veya Plastik Kaplı Kumaşlar – Esnetme ile oluşan hasara karşı direncin tayini Metot C (Bükülme /Esneklik Test) (*)
220 mm boy x 190 mm en ebatlarında 2 numune hazırlanır.
Devir tamamlanınca varsa hasar tespit edilir ve sınıflandırma Tablo 2 ye göre yapılır.

SONUÇ

>40.000 devir

Hasar gözlenmemiştir.

SINIF

Sınıf 5
Tablo-2' e göre yapılır

Tablo-2 Bükülme ve Esneklik Direncinin Sınıflandırılması

Sınıf	Devir Sayısı
6	> 100 000
5	>40 000
4	> 15 000
3	> 5 000
2	> 2 500
1	> 1000

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TEST SONUÇLARI

Test Metodu: BS EN 22610:2006 (Hastalar, hastane personeli ve donanım için tıbbi cihaz olarak kullanılan cerrahi örtüler, giysiler ve temiz hava giysileri - Islak bakteriyel geçirgenliğe olan direncin tayini için deney yöntemi)
Dönen bir disk üzerindeki agar plakasına bir test örneği konur. Test örneğinin üzerine bakteri taşıyıcı materyali ve kaplama filmi yerleştirilir ve bütün parçalar disk üzerinde sabitlenir. Test örneğine belirli bir kuvvet (3N ±0,02) uygulamak üzere bir parmak yerleştirilir. Parmak, 15 dakika içinde agarın tüm yüzeyi boyunca test örneği üzerinde hareket eder. 15 dakikalık 5 çalışma yapılır. 6. çalışma numune ters çevrilerek tekrarlanır.

Numune miktarı :	5 adet 25x25cm^2
Taşıyıcı Materyal:	30 µm inceliğinde , 25x25cm^2 Poliüretan Film
Kaplama Materyali:	25x25cm^2 HDPE Film
Mikroorganizma:	Staphylococcus aureus ATCC 29213
Bakteri Konsantrasyonu (kob/ml) :	1-4x10^4 kob/ml
İnkübasyon Koşulları:	(36±1)°C 48 saat

SONUÇLAR				
Nüfus Etme Zamanı (min)	**Nüfus Eden Bakteri Sayısı (cfu)**		**Nüfus Etme Oranı**	
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 : Aynı numunedeki 5 paralel petride üreyen koloni sayısı
Z : altıncı petride üreyen koloni sayısı

T: X1 + X2 + X3 + X4 + X5
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

DEĞERLENDİRME

Sonuç	Sınıf
$30 < t \leq 45$	3

** EN 14126 :2003 Koruyucu Giysi – Enfekte Edici Ajanlara Karşı Koruyuc Giysilerin Performans Özellikleri ve Test Metotları Tablo-2'e göre değerlendirilmiştir.*

Sınıf	Nüfus Etme Zamanı t (min)
6	$t > 75$
5	$60 < t \leq 75$
4	$45 < t \leq 60$
3	$30 < t \leq 45$
2	$15 < t \leq 30$
1	≤ 15 min

ANALYSIS REPORT

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

Applicant : UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİC. 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

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
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

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08/07/2020
Ömer Yasin BALIK
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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

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Assistant Laboratory Responsible of Microbiology Laboratory

Approved by
08/07/2020
Ömer Yasin BALIK
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 B□RAH
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 / □stanbul

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

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

AB-0583-T
20028903-ing
08-20

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	Yukarı Dudullu Mahallesi, KEYAP E2 No:84, 34775 Dudullu Organize Sanayi Bölgesi/Ümraniye/İstanbul
Buyer name:	YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ
Contact Person:	SUAT KAÇMAZ
Order No:	
Article No:	
Name and identity of test item:	White boot covers.
The date of receipt of test item:	17.08.2020
Re-submitted/re-confirmation date:	-
Date of test:	17.08.2020-21.08.2020
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:	3

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 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.

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
TESTED BY EKOTEKS TESTING LIMITED	24.08.2020	Servin KURTSEVEN	Sevim A. RAZAK 24.08.2020

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Seam Strength	-	Class 2

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

Tests were classified according to BS EN 14325:2018
BS EN 14126 :2003 Protective clothing —Performance requirements and tests methods for protective clothing against infective agents

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.

AB-0583-T
20028903-ing
08-20

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
Single seam	90.9 N	FTJ	2 Classified according to the Table-13
Single seam	58.2 N	STB	
Single seam	97.1 N	FTJ	
Single seam	113.1 N	FTJ	
Average (Single seam)	89.8 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

Gen.f136-2/03

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

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

AB-0583-T
20030503-ing
08-20

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	Yukarı Dudullu Mahallesi, KEYAP E2 No:84, 34775 Dudullu Organize Sanayi Bölgesi/Ümraniye/İstanbul
Buyer name:	YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ
Contact Person:	SUAT KAÇMAZ
Order No:	
Article No:	
Name and identity of test item:	White armband.
The date of receipt of test item:	17.08.2020
Re-submitted/re-confirmation date:	-
Date of test:	17.08.2020-21.08.2020
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:	3

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 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.

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
TESTED BY EKOTEKS	25.08.2020	Servin YURTSEVEN	Sevim A. RAZAK 25.08.2020

Gen.f136-2/03

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Seam Strength	-	Class 3

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

Tests were classified according to BS EN 14325:2018
BS EN 14126 :2003 Protective clothing —Performance requirements and tests methods for protective clothing against infective agents

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.

AB-0583-T
20030503-ing
08-20

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
Sleeve seam	103.5 N	FTJ	3 Classified according to the Table-13
Sleeve seam	90.8 N	FTJ	
Sleeve seam	87.0 N	FTJ	
Average	93.8 N	FTJ	

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

Gen.f136-2/03

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

TEST REPORT
DENEY RAPORU

20024114
07-20

Müşterinin adı:	YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Adresi:	Selimpaşa Mah. 5001. Sokak No:6 SİLİVRİ/ İSTANBUL
Alıcı firma:	-
İlgili kişi:	GÜRSEL ÖZCANLI
İstek numarası:	-
Model numarası:	-
Numunenin adı ve tarifi:	Kaplamalı beyaz bone. (Müşteri tarafından belirtilmiştir; Lamineli Tek Kullanımlık Bone; Ürün kodu: CP 0045)
Numunenin kabul tarihi:	08.07.2020
İlave numune ve/veya ilave bilgi geliş tarihi:	22.07.2020
Deneyin yapıldığı tarih:	22.07.2020-28.07.2020
Açıklamalar:	-
Numune alımı:	Bu raporda verilen sonuçlar müşteri tarafından gönderilen numuneye aittir.
Numunenin son kullanımı:	-
Yıkama talimatı:	Belirtilmedi.
Raporun sayfa sayısı:	10

Mühür	*Tarih*	*Müşteri Temsilcisi*	*Laboratuvar Müdürü*
TESTED BY EKOTEKS TESTEDİLMİŞTİR	29.07.2020	Özlem [illegible]	Sevim A. RAZAK

İSTENEN TESTLER	SONUÇ	AÇIKLAMA
FİZİKSEL TESTLER		
Aşınma	-	Sınıf 6
Su Geçirgenliği	-	Sınıf 6
Yırtılma Mukavemeti	-	Sınıf 1
Kopma Mukavemeti	-	Sınıf 1
Sıvılara Karşı İticilik	-	Sınıf 3
Sıvıların Nüfus Etmesine Karşı Direnci	-	Sonuçlara bakınız
Dikiş Mukavemeti	-	Sınıf 3
Delinme Dayanımı	-	Sınıf 1
Esnetme ile oluşan hasara karşı direncin Tayini	-	Sınıf 3
MİKROBİYOLOJİ TESTLERİ		
Islak-Bakteri Penetrasyonu	-	Sınıf 6
Kuru-Bakteri Penetrasyonu	-	Sınıf 3
Kan ve Vücut Sıvılarının Nüfuz Etmesine Karşı Direncin Tayini	P	

P:Geçer
F:Kalır
R: Alıcı firmanın teknik kişisine başvurunuz.
Test sonuçları BS EN 14325:2018 limit değerlerine göre değerlendirilmiştir.
(Referans Standart BS EN 14126 :2003 Enfekte Edici Ajanlara Karşı Koruyucu Giyecekler –Performans Özellikleri ve Deney Metotları)

NOT: Aksi belirtilmediği taktirde testler ile ilgili kayıtlar 5 yıl, orjinal numuneler 3 ay saklanır. Müşteri tarafından talep edildiğinde, testlere ait ölçüm belirsizliği raporlanır fakat "Geçer/Kalır" değerlendirmesinde ölçüm belirsizliği değeri dikkate alınmaz. Raporlanan belirsizlik, genişletilmiş belirsizlik olup standart belirsizlik kapsam faktörü k=2 kullanılarak elde edilmiştir. Güvenilirlik düzeyi % 95'tir. Bu raporda (*) işaretli deneyler akreditasyon kapsamına dahil değildir.

