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CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1772

ASEL TIP MEDİKAL VE TEKSTİL SAN. VE TİC. LTD. ŞTİ.
Halkalı Merkez Mahallesi Çalışkan Sokak Burcu İş Merkezi No:1/B Halkalı Küçükçekmece
İstanbul / TURKEY

It is certified that the manufacturer's technical file (Dated 01.11.2020) 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: ASELTIP hcare, **Model:** M100005

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

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)
EN 14605:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type 3, Type 4, limited wear life clothing,
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type 3-B, 4-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 **09/12/2020** 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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TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 09.12.2020 / 2163-KKD-1772

Manufacturer: ASEL TIP MEDİKAL VE TEKSTİL SAN. VE TİC. LTD. ŞTİ.
Address: Halkalı Merkez Mahallesi Çalışkan Sokak Burcu İş Merkezi No:1/B Halkalı Küçükçekmece İstanbul / TURKEY

Introduction

This report is prepared based on the evaluations on the technical file of the manufacturer dated 15 June, 2020 Version 00, 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, for the use of same fabric. The fabric mechanical strength tests were conducted for the M100003 coverall model are used as a reference for M100005 model Coveralls as well. The fabrics and seam technology are claimed to be identically same by the manufacturer. The seams are covered by hotmelt tape for M100003 model coverall and this model is evaluated by conducting jet and spray tests. The samples for evaluation are provided by the manufacturer for type examination and samples are delivered to the laboratories under UNIVERSAL supervision. The test results and all evaluations within this report belongs to the samples provided.

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

PPE Identification: Protective coverall manufactured from laminated polypropylene non-woven fabric with hood, overlock seams, seams are covered with hotmelt tape, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.

Component and Materials:

Fabric: 55 gr Non Woven Fabric (40gr Non Woven + 13gr PE Film + 2gr Adhesive)

Zipper: Wowen Zipper

Coverall Type: Type 3-B / Type 4-B

Brand Name: ASELTIP hcare **Model:** M100005 **Sizes Available:** S - M – L – XL – 2XL - 3XL

Applied Harmonised Standards

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

EN 14605:2005+A1:2009, (Chemical protective clothing protective performance against chemicals in the forms liquid and spray) Type 3 and Type 4, limited wear life clothing,

EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type 3-B, 4-B limited life, full body protection

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 11.11.2020 Number: 20041201-Ing	Holds TURKAK Accreditation with No: AB-0583-T
2	Ekoteks Laboratuar ve Gözetim Hizmetleri A.Ş.	Dated 01.12.2020 Number: 20044390-Ing	Holds TURKAK Accreditation with No: AB-0583-T
3	Ekoteks Laboratuar ve Gözetim Hizmetleri A.Ş.	Dated 01.12.2020 Number: 2004396-Ing	Holds TURKAK Accreditation with No: AB-0583-T
4	Çevre Endüstriyel Analiz Laboratuarı	Dated 13.11.2020 Number: 2028092E	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.

UNIVERSAL CERTIFICATION CE 2163 Notified Body

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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.

UNIVERSAL CERTIFICATION 2163 Notified Body

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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. Ref: Technical File Article 3
Article 4.4	EHSR Ref 1.2.1.2; The comfort of the PPE was subject to visual inspection by our experts for rough, sharp or hard surfaces that irritate or injure the user and found to be appropriate for use. In addition such properties of the PPE was subject to evaluation during the practical exercise testing as defined in the EN ISO 17491-4 testing standard and the PPE is reported as to be comfortable enough to allow the wearer to complete the excercises. Ref: Test Reports.
Article 5.3	EHSR Ref 1.2.1; The samples received from the manufacturer are claimed to be single use. No further evaluation is conducted on the dimensional change due to cleaning. Ref: Technical File Article 6.
Article 6	EHSR Ref 2.12; The coverall is available in 6 nominal sizes. The nominal sizes are defined in the technical file of the manufacturer. The given dimensions in chest or bust girth and height are found in the limits defined in Annex D of the standard. **Aseltıp Coverall Measurement Cha** SIZES: S, M, L, XL, 2) Length: 92,0, 100,0, 107,0, 114,0, 1: Ref: Technical File Article 10.
Article 7	EHSR Ref 2.12; Each piece of coverall have marking with the following information; • Name / trademark of the manufacturer, type of product • Size of the coverall • Applied product standards (Type defining product standards) • Applied protection pictograms with standard references The markings on the coverall / label are found to be easily visible and enough big to read. The marking rules are explained in the marking section of the technical file. For further clarifications for the marking requirements of applied product standards are available in the relevant standard section of this report.

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EN ISO 13688 Standard Requirements Evaluation	
Article 8	EHSR Ref 1.4; The information supplied by the manufacturer is defined in the relevant section of the technical file. This information includes explanation required by all applied product standard requirements. The defined user information text in the technical file includes the following data; • Name / trademark of the manufacturer, its address, • Applied standards and relevant classification, marking, size information • Pictograms and explanations • Coverall constituent materials used • Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary PPEs, re-usability, instructions for disposal The above user information text is available in Turkish.

