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# TECHNICAL EVALUATION REPORT

**REPORT DATE / NO:** 22.09.2020 / 2163-KKD-1481

**Applicant:** CARINE EUROPE GMBH
**Applicant Address:** Ammann Strasse No:12 86167 Augsburg / Germany

**Manufacturer:** Aydağ Tedavi ve Sağlik Hizmetleri San. ve Tic. A.Ş.
**Manufacturer Address:** Orta Mah. Menderes Cad. No:7/3 K1 Bayrampaşa / İSTANBUL

**Introduction**

This report is prepared based on the evaluations on the technical file of the manufacturer dated 25 August, 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. There exists a subcontracting agreement (OBM) between the brand name owner (Applicant) and the manufacturer based on the technical file of the PPE. 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 3, 4 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, on the use of same fabric. The fabric mechanical and microbiological strength tests were conducted for the CRM-PCA-100 coverall model and used as a reference for CRM-PCA-200 model as well. 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, inside overlock seams, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.

**Component and Materials:**

Fabric: 60 gr Non Woven Fabric (33gr Non Woven + 22gr PE Film + 2gr Hotmelt)

Zipper: Type 5 Nylon Sewing Thread: Mercerized sewing thread

**Coverall Type:** Type 5-B / Type 6-B

**Brand Name:** Carine Medical

**Model:** CRM-PCA-200

*The model code for the product is updated during the evaluation period. The received samples were marked as CRM-PCA, which was used for Type 3-B, 4-B model coveralls as well, the manufacturer updated Type 5-B, 6-B model to CRM-PCA-200.*

**Sizes Available:** S - M – L – XL – 2XL - 3XL

**Applied Harmonised Standards**

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

EN ISO 13982-1:2004/A1:2010, (Chemical protective clothing providing protection to the full body against airbone solid particulates) Type 5, limited wear life clothing,

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

EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type 5-B, 6-B

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

TEST REPORT INFORMATION

| Report # | Laboratory Name | Report Date and Number | Competency Reference |
|---|---|---|---|
| 1 | Ekoteks Laboratuar ve Gözetim Hizmetleri A.Ş. | Dated 18.09.2020 Number: 20032970-Ing | Holds TURKAK Accreditation with No: AB-0583-T |
| 2 | GCNTR – Global Technology Laboratory | Dated 18.09.2020 # GTL-TLM-0063A/20 | Holds TURKAK Accreditation with No: AB-1252-T |
| 3 | GCNTR – Global Technology Laboratory | Dated 17.09.2020 # GTL-TLM-0063/20 | Holds TURKAK Accreditation with No: AB-1252-T |
| 4 | Çevre Endüstriyel Analiz Laboratuarı | Dated 15.09.2020 Number: 2022130 E | 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;<br>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.<br>Ref: Technical File Article 3.6. |
| *Article 4.4* | EHSR Ref 1.2.1.2;<br>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.<br>Ref: Test Reports. |
| *Article 5.3* | EHSR Ref 1.2.1;<br>The samples received from the manufacturer are claimed to be single use. No further evaluation is conducted on the dimensional change due to cleaning.<br>Ref: Technical File Marking Section. |
| *Article 6* | EHSR Ref 2.12;<br>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.<br>Product Dimension Table / Produkt Maßtabell<br>Size \| H \| C<br>S \| 64 - 67 in 164 - 170 cm \| 33 - 36 in 84 -<br>M \| 66 - 69 in 167 - 176 cm \| 36 - 39 in 92 -<br>L \| 69 - 71 in 174 - 181 cm \| 39 - 43 in 100<br>XL \| 70 - 74 in 179 - 187 cm \| 43 - 45 in 108<br>XXL \| 73 - 76 in 186 - 194 cm \| 45 - 49 in 115<br>Ref: Technical File Annex C. |
| *Article 7* | EHSR Ref 2.12;<br>Each piece of coverall have marking with the following information;<br>• Name / trademark of the manufacturer, type of product<br>• Size of the coverall<br>• Applied product standards (Type defining product standards)<br>• Applied protection pictograms with standard references<br>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;<br>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;<br>• Name / trademark of the manufacturer, its address,<br>• Applied standards and relevant classification, marking, size information<br>• Pictograms and explanations<br>• Coverall constituent materials used<br>• Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary PPEs, re-usability, instructions for disposal<br>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 13982-1:2004 + A1:2010 STANDARD**

## 1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

### 1.1. Design principles

#### 1.1.1. Ergonomics

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

#### 1.1.2 Levels and classes of protection

#### 1.1.2.1 Optimum level of protection

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

### 1.2. Innocuousness of PPE

#### 1.2.1. Absence of inherent risks and other nuisance factors

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

#### 1.2.1.1. Suitable constituent materials

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

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

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

#### 1.2.1.3. Maximum permissible user impediment

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

### 1.3. Comfort and effectiveness

#### 1.3.1. Adaptation of PPE to user morphology

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

#### 1.3.2. Lightness and strength

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

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

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

### 1.4. Manufacturer's instructions and information

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

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



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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.