TEST SONUÇLARI

Test Metodu: BS EN 14325:2018 (KIMYASALLARA KARŞI KORUYUCU GİYSİLER- KIMYASAL KORUYUCU GİYSİ MALZEMELERİNİN, DİKİŞLERIN VE BIRLEŞTIRICI MALZEMELERİN PERFORMANS SINIFLANDIRILMASI VE TEST METOTLARI) (*)

AŞINMA DAYANIMI ve SIZDIRMAZLIK

Madde 4.4.Aşınma Dayanımı (EN ISO 12947-2) EK-B

Lissajous deseni oluşturan Martindale Test Cihazı (47.5±2 rpm)
9 kPa basınç, (595±7) g kütle.
Kondüsyon şartlarında test edilmiştir.(20±2°C-65%±4)

SONUÇ	SINIF
Aşınmadı @ 2.000 devir	6 Tablo-1 'e gore yapılır

Malzemeye zarar vermeyen en yüksek aşınma devri Tablo-1 e göre tayin edilir.
Aşınma Dayanımının Sınıflandırılması (Tablo-1)

Sınıf	*Devir Sayısı*
6	>2000
5	>1000
4	>400
3	>100
2	>40
1	>10

Madde 4.4.2.3 Su geçirmezlik tayini hidrostatik basınç metodu (EN 20811)
Orijinal numune (aşındırılmamış) test sonucu > 200 mmSS olmalıdır.Bunu sağlarsa madde 4.4'e göre en yüksek devirde bulunan numuneye EN 20811 uygulanır.

SU GEÇİRGENLİĞİ; EN ISO 811:2018

Hidrostatik Başlık Cihazı, Textest marka Fx 3000 model
Su sıcaklığı 10 .°C. Basınç artış oranı 10 mbar/dk.
Kondüsyonlu ortamda test edilmiştir. (20±2°C-65%±4).

	SONUÇ	İSTENEN
Numune 1	387.6 mm SS	>200 mmSS
Numune 2	357.0 mm SS	
Numune 3	492.3 mm SS	
Numune 4	374.3 mm SS	
Numune 5	362.1 mm SS	
Ortalama	394.7 mm SS	

TEST SONUÇLARI

YIRTILMA MUKAVEMETİ;
Madde 4.7.Trapezoidal Yırtılma Dayanımı TS EN ISO 9073-4:2002(*)
Instron 4411 Hız: 100 mm/dk±10, Çene mesafesi 5 cm.
En boy yönlerinde 4 adet sonucun ortalaması verilmiştir.
2N Ön gerilim uygulanmıştır.
Kondüsyon şartlarında test edilmiştir. (20±2°C - %65±4)

	SONUÇ	SINIF
EN	16.5 N	1
BOY	41.7 N	Tablo-4 'e gore yapılır

Yırtılma Dayanımının Sınıflandırılması (Tablo-4)

Sınıf	*Yırtılma Mukavemeti*
6	>150 N
5	>100 N
4	>60 N
3	>40 N
2	>20 N
1	>10 N

KOPMA MUKAVEMETİ;
Madde 4.9.Kopma Mukavemeti EN ISO 13934-1:2013
Hız: 100 mm/dk±10, Çene mesafesi 200 mm.
Ön gerilme uygulanmamıştır. Islatma işlemi yapılmamıştır.
En ve Boy yönlerinde 4 adet sonucun ortalaması verilmiştir.
Kondüsyon şartlarında test edilmiştir. (20±2°C - %65±4)

	SONUÇ	SINIF
En	37.8 N	1
Boy	39.5 N	Tablo-5 'e gore yapılır

Kopma Mukavemeti Sınıflandırılması (Tablo-5)

Class	Kopma Mukavemeti
6	>1000 N
5	>500 N
4	>250 N
3	>100 N
2	>60 N
1	>30N

TEST SONUÇLARI
SIVILARA KARŞI İTİCİLİK ÖZELLİĞİ

Madde 4.12 Sıvılara Karşı İticilik (EN ISO 6530:2005)

Sıvı dayanımı Tablo-9 da verilen sıvı kimyasallar yada genel amaçlı bir izlenimi görmek için test sıvısı olarak su da kullanılabilir.
Kondüsyon şartlarında test edilmiştir. (20±2°C - %65±4)
Test edilecek herbir kimyasal sıvıya dayanımı ölçmek için 3 en, 3 boy numune (360±2)mm x (235±5)mm alınmıştır.
Analitik saflıkta kimyaal kullanılmıştır.Test sıvısı (10cm ^{3}) . (10±1)s de numune yüzeyinden geçirilmiştir. Bkz Tablo-9
Sonuç Değerlendirmesi Tablo-10 ve tbalo-11'e göre yapılmıştır.

Absorbsiyon,Penetrasyon (nüfuz etme) ve iticilik testlerinde kullanılan kimyasallar (Tablo-9)

Kimyasal	*Kimyasal Marka*	*% Konsantrasyon*	*Sıcaklık (±2°C)*
Sülfürik Asit (H2SO4)		*30*	*20*
Sodyum Hidroksit(NaOH)		*10*	*20*
o-Xylene		*Seyreltik değil*	*20*

Sıvı İticiliğinin Sınıflandırılması (Tablo-10)

Sınıf	*İticilik İndeksi (IR)*
3	*> 90 %*
2	*>80 %*
1	*>70 %*

Madde 4.13 Sıvıların Nüfus Etmesine Karşı Direnci (EN ISO 6530)

Sıvılara Karşı Nüfus Etme Direncinin Sınıflandırılması (Tablo-11)

Sınıf	*Nüfus Etme İndeksi (Ip)*
3	< 1 %
2	< 5 %
1	<10 %

SONUÇ

Kimyasal	*%Konsantrasyon*	I_P	*Sınıf*	I_R	*Sınıf*
Sülfürik Asit (H2SO4)	30	0 %	3	92.3%	3
Sodyum Hidroksit (NaOH)	10	0 %	3	95.7%	3
o-Xylene	Seyreltik değil	0%	3	67.6%	-

I_P *:Penetrasyon İndeksi*
I_R *:* İticilik İndeksi

TEST SONUÇLARI

DİKİŞ MUKAVEMETİ-GRAB METOT ;
Madde 5.5 Dikiş Mukavemeti ISO 13935-2: 2014
NSTRON 5969
Hız: 50±5 mm/dk, Çene Aralığı: 100 ±1 mm
5kN yük uygulanmıştır.
Kondüsyon şartlarında test edilmiştir.(20±2°C-65%±4)

	Dikiş Mukavemeti (N)	Hata	SINIFLANDIRMA
	80.8	FTS	Sınıf 3 Tablo-13 'e gore yapılır

FTS: Kumaşta dikiş kopması.

Dikiş Mukavemeti Sınıflandırılması (Tablo-13)

SINIF	*Dikiş Mukavemeti*
6	*>500 N*
5	*>300 N*
4	*>125 N*
3	*>75 N*
2	*>50 N*
1	*>30 N*

TEST SONUÇLARI

DELİNME DAYANIMI

Madde 4.10.Delinme Dayanımı EN 863 :1995 (*)

SONUÇ	SINIF
7.4 N	1 Tablo-6 'ya göre yapılır

Delinme Dayanımının Sınıflandırılması (Tablo-6)

Sınıf	*Delinme Dayanımı*
6	>250 N
5	>150 N
4	>100 N
3	>50 N
2	>10 N
1	>5N

ESNETME İLE OLUŞAN HASARA KARŞI DİRENCİN TAYİNİ METOT C (BÜKÜLME /ESNEKLİK TESTİ) (*)

Test Metodu : ISO 7854 :1995 Kauçuk veya Plastik Kaplı Kumaşlar – Esnetme ile oluşan hasara karşı direncin tayini Metot C (Bükülme /Esneklik Test) (*)
220 mm boy x 190 mm en ebatlarında 2 numune hazırlanır.
Devir tamamlanınca varsa hasar tespit edilir ve sınıflandırma Tablo 2 ye göre yapılır.
Tablo-2 Bükülme ve Esneklik Direncinin Sınıflandırılması

SONUÇ	SINIF
8.000 devir	Sınıf 3 Tablo-2' e göre yapılır

Hasar gözlenmemiştir.