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap 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

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

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

1.1. Design principles

1.1.1. Ergonomics

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

1.2. Innocuousness of PPE

1.2.1. Absence of inherent risks and other nuisance factors

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

1.2.1.1. Suitable constituent materials

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

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

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

1.2.1.3. Maximum permissible user impediment

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

1.3. Comfort and effectiveness

1.3.2. Lightness and strength

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

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

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

1.4. Manufacturer's instructions and information

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

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

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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.

2.3. PPE for the face, eyes and respiratory system

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

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

2.4. PPE subject to ageing

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

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

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

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

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

3.10.2. Protection against cutaneous and ocular contact

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

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

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

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

EN 14605:2005 + A1:2009 Standard Requirements Evaluation

Article 4.1

EHSR Ref 1.2.1.1, 1.3.2, 3.10.2;
The coverall material performance are tested according to EN 14325:2018 standard for the following properties, since the coverall is claimed to be for single use no cleaning cycle is applied;

Property of Material EN 14325:2018	Result Classification		Requirement of EN 14605	Evaluation
4.4 Abrasion Resistance	No Abrasion @2000 revs	Class 6	Class 1 or above	Success
4.5 Flex cracking resistance	> 5,000 Cycles	Class 3	Class 1 or above	Success
4.7 Trapezoidal tear resistance	Width 42.6 N Length 16.3 N	Class 2	Class 1 or above	Success
4.9 Tensile Strength	W 87.7 N L 42.8 N	Class 2	Class 1 or above	Success
4.10 Puncture Resistance	6,0 N	Class 1	Class 1 or above	Success
4.11 Resistance to Permeation of Liquids	Sulfuric Acid (H2SO4) (Concentration 30%) IR is 93.93 % Sudium Hydroxide (NaOH) (Concentration 10%) IR is 93.11 % o-Xylene (Undiluted) IR is 97.35 %	Class 3 Class 3 Class 3	Class 3 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. Since the PPE are single use no cleaning or disinfection process is applied. The results fulfils the minimum requirements of the standard.
The manufacturer do not claim a performance for the resistance to ignition or flammability of the product, in the user information sheet it is explained that the coveralls must be kept away of fire.
Other requirements refered for skin compatibility, no irritation or adverse effects are evaluated in EN ISO 13688 section of this report.

Ref: Laboratory Test Report 1, Technical File

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EN 14605:2005 + A1:2009 Standard Requirements Evaluation

Article 4.2

EHSR Ref 1.3.2, 3.10.2;

The affects of seams to the performance of the coverall in penetration of liquids through sealed stitch holes are evaluated in the jet and spray tests of whole suit and evaluated in Article 4.3 of this section. In addition the seam strength and permeation of chemicals through the seams are tested and the results are given in the below table.

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

Property of Material EN 14325:2018	Result Classification		Requirement of EN 14605	Evaluation
4.11 Resistance to Permeation of Liquids	Sulfuric Acid (H2SO4) (Concentration 30%) IR is 93.93 %	Class 3	Class 3 at least for 1 chemical	Success
	Sudium Hydroxide (NaOH) (Concentration 10%) IR is 93.11 %	Class 3		
	o-Xylene (Undiluted) IR is 97.35 %	Class 3		
5.5 Seam Strength	Refer to the strength values for seams at different parts of coverall. The lowest Class is given among all kinds of seams	Class 2	Class 1 or above	Success

Ref: Laboratory Test Report 1, 3

Article 4.3

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

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

The coverall under evaluation is a one piece full body clothing, without a visor and foot protection. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested as a part of the Jet and spray tests (Seven Movements) and found to be appropriate.

According to the test results reported;

The test report claims the jet test that it is conducted according to EN ISO 17491-3 and the spray test that is conducted according to EN ISO 17491-4 Method B which is given in Clause 4.3.4.2 and 4.3.4.3 of this standard.

- The subjects were able to complete the excercises described comfortably. The inspection on the tested samples states that there was no damage, tears or rips in fabrics, seams and connection points to the additionaly worn PPEs like gloves, boots etc.
- For spray test, the calibrated stain area is calculated for the undergarment is 3.45 cm^2. The laboratory reports that for the 3 samples tested the total stain are of undergarments are smaller then three times the calibrated stain area, values are (0 cm^2, 0 cm^2, 0 cm^2). For more details please refer to the test report.
- For jet test, the calibrated stain area is calculated for the undergarment is 3.45 cm^2. The laboratory reports that for the 3 samples tested the total stain are of undergarments are smaller then three times the calibrated stain area, values are (0 cm^2, 0 cm^2, 0 cm^2). For more details please refer to the test report.

The above results indicates that the tested coveralls complies with the resistance to penetration by liquids in the form of spray test and jet test requirement of this standard. Which is based on a test report conducted according to EN ISO 17491-4:2008+A1:2016 and EN ISO 17491-3:2008.