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

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

*Article 4.1*

EHSR Ref 1.2.1, 1.3.2;

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

| Property of Material EN 14325:2018 | Result Classification | | Requirement of EN ISO 13982-1 | Evaluation |
|---|---|---|---|---|
| 4.4 Abrasion Resistance | No Abrasion @2000 revs | Class 6 | Class 1 or above | Success |
| 4.5 Flex cracking resistance | > 8,000 Cycles | Class 3 | Class 1 or above | Success |
| 4.7 Trapezoidal tear resistance | Width 27.2 N<br>Length 59.8 N | Class 2 | Class 1 or above | Success |
| 4.10 Puncture Resistance | 8.8 N | Class 1 | Class 1 or above | Success |

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

Ref: Laboratory Test Report 1, Technical File

*Article 4.2*

EHSR Ref 1.3.2, 3.10.2;

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

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

| Property of Material EN 14325:2018 | Result Classification | | Requirement of EN ISO 13982-1 | Evaluation |
|---|---|---|---|---|
| 5.5 Seam Strength | Refer to the strength values for seams at different parts of coverall. The lowest Class is given among all kinds of seams | Class 2 | Class 1 or above | Success |

Ref: Laboratory Test Report 1



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| EN ISO 13982-1:2004 + A1:2010 Standard Requirements Evaluation | |
|---|---|
| *Article 4.3* | EHSR Ref 1.1.1, 1.1.2.1, 1.2.1.2, 1.2.1.3, 1.3.1, 1.3.3, 3.10.2;<br>The requirements of the coverall with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.<br>The coverall under evaluation is a one piece full body clothing, without a visor and foot protection. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested as a part of the Total Inward Lekage test and found to be appropriate.<br>According to the test results reported;<br>• 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.<br>• The results of percentages of inward lekage values reported claims that All 90 measurements are smaller and equal to 30. Which means all 90 of the total lekage measurements among all excercises for all positions and all samples are smaller than 30%.<br>• All 10 of the average total inward lekage per tested suit of 10 is smaller or equal to 15%.<br>The above results indicates that the tested coveralls complies with the total inward leakage of aeroslols of solid particles requirement of this standard. Which is based on a test report conducted according to EN ISO 13982-2:2005<br>Ref: Laboratory Test Report 2 |
| *Article 5* | EHSR Ref 2.12;<br>Each piece of coverall have marking with the following information on the single PPE package / PPE itself;<br>• Name / trademark of the manufacturer, type and model of PPE<br>• Size of the coverall<br>• Applied product standards (EN ISO 13982-1+A1:2010)<br>• Pictograms for protection against chemicals, invitation to read manufacturer's instructions, single use<br>• Shelf life and date of manufacturing<br>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.<br>Ref: Technical File PPE Marking section. |
| *Article 6* | EHSR Ref 1.4;<br>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;<br>• Name / trademark of the manufacturer, its address, or the authorised representative for EU community<br>• Type and model of PPE<br>• Applied product standards (EN ISO 13982-1+A1:2010)<br>• Size designation table<br>• Type of protection against chemicals (Type-5). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, |

| EN ISO 13982-1:2004 + A1:2010 Standard Requirements Evaluation | |
|---|---|
| | mask and visor / face shield).<br>• The statement that the coverall provides a total inward lekage $L_{jmn,82/90} \leq 30$ % and $L_{S,8/10} \leq 15$ %<br>• Material test performance classifications (Based on EN 14325:2018 classification)<br>• Pictogram and information that the PPE is non-reusable also the shelf life is mentioned<br>• Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary, instructions for disposal<br>The above user information text is available in Turkish<br>Ref Technical File, User Information Sheet |