Tablo 2

Sınıf	Devir Sayısı
6	> 100 000
5	>40 000
4	> 15 000
3	> 5 000
2	> 2 500
1	> 1000

TEST RESULTS

Test Metodu: BS EN 22610:2006 (Hastalar, hastane personeli ve donanım için tıbbi cihaz olarak kullanılan cerrahi örtüler, giysiler ve temiz hava giysileri - Islak bakteriyel geçirgenliğe olan direncin tayini için deney yöntemi) (*)
Dönen bir disk üzerindeki agar plakasına bir test örneği konur. Test örneğinin üzerine bakteri taşıyıcı materyali ve kaplama filmi yerleştirilir ve bütün parçalar disk üzerinde sabitlenir. Test örneğine belirli bir kuvvet (3N ±0,02) uygulamak üzere bir parmak yerleştirilir. Parmak, 15 dakika içinde agarın tüm yüzeyi boyunca test örneği üzerinde hareket eder. 15 dakikalık 5 çalışma yapılır. 6. çalışma numune ters çevrilerek tekrarlanır.

Numune miktarı :	5 adet 25x25cm^2
Taşıyıcı Materyal:	30 µm inceliğinde , 25x25cm^2 Poliüretan Film
Kaplama Materyali:	25x25cm^2 HDPE Film
Mikroorganizma:	Staphylococcus aureus ATCC 29213
Bakteri Konsantrasyonu (kob/ml) :	1-4x10^4 kob/ml
İnkübasyon Koşulları:	(36±1)°C 48 saat

SONUÇLAR				
Nüfus Etme Zamanı (min)	**Nüfus Eden Bakteri Sayısı (cfu)**		**Nüfus Etme Oranı**	
15	X_1	0	R_{CUM1}	0
30	X_2	0	R_{CUM2}	0
45	X_3	0	R_{CUM3}	0
60	X_4	0	R_{CUM4}	0
75	X_5	0	R_{CUM5}	0
	Z	389		
	T	389		

X_1 ..... X_5 : Aynı numunedeki 5 paralel petride üreyen koloni sayısı
Z : altıncı petride üreyen koloni sayısı
T: $X_1 + X_2 + X_3 + X_4 + X_5$
$R_{CUM1} = X1/T$
$R_{CUM2} = (X2 + X1)/T$
$R_{CUM3} = (X3 + X2 + X1)/T$
$R_{CUM4} = (X4 + X3 + X2 + X1)/T$
$R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T$

DEĞERLENDİRME	
Sonuç	**Sınıf**
t > 75	*6*

** EN 14126 :2003 Koruyucu Giysi – Enfekte Edici Ajanlara Karşı Koruyuc Giysilerin Performans Özellikleri ve Test Metotları Tablo-2'e göre değerlendirilmiştir.*

Sınıf	**Nüfus Etme Zamanı t (min)**
6	*t* > 75
5	60 < *t* ≤ 75
4	45 < *t* ≤ 60
3	30 < *t* ≤ 45
2	15 < *t* ≤ 30
1	≤ 15 min

TEST SONUÇLARI

Numune miktarı:	6 adet 20x20 cm^2
Mikroorganizma:	*Bacillus subtilis ATCC 9372*
Bakteri Konsantrasyonu (kob/ml):	$1x10^8$
İnkübasyon Koşulları:	35°C / 24 saat

SONUÇLAR	
Nüfuz Eden Bakteri Sayısı (kob)	
1	0
2	0
3	1
4	0
5	0
6 (Kontrol)	0
Toplam	1
Logaritma	0

DEĞERLENDİRME	
Sonuç	**Sınıf**
< 1	3

** EN 14126 :2003 Koruyucu Giysi– Enfekte Edici Ajanlara Karşı Koruyucu Giysilerin Performans Özellikleri ve Test MetotlarıTablo-4'e göre değerlendirilmiştir.*

Sınıf	**Penetrasyon (log kob)**
3	≤ 1
2	1 < log kob ≤ 2
1	2 < log kob ≤ 3

**EN 13795:2011 Cerrahi giysiler ve örtüler – Gereklilikler ve Deney Yöntemleri Bölüm 1: Cerrahi Örtüler ve önlükler Tablo 1'e göre değerlendirilmiştir.*

SONUÇ	
Sonuç (kob/gr)	**Beklenen Değer**
1	≤300 kob/gr

Standart Adı: ISO 22612 : 2005 (Enfeksiyöz ajanlara karşı koruyucu giysiler - Kuru mikrobiyal penetrasyona karşı direnç için test yöntemi)

Numuneler ve konteynerler steril edilir. Her bir konteynere agar plakaları konulur. Numuneler aseptik bir şekilde aparata yerleştirilir. Kapaklar kapatılır. Piston ile numunede bir potluk yapıldıktan sonra pistonlar çıkarılır ve beş adet numuneye bakteri ile kontamine edilmiş pudradan, altıncıya ise kontamine olmamış pudradan kontrol olarak 0,5 g ± 0,1 g eklenir. Ardından tüm açıklıklar plastik bir poşetle kapatılır. Dakikada 20.800 titreşim verecek şekilde cihaz çalıştırılır. Test süresi 30 dakikadır. Test bittikten sonra tüm agar plakaları 35°C'de 24 saat inkübe edilir.

20024114
07-20

TEST SONUÇLARI

KAN VE VÜCUT SIVILARININ NÜFUZ ETMESİNE KARŞI DİRENCİN TAYİNİ-SENTETİK KAN KULLANILARAK; ISO 16603:2004 (*)					
Textest, FX 3000-IV model + Dahili Kan Hücresi Test numuneleri test öncesi % 60±10 relatif nemde ve 21±5°C sıcaklıkta en az 24 saat kondüsyonlanmıştır.					
Uygulanan Test Prosedürü:	A prosedürü				
Basınç (kPa)	**Zaman (Dakika)**	**Test Sonucu**			**Genel Değerlendirme**
		Test 1	**Test 2**	**Test 3**	
0	5	Geçer	Geçer	Geçer	GEÇER
14	1	Geçer	Geçer	Geçer	
0	4	Geçer	Geçer	Geçer	
Test edilen malzemenin kalınlığı (mm) :	0.4				
Test edilen malzemenin gramajı (g/m^2) :	5.9				

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

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 B□RAH
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 / □stanbul

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 B□RAH
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 / □stanbul

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TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 31.08.2020 / 2163-KKD-1390/R1

This report is re-issued on 10.09.2020 with addition of 2 models (PB 0065 OverShoe Taped and SC 0065 OverSleeve seamless). The details of the report for PB 0060 and SC 0060 remains same.

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

Introduction

This report is prepared based on the evaluations on the technical file of the manufacturer dated 05.09.2020 version 1, 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 manufacturer have different PPE products made of same fabrics (Type 5, 6 Coveralls) and the common fabric tests are not repeated for each PPE or PPE model which are manufactured from the same fabric, which is guaranteed by the manufacturer in the technical file, the use of same fabric. The fabric mechanical strength tests were conducted for the BIOBLOCKED PS 5657 coverall model and used as a reference for PB 0060 model OverShoe / Boot Cover and SC 0060 Over Sleeve as well. The fabrics and seam technology are claimed to be identically same by the manufacturer. The seams on the OverShoe and OverSleeve products re-evaluated by the laboratory for their strength. The manufacturer also have models PB 0065 OverShoe Taped (same model of PB 0060 OverShoe where seams are covered with hotmelt tape) and SC 0065 OverSleeve (same model of SC 0060 OverSleeve where ultrasonic welding is used instead over lock sewing). The evaluated design and other properties remains same of the OverShoes and OverSleeves. These products considered as complementary PPEs for use with other clothing PPE products. 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 OverShoes and OverSleeves, as a protective clothing for the part of body Type PB-[6]-B, manufactured from white laminated polypropylene non-woven fabric, inside over lock seams (OverShoe taped models have hotmelt tape on seams, and sealmless OverSleeve models have ultrasonic sewing on side instead) and elastic under knee, wrist, shoulder parts. The The PPEs are available in 1 size.

The PPE fabric is 57gsm, breathable PE film (35gsm) + 2 gsm glue + SS (20gsm) white PP. Belt is same fabric.
Protective Clothing Type: Type PB [6]-B
Brand Name: BIOBLOCKED
Models: OverShoe - PB 0060, OverSleeve - SC 0060, OverShoe Taped - PB 0065, OverSleeve Seamless - SC 0065.
Sizes Available: Available only one size (to fit all)

Applied Harmonised Standards

EN ISO 13688:2013, (General requirements for protective clothing)
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing.
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB[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 18.08.2020 Number: 20018044-Add-RER	Holds TURKAK Accreditation with No: AB-0583-T
2	Ekoteks Laboratuar ve Gözetim Hizmetleri A.Ş.	Dated 24.08.2020 Number: 20028903-Ing	Holds TURKAK Accreditation with No: AB-0583-T
3	Ekoteks Laboratuar ve Gözetim Hizmetleri A.Ş.	Dated 25.08.2020 Number: 20030503-Ing	Holds TURKAK Accreditation with No: AB-0583-T
4	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.			

UNİVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Kavşak Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

UNIVERSAL
CERTIFICATION

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.

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Kuyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T: +90 216 455 80 80 F: +90 216 455 80 08 info@universalcert.com

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. 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 in practical examination.
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 OverShoe (BootCover) is available only one sizes. The given sizes are expected to fit all sizes depending on the shoe worn by the user. Under normal conditions the product is expected to fit on regular shoes or safety shoes available on the market. Ref: Technical File Sizes section.
Article 7	EHSR Ref 2.12: Each piece of OverShoe and OverSleeve have marking with the following information: • Name / trademark of the manufacturer, type of product • Applied product standards (Type defining product standards) • Applied protection pictograms with standard references The markings on the product / 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 • OverShoe 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 SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Kayışı Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/64 Y. Dudullu - Ümraniye - İSTANBUL T: +90 216 455 80 80 F: +90 216 455 80 08 info@universalcert.com

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CERTIFICATION

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 SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Kavşak Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - 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.

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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 OverShoe and OverSleeve material performance are tested according to EN 14325:2018 standard for the following properties, since OverShoe and OverSleeve 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 %30 concentration) I_R > 90 %	Class 3	Class 3 at least for 1 chemical	Success
4.10 Resistance to penetration by liquids	Sulfuric Acid (H2SO4 %30 concentration) Sudium Hydroxide (NaOH %10 concentration) o-Xylene (Non diluted) I_P < 1 %	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 OverShoe and OverSleeve 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 OverShoe and OverSleeve in penetration of liquid through stitch holes or through other components of a seam are evaluated in the seam strength and resistance to penetration by chemicals.

The seam strength is evaluated based on the test report as shown below; Hence the seam strength value is selected among the smallest strength among constructive seams as stated corresponding clause of this standard.

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 the OverShoe and OverSleeve. The lowest Class is given among constructive kinds of seams	Class 2 Class 3	Class 1 or above	Success
4.10 Resistance to penetration by liquids	Sulfuric Acid (H2SO4 %30 concentration) I_P < 1 %	Class 3	Class 3 at least for 1 chemical	Success

Ref: Laboratory Test Report 2 and 3

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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 for the OverShoe and OverSleeve with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report. The OverShoe and OverSleeve under evaluation is a one piece part of body clothing. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested with subjects and found to be appropriate. Since the PPE is part of body clothing, the mist test is not conducted according to Clause 5.2. The results of tested same fabric indicates that the tested OverShoe and OverSleeve, made of same fabric, complies with the resistance to penetration by liquids. Ref: Laboratory Test Report 1
Article 6	EHSR Ref 2.12: Each piece of OverShoe and OverSleeve have marking with the following information on the single PPE package / PPE itself: • Name / trademark of the manufacturer, type and model of PPE • 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, OverShoe and OverSleeve, 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 (Type PB [6]). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e coveralls, boots, gloves, mask and visor / face shield etc.). • The standard code / name with the published year • The statement that the OverShoe and OverSleeve 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 and English 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	
	EHSR Ref 1.3.2;
Article 4.1.2	The OverShoe and OverSleeve material performance are tested according to EN 14325:2018 standard for the relevant properties required by the Type defining standards for protective clothing. The OverShoe and OverSleeve under evaluation claims compliance with Type PB [6]. The required mechanical and flammability performance levels are evaluated in the corresponding clauses of EN ISO 13034 standard within this report. No further evaluation is necessary for this standard.
	EHSR Ref 1.1.2.2, 3.10.2;
	Evaluation of the performance requirements against penetration by infactive agents; The OverShoe and OverSleeve 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 OverShoe and OverSleeve 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 OverShoe and OverSleeve 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 OverShoe and OverSleeve 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.
Article 4.1.4	The OverShoe and OverSleeve 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 is 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 2

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EN 14126:2003 + AC:2004 Standard Requirements Evaluation

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 EN 14126
5.5 Seam Strength	Refer to the strength values for seams at different parts of OverShoe and OverSleeve. The lowest Class is given among all kinds of seams	Class 2 Class 3	To be Classified

Article 4.2

Ref: Laboratory Test Report 2 and 3

EHSR Ref 1.3.1, 3.10.2:

Article 4.3

The PPE under evaluation conforms the relevant requirements of EN ISO 13688 standard. The requirements of the OverShoe and OverSleeve with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.

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 OverShoe and OverSleeve 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 PB [6]-B
- the pictogram "protection against biological hazard"

Article 5

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.

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;

Article 6

- Name / trademark of the manufacturer, its address, or the authorised representative for EU community
- Type of protection against chemicals (Type PB [6]-B). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e coveralls, boots, gloves, mask and visor / face shield).
- The standard number (EN 14126)

EN 14126:2003 + AC:2004 Standard Requirements Evaluation

- 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 and English
Ref Technical File, User Information Sheet

PPE Experts contributed to this report:

Arzu ŞEREMETLİ

Osman CAMCI

Approval
Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 14.09.2020 / 2163-KKD-1445

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

Introduction

This report is prepared based on the evaluations on the technical file of the manufacturer dated 05.09.2020 version 1, 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 manufacturer have different PPE products made of same fabrics (Type 5, 6 Coveralls) and the common fabric tests are not repeated for each PPE or PPE model which are manufactured from the same fabric, which is guaranteed by the manufacturer in the technical file, the use of same fabric. Some of the tests (minority of tests) tests were conducted for the BIOBLOCKED PS 5657 coverall model used as a reference for CP 0045 model Bouffant Cap as well. These products considered as complementary PPEs for use with other clothing PPE products. 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 bouffant cap, as a protective clothing for the part of body Type PB-[6]-B, manufactured from white laminated polypropylene non-woven fabric, inside over lock seams and elastic around head with latex free. The PPE is available in 1 standard size.

The PPE fabric is 57gsm, breathable PE film (35gsm) + 2 gsm glue + SS (20gsm) white PP. Belt is same fabric.

Protective Clothing Type: Type PB [6]-B

Brand Name: BIOBLOCKED

Models: Bouffant Cap - CP 0045.

Sizes Available: Available only one size (to fit all)

Applied Harmonised Standards

EN ISO 13688:2013, (General requirements for protective clothing)

EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing,

EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB[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 29.07.2020 Number: 20024114	Holds TURKAK Accreditation with No: AB-0583-T
4	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. 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 and the PPE is reported as to be comfortable enough to allow the wearer to move comfortably without any vision problem as well.
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 Bouffant Cap is available only one sizes. The given sizes are expected to fit all sizes depending on the shoe worn by the user. Under normal conditions the product is expected to fit everybody. Ref: Technical File Sizes section.
Article 7	EHSR Ref 2.12: Each piece of Bouffant Cap have marking with the following information: • Name / trademark of the manufacturer, type of product • Applied product standards (Type defining product standards) • Applied protection pictograms with standard references The markings on the product / 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 • Bouffant Cap 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.

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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.

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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.

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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

EHSR Ref 1.2.1, 1.2.1.1, 1.3.2, 3.10.2;

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

Article 4.1

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 16.5 N Length 41.7 N	Class 1	Class 1 or above	Success
4.9 Tensile Strength	W 37.8 N L 39.5 N	Class 1	Class 1 or above	Success
4.10 Puncture Resistance	7.4 N	Class 1	Class 1 or above	Success
4.12 Liquid repellency	Sulfuric Acid (H_2SO_4 %30 concentration) Sudium Hydroxide (NaOH %10 concentration) $I_R > 90$ %	Class 3	Class 3 at least for 1 chemical	Success
4.10 Resistance to penetration by liquids	Sulfuric Acid (H2SO4 %30 concentration) Sudium Hydroxide (NaOH %10 concentration) o-Xylene (Non diluted) $I_P < 1$ %	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 Bouffant Cap 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

EHSR Ref 1.3.2, 3.10.2;

The affects of seams to the performance of the Bouffant Cap in penetration of liquid through stitch holes or through other components of a seam are evaluated in the seam strength and resistance to penetration by chemicals.

The seam strength is evaluated based on the test report as shown below; Hence the seam strength value is selected among the smallest strength among constructive seams as stated corresponding clause of this standard.

Article 4.2

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 the Bouffant Cap. The lowest Class is given among constructive kinds of seams	Class 3	Class 1 or above	Success

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EN ISO 13034:2005 + A1:2009 Standard Requirements Evaluation				
4.10 Resistance to penetration by liquids	Sulfuric Acid (H_2SO_4 %30 concentration) Sudium Hydroxide (NaOH %10 concentration) $I_R > 90$ %	Class 3	Class 3 at least for 1 chemical	Success

Ref: Laboratory Test Report 2 and 3

EHSR Ref 1.2.1.3, 2.4, 3.10.2:

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

The Bouffant Cap under evaluation is a one piece part of body clothing. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested with subjects and found to be appropriate.

