

## EU TYPE EXAMINATION CERTIFICATE

**Certificate No: 2163-PPE-1847**

**DURUTEKS İNŞAAT GIDA TEKSTİL SAN. VE TİC. LTD. ŞTİ.**

Batı Sitesi Mahallesi Gersan Sanayi Sitesi 2308. Sokak NO:51 Yenimahalle Ankara TURKEY

Manufacturing Site: Hürriyet Mahallesi 2201 Sokak NO:2/A Esenyurt İstanbul TURKEY

It is certified that the manufacturer's technical file (Dated 26.12.2020 Rev1) 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: DURUTEKS, Model: DRT GOWN L01**

Protective gown, as a protective clothing for the part of body [PB], manufactured from blue laminated polypropylene non-woven fabric, inside over lock seams, inbound seams on the neck, touch and close fastener on the nape and with belts. The gown is available in 6 nominal sizes.

For more details, refer technical evaluation report provided to the manufacturer, dated 27.12.2020 and number 2163-KKD-1847.

**The following harmonised standards have been applied:**

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

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

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

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

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

This certificate is initially issued on 27/12/2020 and will be valid for 5 years from the issue date.





Suat KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director

UNIVERSAL





## TECHNICAL EVALUATION REPORT

**REPORT DATE / NO:** 27.12.2020 / 2163-KKD-1847

**Applicant:** DURUTEKS İNŞAAT GIDA TEKSTİL SAN. VE TİC. LTD. ŞTİ.

**Address:** Batı Sitesi Mahallesi Gersan Sanayi Sitesi 2308. Sokak NO:51 Yenimahalle Ankara TURKEY

**Manufacturer:** CARİNO TEKSTİL SAN. VE TİC. LTD.ŞTİ.

**Address:** Hürriyet Mahallesi 2201 Sokak NO:2/A Esenyurt İstanbul TURKEY

### Introduction

This report is prepared based on the evaluations on the technical file of the manufacturer dated 26.12.2020 Version 1, and the test reports obtained from the laboratories for the analysis referenced by the applied harmonised standards for the personal protective equipment identified below. The applicant body holds a subcontracting manufacturing agreement based on the technical file. A list to the test reports is given below which are referenced within this report. The samples for evaluation are provided by the manufacturer for type examination and samples are delivered to the laboratories under UNIVERSAL supervision. The test results and all evaluations within this report belongs to the samples provided. The marking and information were missing on the samples. The evaluation of the marking and information requirements are conducted on the technical file. The manufacturer shall follow the instructions defined in its technical file.

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 gown, as a protective clothing for the part of body [PB], manufactured from blue laminated polypropylene non-woven fabric, inside over lock seams, inbound seams on the neck, touch and close fastener on the nape and with belts. The gown is available in 6 nominal sizes.

**Fabric:** 40 g/m<sup>2</sup> Laminated Spunbond. (20 gsm Spunbond Nonwoven + 18 gsm PP Breathable Film Laminated + 2 gsm Hotmelt)

Belt is same fabric.

**Protective Gown Type:** Type PB [6]-B

**Brand Name:** DURUTEKS

**Model:** DRT GOWN L01

**Sizes Available:** S – M – L – XL – XXL – XXXL

### Applied Harmonised Standards

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

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

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

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

### TEST REPORT INFORMATION

Report #	Laboratory Name	Report Date and Number	Competency Reference
1	Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.	Dated 10.12.2020 Number: 20045847-Ing	Holds TURKAK Accreditation with No: AB-0583-T
2	Çevre Endüstriyel Analiz Laboratuvarı	Dated 23.12.2020 Number: 2030397E-R1	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.





**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.

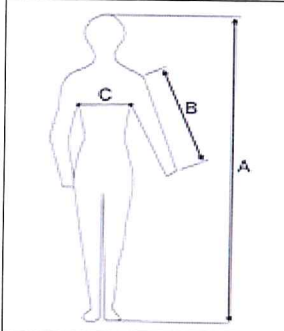

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.





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	<p>EHSR Ref 1.2.1.1;</p> <p>The manufacturer declares in his technical file that the materials used in the manufacturing process of this specific PPE do not adversely affect the health or hygiene of the user. The manufacturer claims that the materials do not, in the foreseeable conditions of normal use, release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, toxic to reproduction or otherwise harmful. These declarations are supported with Material Safety Data Sheets belonging to the materials used in the manufacturing of the PPE. These datasheets claims that the materials are not toxic and do not have risks under normal conditions.</p> <p>The claim of the manufacturer includes non existence of heavy metals including Chromium VI, nonexistence of carcinogenic amines and the pH value of the material is between the allowed range by the standard (3,5 to 8,5).</p> <p>Ref: Technical File Material Identification section.</p>																
Article 4.4	<p>EHSR Ref 1.2.1.2;</p> <p>The comfort of the PPE was subject to visual inspection by our experts for rough, sharp or hard surfaces that irritate or injure the user and found to be appropriate for use. In addition such properties of the PPE was subject to evaluation during the practical exercise testing as defined in the EN ISO 17491-4 testing standard and the PPE is reported as to be comfortable enough to allow the wearer to complete the excercises in practical examination.</p>																
Article 5.3	<p>EHSR Ref 1.2.1;</p> <p>The samples received from the manufacturer are claimed to be single use. No further evaluation is conducted on the dimensional change due to cleaning</p> <p>Ref: Technical File Material Identification section.</p>																
Article 6	<p>EHSR Ref 2.12;</p> <p>The gown 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.</p> <div><div></div><table><thead><tr><th>Size</th><th>A (cm)</th><th>B (cm)</th><th>C (cm)</th></tr></thead><tbody><tr><td>S-M</td><td>115-120</td><td>60-65</td><td>84-100</td></tr><tr><td>L-XL</td><td>120-125</td><td>65-70</td><td>100-116</td></tr><tr><td>XXL-3XL</td><td>125-130</td><td>70-75</td><td>116-132</td></tr></tbody></table></div>	Size	A (cm)	B (cm)	C (cm)	S-M	115-120	60-65	84-100	L-XL	120-125	65-70	100-116	XXL-3XL	125-130	70-75	116-132
Size	A (cm)	B (cm)	C (cm)														
S-M	115-120	60-65	84-100														
L-XL	120-125	65-70	100-116														
XXL-3XL	125-130	70-75	116-132														
Article 7	<p>Ref: Technical File Sizes section.</p> <p>EHSR Ref 2.12;</p> <p>Each piece of gown have marking with the following information;</p> <ul style="list-style-type: none"><li>• Name / trademark of the manufacturer, type of product</li><li>• Size of the gown</li><li>• Applied product standards (Type defining product standards)</li><li>• Applied protection pictograms with standard references</li></ul> <p>The markings on the gown / label are found to be easily visible and enough big to read. The marking</p> <div></div>																