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

| Property of Material EN 14325:2018 | Result Classification | | Requirement of EN ISO 13034 | Evaluation |
|---|---|---|---|---|
| 4.4 Abrasion Resistance | No Abrasion @2000 revs | Class 6 | Class 1 or above | Success |
| 4.7 Trapezoidal tear resistance | Width 27.2 N<br>Length 59.8 N | Class 2 | Class 1 or above | Success |
| 4.9 Tensile Strength | W 37.0 N<br>L 122.1 N | Class 1 | Class 1 or above | Success |
| 4.10 Puncture Resistance | 8.8 N | Class 1 | Class 1 or above | Success |
| 4.12 Liquid repellency | Sulfuric Acid ($H_2SO_4$)<br>$I_R$ is 100 % | Class 3 | Class 3 at least for 1 chemical | Success |
| | Sudium Hydroxide (NaOH)<br>$I_R$ is 92.2 % | Class 3 | | |
| | o-Xylene $I_R$ is 90.8 % | Class 3 | | |
| 4.13 Resistance to penetration by liquids | Sulfuric Acid (H2SO4)<br>$I_P$ is 0 % | Class 3 | Class 2 at least for 1 chemical | Success |
| | Sodium Hydroxide (NaOH)<br>$I_P$ is 0 % | Class 3 | | |
| | o-Xylene (Undiluted)<br>$I_P$ is 0 % | Class 3 | | |

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

Ref: Laboratory Test Report 1, Technical File

*Article 4.2*

EHSR Ref 1.3.2, 3.10.2;

The affects of seams to the performance of the coverall in penetration of liquid through stitch holes or through other components of a seam are evaluated in the whole suit mist test and evaluated in Article 5.2 of this section.
The seam strength is evaluated based on the test report as shown below;

| Property of Material EN 14325:2018 | Result Classification | | Requirement of EN ISO 13982-1 | Evaluation |
|---|---|---|---|---|
| 5.5 Seam Strength | Refer to the strength values for seams at different parts of coverall. The lowest Class is given among all kinds of seams | Class 2 | Class 1 or above | Success |

Ref: Laboratory Test Report 1



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| EN ISO 13034:2005 + A1:2009 Standard Requirements Evaluation | |
|---|---|
| *Article 5.1,5.2* | EHSR Ref 1.2.1.3, 2.4, 3.10.2;<br>The requirements of the coverall with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.<br>The coverall under evaluation is a one piece full body clothing, without a visor and foot protection. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested as a part of the light spray (mist) test (Seven Movements) and found to be appropriate.<br>The test report claims the light spray test that it is conducted according to Method A of EN ISO 17491-4 which corresponds the test setup defined in Clause 5.2 of this standard.<br>According to the test results reported;<br>• The subjects were able to complete the excercises (seven movements) described comfortably. The inspection on the tested samples states that there was no damage, tears or rips in fabrics, seams and connection points to the additionaly worn PPEs like gloves, boots etc.<br>• The calibrated stain area is calculated for the undergarment is 4.56 $cm^2$. The laboratory reports that for the 3 samples tested the total stain are of undergarments are smaller then three times the calibrated stain area, values are (0 $cm^2$, 2 $cm^2$, 0 $cm^2$). For more details please refer to the test report. The values are very close to the limits.<br>The above results indicates that the tested coveralls complies with the resistance to penetration by liquids in the form of a light spray (mist) test requirement of this standard. Which is based on a test report conducted according to EN ISO 17491-4:2008+A1:2016 Method A.<br>Ref: Laboratory Test Report 3 |
| *Article 6* | EHSR Ref 2.12;<br>Each piece of coverall have marking with the following information on the single PPE package / PPE itself;<br>• Name / trademark of the manufacturer, type and model of PPE<br>• Size of the coverall<br>• Applied product standards (EN ISO 13034:2005+A1:2009)<br>• Pictograms for protection against chemicals, invitation to read manufacturer's instructions<br>• Shelf life and date of manufacturing<br>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.<br>Ref: Technical File PPE Marking section. |
| *Article 7* | EHSR Ref 1.3.3, 2.4, 2.12;<br>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;<br>• Name / trademark of the manufacturer, its address, or the authorised representative for EU community<br>• Type of protection against chemicals (Type-6). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, mask and visor / face shield).<br>• Size of the coverall and model name<br>• The standard code / name with the published year<br>• 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)<br>• Pictogram and information that the PPE is non-reusable also the shelf life is mentioned |