Article 5.1.5.2

Since the PPE is part of body clothing, the mist test is not conducted according to Clause 5.2.

The results of tested same fabric indicates that the tested Bouffant Cap, made of same fabric, complies with the resistance to penetration by liquids.

Ref: Laboratory Test Report 1

EHSR Ref 2.12:

Each piece of Bouffant Cap have marking with the following information on the single PPE package / PPE itself;

- Name / trademark of the manufacturer, type and model of PPE
- 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

Article 6

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, Bouffant Cap, is for single use, the markings for re-use cleaning or disinfection is discarded.

Ref: Technical File PPE Marking section.

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 (Type PB [6]). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e coveralls, boots, gloves, mask and visor / face shield etc.).
- The standard code / name with the published year
- The statement that the Bouffant Cap 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

Article 7

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EN ISO 13034:2005 + A1:2009 Standard Requirements Evaluation

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 and English

Ref Technical File, User Information Sheet

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UNIVERSAL
CERTIFICATION

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

EHSR Ref 1.3.2:

Article 4.1.2

The Bouffant Cap material performance are tested according to EN 14325:2018 standard for the relevant properties required by the Type defining standards for protective clothing. The Bouffant Cap under evaluation claims compliance with Type PB [6]. The required mechanical and flammability performance levels are evaluated in the corresponding clauses of EN ISO 13034 standard within this report. No further evaluation is necessary for this standard.

EHSR Ref 1.1.2.2, 3.10.2:

Evaluation of the performance requirements against penetration by infactive agents:

The Bouffant Cap 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 Bouffant Cap 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 Bouffant Cap 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 Bouffant Cap 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 75 minutes and classified as **Class 6** 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.

Article 4.1.4

The Bouffant Cap 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 is 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 > 75 min	Class 6	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 2

EN 14126:2003 + AC:2004 Standard Requirements Evaluation

EHSR Ref 1.3.2:

The seam strength is evaluated and classified based on the test report as shown below:

Article 4.2

Property of Material EN 14325:2018	Result Classification		Requirement of EN EN 14126
5.5 Seam Strength	Refer to the strength values for seams at different parts of Bouffant Cap. The lowest Class is given among all kinds of seams	Class 3	To be Classified

Ref: Laboratory Test Report 2 and 3

EHSR Ref 1.3.1, 3.10.2:

Article 4.3

The PPE under evaluation conforms the relevant requirements of EN ISO 13688 standard. The requirements of the Bouffant Cap with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.

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 Bouffant Cap have marking with the following information on the single PPE package / PPE itself:

Article 5

- Applied product standards (EN 14126:2003+AC:2004)
- Type marking of the PPE as Type PB [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.

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;

Article 6

- Name / trademark of the manufacturer, its address, or the authorised representative for EU community
- Type of protection against chemicals (Type PB [6]-B). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e coveralls, boots, gloves, mask and visor / face shield).
- The standard number (EN 14126)
- The performance levels identified with the tests against infactive agents

EN 14126:2003 + AC:2004 Standard Requirements Evaluation

- 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 and English
Ref Technical File, User Information Sheet

PPE Experts contributed to this report:

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Approval
Suat KAÇMAZ
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 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-06**), 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".

PREPARED BY		APPROVED BY
Production Control Representative SABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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; is prepared as a part of the system used to evaluate the conformity of standards

- EN 14126/AC:2004 Protective Clothing - Against Pathogenic Organisms
- EN 13034: 2005 + A1: 2009 Protective Clothing Against Liquid Chemical Substances - Performance Rules for Protective Clothing Providing Limited Protection Against Liquid Chemical Substances (Type PB [6] - B 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.

Basic Requirements of the European Union Directive 2016/425 / EU:

8.1. Medical devices and manufacturing processes should be designed in such a way that the infection risk of the patient, practitioner and third parties is eliminated or reduced as much as possible. The design should be easy to implement and, if necessary, minimize contamination of the patient from the medical device or from the patient during use.

- **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
EN ISO 13688	Protective Clothing - General Features
EN 14126	Protective Clothing - Against Pathogenic Organisms - Performance Properties and Test Methods
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)
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

3. Product Information

3.1 Product Description

Protective Clothing (Overshoes, Oversleeves, Bones) that we manufacture have a suitable microbial barrier, which aims to limit the transmission of infective agents between personnel and patients during surgical procedures and in other medical environments with similar requirements. It can be effective in reducing the spread of infective agents in asymptomatic carrier or patient with clinical symptoms, our company produces Protective Clothing with these features in a high quality and hygienic environment.

2 Brand Name: BIOBLOCKED

3.3 Product Model No:

PB 0060 Overshoe Long - Laminated
SC 0060 Protective Oversleeve - Laminated
CP 0045 Bouffant Cap - Laminated
PB 0065 Overshoe Taped - Long
SC 0065 Protective Oversleeve - Seamless

3.4 Product Dimension: Tek Beden

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	FABRIC	Laminated Fabric 57 gr	Pelsan Tekstil
2	SEWING THREAD		COATS
3	PACKING MATERIAL - BAG	Coast 120 Number Yarn	DEKA PLASTİK
4	PARCEL		MERCAN AMBALAJ
5	RUBBER	PRINTED BAG	SANCAK ÖRME
6	Wigan Non-Slip Fabric	KSSK QUALITY	Mahmut Tekstil
7	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 Essential Health and Safety Requirements Fulfilled by the Product (Annex E)
3.12 Machinery and equipment used in the production of the product;

- Flat Machine
- Overlock Machine
- Cutting Engine
- Marker Table

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

- Modelroom Mold Drawing Machine
- Cutter Cutting Machine (for narrow fabrics)
- Tape Welding Machine
- Ultrasonic Sewing Machine

3.13 Stitch Joining Section

PB 0060 & SC 0060 & CP 0045 = All stitches are made with 5 thread overlock stitch. A single needle sewing machine is used for sewing elastics, laces, labels and non-slip tapes.

PB 0065 = All stitches are made with 5 threads overlock stitch. A single needle sewing machine used for sewing elastics , laces, labels and non-slip tapes. Welding tape is welded on all seams from the outer surface.

SC 0065 = The whole pieces are performed with ultrasonic sewing. A single needle sewing machine is used for sewing elastics , laces, labels and non-slip tapes.

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 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

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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.

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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)

f) Label user manual and packaging control

5.4 Transport, Storage and Distribution

It includes the procedures that will ensure the hygiene rules during the transportation and storage of Surgical Garments and Covers.

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

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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 (Overalls) 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

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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

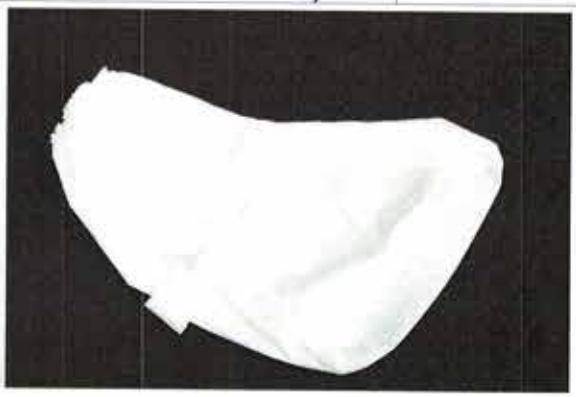
PRODUCT PHOTOS

Disposable Protective Sleeve

Product: SC 0060

Product: CP 0045

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

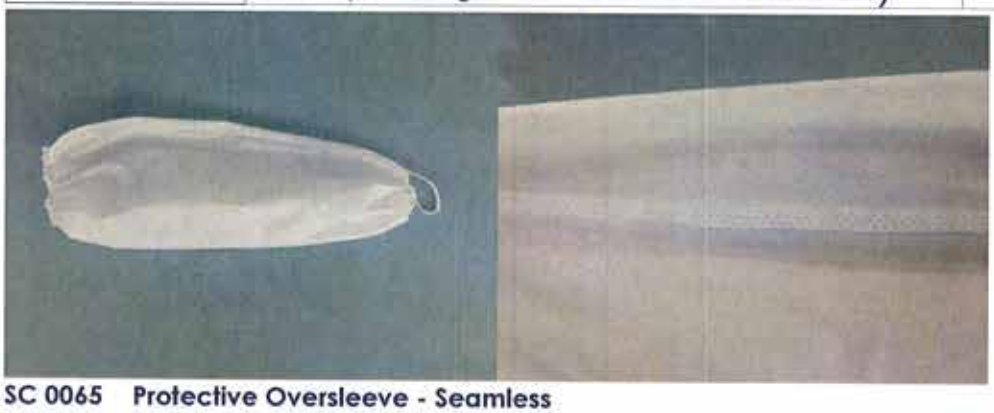


PB 0060 Uzun Galoş (Overshoe Long - Laminated)

PB 0065 Overshoe Taped - Long

PREPARED BY		APPROVED BY
Production Control Representative SABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.