Ref: Laboratory Test Report 2

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap 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

EN 14605:2005 + A1:2009 Standard Requirements Evaluation	
Article 4.4	EHSR Ref 1.1.1, 1.1.2.1, 1.2.1.2, 1.2.1.3, 1.3.1, 1.3.3, 3.10.2; The coverall do not have visor.
Article 5	EHSR Ref 2.12; Each piece of coverall have marking with the following information on the single PPE package / PPE itself; • Name / trademark of the manufacturer, type and model of PPE • Size of the coverall • Applied product standards (EN ISO 14605:2005 +A1:2019) • Pictograms for protection against chemicals, invitation to read manufacturer's instructions • Shelf life and date of manufacturing, and non reusable marking The above mentioned marking requirements are stated in the technical file of the manufacturer. The evaluated samples did not have all these marking and information on the PPE. The manufacturer shall follow the instructions in the technical file in case of serial manufacturing of the PPE and verify before putting the PPE on the market. The PPE coverall is for single use, the markings for re-use cleaning or disinfection is discarded. Ref: Technical File PPE Marking section.
Article 6	EHSR Ref 1.4; The information supplied by the manufacturer is defined in the relevant section of the technical file. This information includes explanation required by all applied product standard requirements. The defined user information text in the technical file includes the following data; • Name / trademark of the manufacturer, its address, or the authorised representative for EU community • Type of protection against chemicals (Type-3, Type-4). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, mask and visor / face shield). • Size of the coverall • Material test performance classifications (Based on EN 14325:2018 classification) • The statement that the coverall is tested against the chemical names (tested for) and performance levels for mechanical strengths including repellency and resistance to penetration of liquids (Based on EN 14325:2018 classification) • Pictogram and information that the PPE is non-reusable also the shelf life is mentioned • Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary, instructions for disposal. • Statement for warning the user on flammability, to keep away of fire The above user information text is available in Turkish. Ref User Information Sheet

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

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

1.1. Design principles

1.1.2.2. Classes of protection appropriate to different levels of risk

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

1.3. Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

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

1.3.2. Lightness and strength

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

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

1.4. Manufacturer's instructions and information

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

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

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

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.4. PPE subject to ageing

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

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

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

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

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

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

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

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

3.10.2. Protection against cutaneous and ocular contact

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

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

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

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

EN 14126:2003 + AC:2004 Standard Requirements Evaluation	
Article 4.1.2	EHSR Ref 1.3.2; The coverall material performance are tested according to EN 14325:2018 standard for the relevant properties required by the Type defining standards for protective clothing. The coverall under evaluation claims compliance with Type 3, Type 4. The required mechanical and flammability performance levels are evaluated in the corresponding clauses of EN 14605:2005 + A1:2009 standard within this report. No further evaluation is necessary for this standard.
Article 4.1.4	EHSR Ref 1.1.2.2, 3.10.2; Evaluation of the performance requirements against penetration by infactive agents; The coverall is subjected to the tests according to ISO 16603 and ISO 16604 standards for its resistance to penetration by contaminated liquids under hydrostatic pressure. According to the obtained results of the corresponding test report; • The coverall material with stands and do not allow any penetration of bacteria under 20kPa hydrostatic pressure and is classified as **Class 6** according to Table 1 given in 4.1.4.1 Clause of this standard, • The coverall material was also subjected to evaluation of the bacteriophage test and passes the test according to ISO 16604 at 20kPa, and is classified as **Class 6** according to Table 1 given in 4.1.4.1 Clause of this standard, The coverall is tested for its resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids according to ISO 22610:2018 testing standard. The laboratory environmental conditions and the test setup parameters were inline with the standard requirements. The laboratory results indicates that the tested specimens do not allow penetration in 5 turns a total of 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. The coverall is tested for its resistance to penetration by contaminated solid particles according to ISO 22612:2005 testing standard. The laboratory environmental conditions and the test setup parameters were inline with the standard requirements. The laboratory results indicates that the tested 10 specimens the arithmetic mean of penetration results are smaller than 1 log cfu. The tested sample is classified as **Class 3** according to Table 4 of Clause 4.1.4.4 of EN 14126 standard Classification of resistance to penetration by contaminated solid particles. The results of evaluation for clause 4.1.4 is summarised below;

Resistance to Penetration Propery	Result Classification		Requirement of EN 14126
ISO 16604 - Resistance to penetration by contaminated liquids under hydrostatic pressure	Successful Hydrostatic pressure > 20 kPa	Class 6	To be Classified
EN ISO 22610 - Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.	Breakthrough time t >75min	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 4

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Sample Photo

PPE Experts contributed to this report:

Arzu ŞEREMETLİ

Osman CAMCI

UNIVERSAL CERTIFICATION CE 2163 Notified Body

Approval
Suat KAÇMAZ
UNIVERSAL CERTIFICATION – Director

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