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

<table>
<tr><th colspan="2">EN 14126:2003 + AC:2004 Standard Requirements Evaluation</th></tr>
<tr><td>Article 4.1.2</td><td>EHSR Ref 1.3.2;<br>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 5 and Type 6. The required mechanical and flammability performance levels are evaluated in the corresponding clauses of EN ISO 13982-1 and EN ISO 13034 standards within this report. No further evaluation is necessary for this standard.</td></tr>
<tr><td>Article 4.1.4</td><td>EHSR Ref 1.1.2.2, 3.10.2;<br>Evaluation of the performance requirements against penetration by infactive agents;<br>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;<br>• The coverall material withstands and do not allow any penetration of bacteria under 20kPa hydrostatic pressure and is classified as Class 6 according to Table 1 given in 4.1.4.1 Clause of this standard,<br>• 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,<br>The coverall is tested for its resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids according to ISO 22610:2018 testing standard. The laboratory environmental conditions and the test setup parameters were inline with the standard requirements. The laboratory results indicates that the tested specimens withstands the 5 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.<br>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.<br>The results of evaluation for clause 4.1.4 is summarised below;
<table>
<tr><th>Resistance to Penetration Propery</th><th colspan="2">Result Classification</th><th>Requirement of EN 14126</th></tr>
<tr><td>ISO 16604 - Resistance to penetration by contaminated liquids under hydrostatic pressure</td><td>Successful Hydrostatic pressure<br>> 20 kPa</td><td>Class 6</td><td>To be Classified</td></tr>
<tr><td>EN ISO 22610 - Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.</td><td>Breakthrough time<br>t > 75 min</td><td>Class 6</td><td>To be Classified</td></tr>
<tr><td>EN ISO 22612 - Resistance to penetration by contaminated solid particles</td><td>Penetration<br>log cfu < 1</td><td>Class 3</td><td>To be Classified</td></tr>
</table>
Ref: Laboratory Test Report 1 and Test Report 4</td></tr>
</table>

<table>
<tr><th colspan="2">EN 14126:2003 + AC:2004 Standard Requirements Evaluation</th></tr>
<tr><td>Article 4.2</td><td>EHSR Ref 1.3.2;<br><br>The seam strength is evaluated and classified based on the test report as shown below;
<table>
<tr><th>Property of Material EN 14325:2018</th><th colspan="2">Result Classification</th><th>Requirement of EN EN 14126</th></tr>
<tr><td>5.5 Seam Strength</td><td>Refer to the strength values for seams at different parts of coverall. The lowest Class is given among all kinds of seams</td><td>Class 2</td><td>To be Classified</td></tr>
</table>
Ref: Laboratory Test Report 1</td></tr>
<tr><td>Article 4.3</td><td>EHSR Ref 1.3.1, 3.10.2;<br>The PPE under evaluation conforms the relevant requirements of EN ISO 13688 standard. The requirements of the coverall with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.</td></tr>
<tr><td>Article 5</td><td>EHSR Ref 2.12;<br><br>The marking requiremnts for protective clothing against chemicals are evaluated in the relevant section of this report. Aditionally;<br><br>Each piece of coverall have marking with the following information on the single PPE package / PPE itself;<br>• Applied product standards (EN 14126:2003+AC:2004)<br>• Type marking of the PPE as Type 5-B / Type 6-B<br>• the pictogram “protection against biological hazard”<br><br>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.<br><br>Ref: Technical File PPE Marking Section</td></tr>
<tr><td>Article 6</td><td>EHSR Ref 1.4;<br><br>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;<br><br>• Name / trademark of the manufacturer, its address, or the authorised representative for EU community<br>• Type of protection against chemicals (Type-6). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, mask and visor / face shield).<br>• The standard number (EN 14126)<br>• The performance levels identified with the tests against infactive agents<br>• Pictogram and information that the PPE is non-reusable also the shelf life is mentioned</td></tr>
</table>

| EN 14126:2003 + AC:2004 Standard Requirements Evaluation | |
|---|---|
| | • Instructions for use, controls before use, how to wear / unwear, limitations, instructuions for storage conditions, complemantary, instructions for disposal<br><br>The above user information text is available in Turkish<br>Ref User Information Sheet |

PPE Experts contributed to this report:

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Osman CAMCI

UNIVERSAL CERTIFICATION 2163 Notified Body

Approval
Suat KAÇMAZ
UNIVERSAL CERTIFICATION – Director



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