SC 0065 Protective Oversleeve - Seamless

Labels;

BIOBLOCKED®

Protective Oversleeve - Seamless

PRODUCT: SC 0065

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58767
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

EN 14126:2003+AC:2004 Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Overshoe Taped - Long

PRODUCT: PB 0065

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58765
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

EN 14126:2003+AC:2004 Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Overshoe - Long

PRODUCT: PB 0060

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58764
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

EN 14126:2003+AC:2004 Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

PREPARED BY		APPROVED BY
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YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Protective Oversleeve

PRODUCT: SC 0060

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58763
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

EN 14126:2003+AC:2004 Protective clothing against infective agents

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Bouffant Cap - Laminated

PRODUCT: CP 0045

PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58765
EXP DATE: 15.08.2023

STD SIZE

Protective Clothing Category III

TYPE PB [6] -B

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals

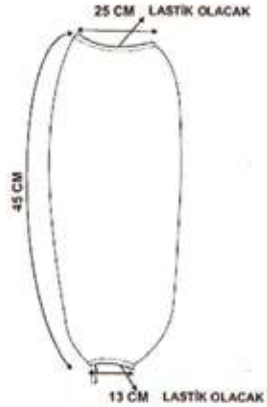
EN 14126:2003+AC:2004 Protective clothing against infective agents

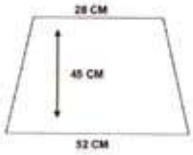
READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

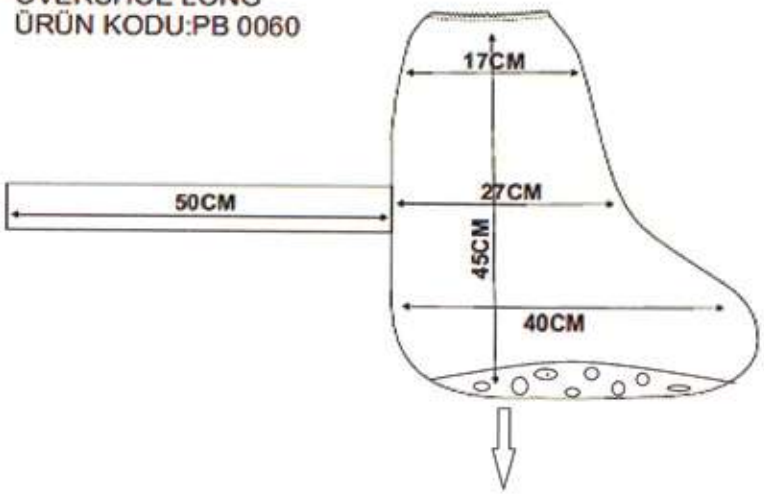
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

PROTECTIVE OVERSLEEVE
ÜRÜN KODU:SC 0060





OVERSHOE LONG
ÜRÜN KODU:PB 0060



KAYMAZ BANT

PREPARED BY		APPROVED BY
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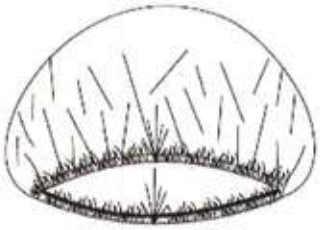
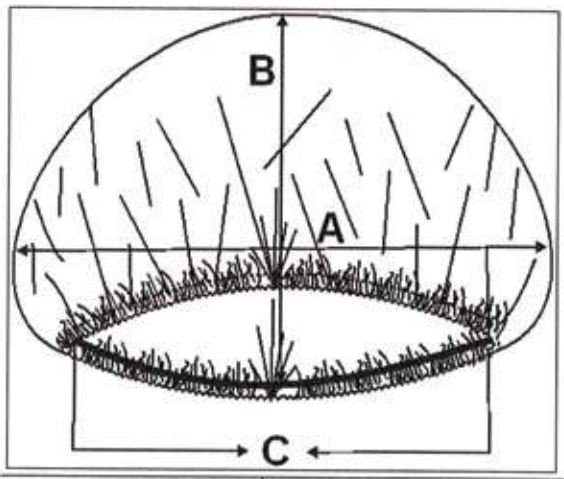
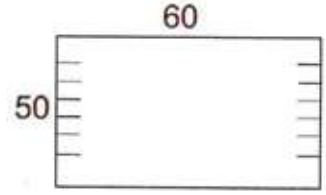
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BOUFFONT CAP
ÜRÜN KODU:CP 0045



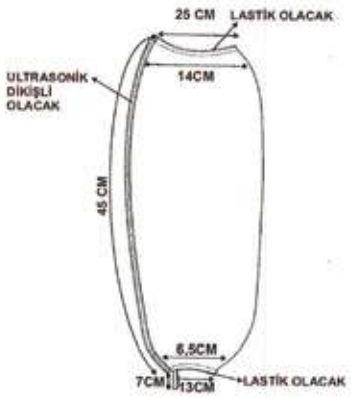


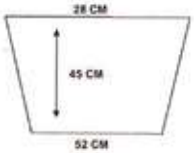
BONE PİLELİ KALIBI



	ÖLÇÜM NOKTALARI	BEDENLER	
		TEK BEDEN	Tolerans
A	Bone eni (bitmiş)	19	-/+1 cm
B	Bone boyu (bitmiş)	32	-/+1 cm
C	Lastik(bitmiş)	19	

PROTECTIVE OVERSLEEVE - SEAMLESS
ÜRÜN KODU:SC 0065





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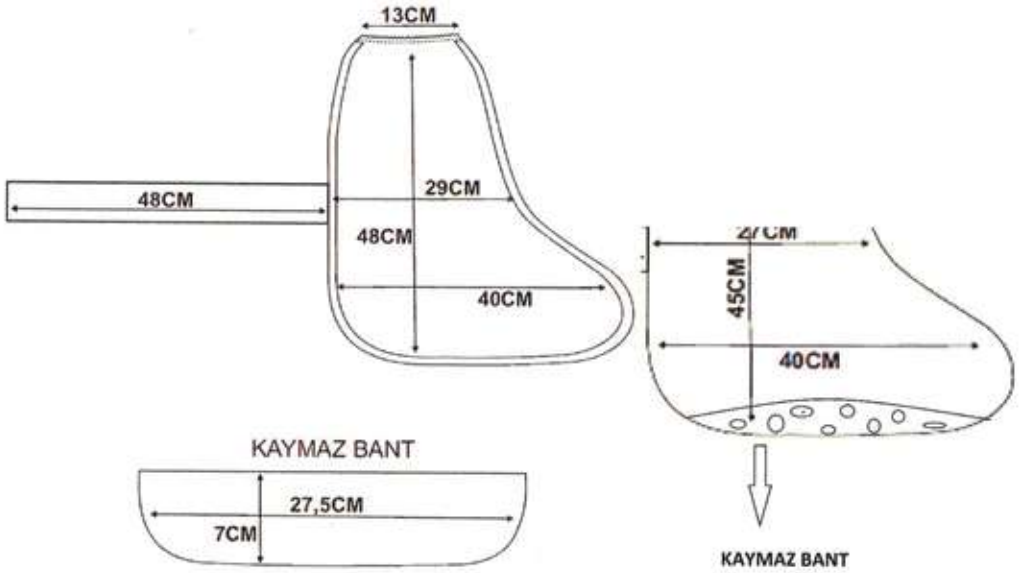
YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

OVERSHOE TAPED-LONG
ÜRÜN KODU:PB 0065



Annex B

MARKING

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET AŞ

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

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif püskürtülen sıvılara karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

13.3. Information that should be included on the label:

a) The name or commercial name and address of the manufacturer, for imported medical devices, as well as the name or commercial name and address of the authorized representative and / or importer must be included on the label or in the sales package or in the user manual.

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

b) Detailed information that defines the contents of the packaging and the medical device and especially for the user,
c) When necessary, the phrase "STERILE",
ç) When necessary, batch code or serial number with the expression "LOT",
d) If necessary, the expiry date in month and year,
e) When necessary, the phrase "for single use",
f) If the medical device is made on order, the phrase "It is a custom-made device",
g) The phrase "For Clinical Research" in clinical research devices,
ğ) Special storage and / or usage conditions,
h) Special user manual,
ı) Warnings and / or measures to be taken,
i) For active medical devices, the date of manufacture to be specified in the batch / lot or serial number, apart from sub-paragraph (d),
j) When required, the method of sterilization,
k) With regard to container and medical devices containing radioactive substances, information on Turkey Atomic Energy Agency permit to be obtained from,
l) If the medical device contains a human blood derivative, the statement stating this is sought.

Annex C

USAGE INSTRUCTIONS

PB 0060

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif püskürtülen partiküllere karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE
2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

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YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- Non-slip sole.
- It provides protection by fully wrapping the shoe covers.
- It is made of superior lightweight and easy-to-wear fabric.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Lamineli Kumaş
- Steril değildir.
- Kaymaz taban.
- Ayakkabıyı tam olarak sararak koruma sağlar.
- Üstün nitelikli hafif ve giyilmesi kolay kumaştan üretilmiştir.

ENGLISH

HOW TO WEAR ?

- The overshoe are opened with both hands to allow the shoes to enter the overshoe easily.
- Laces arte tied so that the foot does not tighten too much.
- The laces prevent the shoe from slipping down.

HOW TO REMOVE ?

- It should be removed by sitting.
- In removal, should be careful to remove the over shoe by inverting.
- Laces are opened, the rubbers are widened to remove the back side of the shoe and then the front side.
- Hands are washed with soap after this process. Disinfectant should be used at times when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Lastiği iki elle açılarak ayakkabının rahat bir şekilde ürünün içine girmesi sağlanılır.
- Ayağı çok sıkmayacak şekilde bağcıklar bağlanılır.
- Bağcıklar galoşun aşağıya doğru kaymasını engeller.

NASIL ÇIKARTILIR ?

- Oturularak çıkarılmalıdır.
- Çıkarma işleminde galoşun ters çevrilerek çıkarılmasına dikkat edilmelidir.
- Bağcıklar açılır, lastikler genişletilerek ayakkabının önce arka tarafı sonra ön tarafının çıkarılması sağlanılır.
- Eller bu işlemden sonra sabun ile yıkanır. Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

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

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 bacteriophase".

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Class 6
Tearing strength	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

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Mahallesi 500/1 Sk. No: 6/A Silivri/İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis spores , ATCC 9372 Bacillus atrophaeus ve ATCC 13706 - B1 Escherichia coli bacteriophase " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Esneme çatlama direnci Sınıf 5
Sıvılara karşı iticilik:
- Sodyum Hidroksit (NaOH) % 10 konsantrasyon, Sınıf 3
- Sülfürik Asit (H2SO4) %30 konsantrasyon Sınıf 3

Üretici YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Mahallesi 500/1 Sk. No: 6/A Silivri/İstanbul

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 500/1 Sokak No:6 Silivri/İST.
Tel: (0 212) 723 86 00 Fax: (0 212) 723 86 15
Silivri Vergi Dairesi 94 011 5570
Ticaret Sicil No: 627834

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

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

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

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

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DİSPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 510306

Product: PB 0060
Exp. Date: 07/23

BIOBLOCKED®

SC 0060

TYPE PB [6] – B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Sıvı kimyasallara karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE 2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

BioBlocked.com

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- It can be used in all environments that require hygiene.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Lamineli Kumaş
- Steril değildir.
- Hijyen gerektiren tüm ortamlarda kullanılabilir.

ENGLISH

HOW TO WEAR ?

- The disposable protective oversleeve cuff is wear on the wide side of the arm.
- To prevent the cuff from sliding towards the elbow, a finger is attached to the thumb.

HOW TO REMOVE ?

- The cuff is removed from the elbow by turning it upside down.
- Hands are washed with soap after this procedure. Disinfectant should be used when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Koruyucu kolluğun geniş tarafından kola giydirilir.
- Kolluğun dirseğe doğru kaymasını engellemek için baş parmağa parmaklık takılır.

NASIL ÇIKARTILIR ?

- Kolluk dirsek kısmından başlanarak ters çevrilerek çıkarılır.
- Eller bu işlemden sonra sabun ile yıkanır.Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

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

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 bacteriophase".

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Class 6
Tearing strength	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

Manufacturer: **YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.** Selimpaşa Merkez Mh. 5001 Sk. No: 6/A Silivri İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis spores , ATCC 9372 Bacillus atrophaeus ve ATCC 13706 - B1 Escherichia coli bacteriophase " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Esneme çatlama direnci: Sınıf 5
Sıvılara karşı iticilik:
- Sodyum Hidroksit (NaOH)% 10 konsantrasyon, Sınıf 3
- Sülfürik Asit (H2SO4)%30 konsantrasyon, Sınıf 3

Üretici: **YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.** Selimpaşa Merkez Mh. 5001 Sk. No: 6/A Silivri İstanbul

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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

GÜVENLİK TALİMATI
Bütün koruyucu giysiler, kullanmadan önce, yırtık, delik, söküK, kir gibi olumsuzluk defo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli ise kesinlikle giyilmemelidir.

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

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

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DİSPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 510405

Product: SC 0060
Exp. Date: 07/23

BIOBLOCKED®

CP 0045

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Sıvı kimyasallara karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE
2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

BioBlocked.com

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

YELKENCI	TECHNICAL FILE MANUFACTURING CONTROL GUIDE Protective Clothing (Long Overshoes, Protective Oversleeve, Bouffant Cap, Overshoe Taped - Long, Protective Oversleeve - Seamless)	DOCUMENT NO	TD-06
		ISSUE DATE	01.05.2020
		REV DATE	----
		REV NO	00
		PAGE NO	19/29

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- It can be used in all environments that require hygiene.

HOW TO WEAR ?

- The bonnet is opened with two hands by its rubbery part.
- The rubber part of the bonnet is placed on the forehead.
- The bonnet is placed on the head, completely covering the hair.

HOW TO REMOVE ?

- The rubber of the bonnet is gripped from the back of the head.
- The rubber is folded in front and the bone is removed.
- Hands are washed with soap after this procedure. Disinfectant should be used when there is no water and soap.

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

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

The biological agents for which the product was tested are "ATCC 9372 Bacillus subtilis spores, ATCC 9372 Bacillus atrophaeus, and ATCC 13/06 - B1 Escherichia coli bacteriophase".

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

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

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Sefaköy Mahallesi Mehmet Mh. 5001 Sk. No: 6/A Eğlenceli/İstanbul

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.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Laminell Kumaş
- Steril değildir.
- Hijyen gerektiren tüm ortamlarda kullanılabilir.

NASIL GİYİLİR ?

- Bone, lastikli kısmından iki elle tutup açılır.
- Bonenin lastikli kısmı alına yerleştirilir.
- Bone, saçlarl tamamen içine alacak şekilde başa yerleştirilir.

NASIL ÇIKARTILIR ?

- Kafanın arka tarafından bonenin lastiği kavranır.
- Lastik ön tarafa doğru içe katlanarak bone çıkarılır.
- Eller bu işlemden sonra sabun ile yıkanır.Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis spores , ATCC 9372 Bacillus atrophaeus ve ATCC 13/06 - B1 Escherichia coli bacteriophase " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Esneme çatlama direnci Sınıf 3
Sıvılara karşı itilicilik
- Sodyum Hidroksit (NaOH)% 10 konsantrasyon, Sınıf 3
- Sülfürik Asit (H2SO4)%30 konsantrasyon, Sınıf 3

Üretici: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Sefaköy Mahallesi Mehmet Mh. 5001 Sk. No: 6/A Eğlenceli/İstanbul

GÜVENLİK TALİMATI

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

DİKKAT!

Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

FRANÇAIS

INSTRUCTION DE SÉCURITÉ

Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

ATTENTION!

Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourissons.

DEUTSCH

SICHERUNGSANWEISUNG

Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

ACHTUNG!

Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 510504

Product: CP 0045

Exp. Date: 07/23

BIOBLOCKED®

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

SC 0065

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif poskurtulen sıvılara karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE 2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

BioBlocked.com

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- It can be used in all environments that require hygiene.
- Ultrasonically stitched.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Laminell Kumaş
- Steril değildir.
- Hijyen gerektiren tüm ortamlarda kullanılabilir.
- Ultrasonik dikişli.

ENGLISH

HOW TO WEAR ?

- The disposable protective oversleeve cuff is wear on the wide side of the arm.
- To prevent the cuff from sliding towards the elbow, a finger is attached to the thumb.

HOW TO REMOVE ?

- The cuff is removed from the elbow by turning it upside down.
- Hands are washed with soap after this procedure. Disinfectant should be used when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Koruyucu kolluğun geniş tarafından kola giydirilir.
- Kolluğun dirseğe doğru kaymasını engellemek için baş parmağa parmaklık takılır.

NASIL ÇIKARTILIR ?

- Kolluk dirsek kısmından başlanarak ters çevrilerek çıkarılır.
- Eller bu işlemden sonra sabun ile yıkanır.Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

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

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
Twisting strength	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

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Salmaşa Mahallesi 5001 Sk. No. 6/A Silivri/İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis sporeə , ATCC 9372 Bacillus atrophaeus ve ATCC 13706 - B1 Escherichia coli bacteriophaeə " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekilme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Esneme çatlama direnci Sınıf 5
Sıvılara karşı iticilik:
•Sodyum Hidroksit (NaOH)%-10 konsantrasyon, Sınıf 3
•Sülfürik Asit (H2SO4)%-30 konsantrasyon, Sınıf 3

Üretici: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Salmaşa Mahallesi 5001 Sk. No. 6/A Silivri/İstanbul

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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

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

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

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

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 513406

Product: SC 0065
Exp. Date: 07/23

BIOBLOCKED®

PB 0065

TYPE PB [6] - B

EN 13034:2005+A1:2009
Protective clothing against liquid chemicals
Hafif püskürtülen partiküllere karşı koruma

EN 14126:2003+AC:2004
Protective clothing against infective agents
Patojen organizmalara karşı koruma

CE 2163

ISO 9001:2015
ISO 14001:2015
ISO 22716:2007

BioBlocked.com

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

ENGLISH

PRODUCT FEATURES

- PP+PE Laminated Fabric
- Non-Sterile.
- Non-slip sole.
- It provides protection by fully wrapping the shoe covers.
- It is made of superior lightweight and easy-to-wear fabric.
- Welding tape is welded on all seams.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- PP+PE Lamineli Kumaş
- Steril değildir.
- Kaymaz taban.
- Ayakkabıyı tam olarak sararak koruma sağlar.
- Üstün nitelikli hafif ve giyilmesi kolay kumaştan üretilmiştir.
- Tüm dikiş yerlerinin üzerine kaynak bant yapıştırılır.

ENGLISH

HOW TO WEAR ?

- The overshoe are opened with both hands to allow the shoes to enter the overshoe easily.
- Laces arte tied so that the foot does not tighten too much.
- The laces prevent the shoe from slipping down.

HOW TO REMOVE ?

- It should be removed by sitting.
- In removal, should be careful to remove the over shoe by inverting.
- Laces are opened, the rubbers are widened to remove the back side of the shoe and then the front side.
- Hands are washed with soap after this process. Disinfectant should be used at times when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Lastiği iki elle açılarak ayakkabının rahat bir şekilde ürünün içine girmesi sağlanılır.
- Ayağı çok sıkmayacak şekilde bağcıklar bağlanılır.
- Bağcıklar galoşun aşağıya doğru kaymasını engeller.

NASIL ÇIKARTILIR ?

- Oturularak çıkarılmalıdır.
- Çıkarma işleminde galoşun ters çevrilerek çıkarılmasına dikkat edilmelidir.
- Bağcıklar açılır, lastikler genişletilerek ayakkabının önce arka tarafı sonra ön tarafının çıkarılması sağlanılır.
- Eller bu işlemden sonra sabun ile yıkanır. Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

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

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 bacteriophase".

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Class 6
Tearing strength	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

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Saltıpazarı Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Ürünün test edildiği biyolojik ajanlar " ATCC 9372 Bacillus subtilis spores , ATCC 9372 Bacillus atrophaeus ve ATCC 13706 - B1 Escherichia coli bacteriophase " dir.

MEKANİK DAYANIM SINIFLARI	
Aşınma direnci	Sınıf 6
Yırtılma direnci	Sınıf 1
Çekme mukavemeti	Sınıf 1
Delinme direnci	Sınıf 2
Dikiş mukavemeti	Sınıf 1

Eklenme çatlama direnci Sınıf 5
Sıvılara karşı iticilik:
- Sodyum Hidroksit (NaOH)%. 10 konsantrasyon, Sınıf 3
- Sülfürik Asit (H2SO4)%30 konsantrasyon, Sınıf 3

Üretici: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Saltıpazarı Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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

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

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zeisseen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

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

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 513307

Product: PB 0065
Exp. Date: 07/23

BIOBLOCKED®

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.

STORAGE/USE BY: It is recommended to keep it in a cardboard or cardboard box, away from sunlight at 15 -25 °C. If stored under appropriate conditions, it should be used within 3 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.

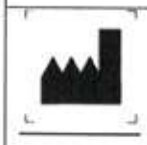
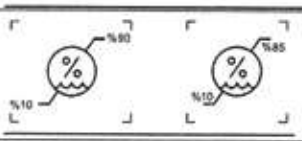
"In case of long-term use in temperate climates and environments, it may cause overheating "

"Flammable material. Keep away from fire."

Disposable, "Do not reuse!"

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR YELKENCİ MAZIR GİYİM SANAYİ VE TİCARET A.Ş.

Meaning of the Symbols on the Product Package

SYMBOL	TITLE OF THE SYMBOL	DESCRIPTION OF THE SYMBOL	SAMPLE
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385 / EEC, 93/42 / EEC and 98/79 / EC.	 **Name Address**
	Production date	Indicates the date the medical device was manufactured.	 **2020 - 06**
	Used by	Shows the expiration date of the medical device.	 **2021 - 06**
	(Non Sterile)	Indicates that a medical device has not been subjected to sterilization.	
	Do not use if the package is damaged.	Indicates that the medical device should not be used if the packaging is damaged or opened.	
	Keep dry	Indicates that the medical device must be protected from moisture.	
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed.	
	Humidity limitation	Indicates the humidity range to which the medical device can be safely exposed.	
	Do not reuse	Indicates that the medical device is intended for single use or for use on a single patient during a single procedure.	Disposable PPE, "Do not reuse!"
	See instructions for use	It shows that I have to look at the user's instructions for use.	

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Control Representative GÜRSEL ÖZCANLI	Company Director ÖZGÜR ÖZENİR

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

- General principles effective in biological evaluation of medical devices within a risk management process,
- General classification based on the structure of the devices in contact with the body and the duration of contact,
- Evaluation of relevant available data obtained from all kinds of sources,
- Identification of gaps in existing data sets based on a risk analysis,
- Identification of additional data groups required to analyze the biological safety of the medical device,
- Determining the biological safety of the medical device

processes and the risk management plan have identified and assigned biological assessment issues that require specific technical competences and the person (s) responsible for biological safety assessment. Hazardous Material Safety Data Sheets (MSDS) are obtained and evaluated from all of our suppliers. (ISO 10993)

EK - E

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

EN 14126/AC:2004 Standardının Karşıladığı Temel Sağlık ve Güvenlik Gerekleri/ Basic Health and Safety Requirements Meets EN 14126 / AC: 2004 Standard

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

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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 referansları/ *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 ; in particular, whwn such marks incorporate 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.*

PRODUCT PERFORMANCE VALUES

MECHANICAL RESISTANCE CLASSES	
Abrasion resistance	Abrasion resistance
Tear resistance	Tear resistance
Tensile strength	Tensile strength
Puncture resistance	Puncture resistance
Seam strength	Seam strength

Flex cracking resistance Class 3

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

EN 14126:2003+AC:2004
Biological agents for which the product is tested are "ATCC 9372 Bacillus subtilis spores, ATCC 9372 Bacillus atrophaeus and ATCC 13706 - B1 Eschericihia coli bacteriophase".

EN 13034:2005+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 dâhil olmak üzere, kullanıcının sağlık ve güvenliğini olumsuz yönde etkilememelidir. / *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.*

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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*

1.3.2.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.*

1.3.3. Aynı Anda Kullanılmak Üzere Tasarlanmış Farklı KKD Tipleri veya Sınıflarının Uyumu / *Compatibility of different types of PPE intended 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 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.*

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

2.4. KKD'nin Kullanım Ömrü ve Kullanımdan Dolayı Özelliğini Kaybetmesi / *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 KKD'nin ambalajı üzerinde de bulunmalıdır. / *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.*

KKD'nin kullanımından dolayı özelliğini ne sürede kaybedeceğinin öngörülemediği durumda imalatçı, tüketici ve nihai kullanıcıya kullanım kılavuzunda KKD modelinin kalite seviyesi ve depolanması, kullanımı, temizlenmesi, hizmete sunumu ve bakımına ilişkin etken koşulları da dikkate alarak makul bir kullanım ömrünü ay ve yıl olarak belirtmelidir. / *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.*

KKD'nin temizlenmesinde periyodik olarak kullanılan ve imalatçının tavsiye ettiği bir temizleme işlemi sonucunda oluşan yıpranmalardan kaynaklanan, KKD'nin performansında hızlı şekilde azalmaya sebep olan koşullar; mümkün olduğu durumda, piyasaya arz edilen her bir KKD'nin üzerine kullanım ömrünün tamamlanmasından önce yapılabilecek azami temizleme sayısını içerecek şekilde gerekli işaretleme iliştirilmelidir. Bunun mümkün olmadığı durumda bu bilgiler kullanım kılavuzunda verilmelidir. / *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. 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 ; in particular, whwn such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.*

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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.*