**EN ISO 13688 Standard Requirements Evaluation**

	rules are explained in the marking section of the technical file. For further clarifications for the marking requirements of applied product standards are available in the relevant standard section of this report.
Article 8	<p>EHSR Ref 1.4;</p> <p>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;</p> <ul style="list-style-type: none"><li>• Name / trademark of the manufacturer, its address,</li><li>• Applied standards and relevant classification, marking, size information</li><li>• Pictograms and explanations</li><li>• Gown constituent materials used</li><li>• Instructions for use, controls before use, how to wear / unwear, limitations, instructions for storage conditions, complementary PPEs, re-usability, instructions for disposal</li></ul> <p>The above user information text is available in Turkish</p>





**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.

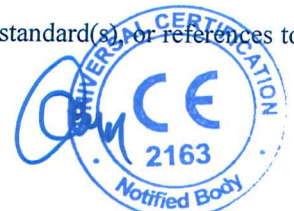
**1.3.3. Compatibility of different types of PPE intended for simultaneous use**

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:

- 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;
- performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;
- where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;
- where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
- where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
- where applicable, the type of packaging suitable for transport;
- the significance of any markings (see point 2.12);
- the risk against which the PPE is designed to protect;
- the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;
- the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;
- references to the relevant harmonised standard(s) used, including the date of the standard(s) or references to the other technical specifications used;
- 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.

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

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

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

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

## **3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS**

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

#### **3.10.2. Protection against cutaneous and ocular contact**

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

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

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



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

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

Article 4.1

EHSR Ref 1.2.1, 1.2.1.1, 1.3.2, 3.10.2;

The gown material performance are tested according to EN 14325:2018 standard for the following properties, since the gown 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 18.5 N Length 38.6 N	Class 1	Class 1 or above	Success
4.9 Tensile Strength	W 36.7 N L 67.6 N	Class 1	Class 1 or above	Success
4.10 Puncture Resistance	5.8 N	Class 1	Class 1 or above	Success
4.12 Liquid repellency	Sulfuric Acid (H <sub>2</sub> SO <sub>4</sub> %30 concentration) Sodium Hydroxide (NaOH %10 concentration) I <sub>R</sub> > 90 %	Class 3	Class 3 at least for 1 chemical	Success
4.10 Resistance to penetration by liquids	Sulfuric Acid (H <sub>2</sub> SO <sub>4</sub> %30 concentration) Sodium Hydroxide (NaOH %10 concentration) o-Xylene (Non diluted) I <sub>P</sub> < 1 %	Class 3	Class 2 at least for 1 chemical	Success

The above results are derived from the test report in the reference below. In the evaluation of the test report it was stated that all the tests are conducted with the completion of conditioning requirements as (20 ± 2) C° and (65 ± 5) % relative humidity for 24 hours.

The manufacturer do not claim a performance for the resistance to ignition or flammability of the product, in the user information sheet it is explained that the gowns must be kept away of fire.

Other requirements referred 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 gown in penetration of liquid through stitch holes or through other components of a seam are evaluated in the seam strength and resistance to penetration by chemicals.

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

Property of Material EN 14325:2018	Result Classification		Requirement of EN ISO 13034	Evaluation
5.5 Seam Strength	Refer to the strength values for seams at different parts of gown. The lowest Class is given among constructive kinds of seams	Class 1	Class 1 or above	Success
4.10 Resistance to penetration by liquids	Sulfuric Acid (H <sub>2</sub> SO <sub>4</sub> %30 concentration) Sodium Hydroxide (NaOH %10 concentration) o-Xylene (Non diluted) I <sub>P</sub> < 1 %	Class 3	Class 3 at least for 1 chemical	Success

Ref: Laboratory Test Report 3





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

<p><i>Article 5.1,5.2</i></p>	<p>EHSR Ref 1.2.1.3, 2.4, 3.10.2;</p> <p>The requirements of the gown with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.</p> <p>The gown under evaluation is a one piece part of body clothing. The necessary additional PPEs must be worn by the wearer for the intended use. The freedom of movements of the wearer is tested (Seven Movements) and found to be appropriate.</p> <p>Since the PPE is part of body clothing, the mist test is not conducted according to Clause 5.2.</p> <p>The above results indicates that the tested gowns complies with the resistance to penetration by liquids.</p> <p>Ref: Laboratory Test Report 1</p>
<p><i>Article 6</i></p>	<p>EHSR Ref 2.12;</p> <p>Each piece of gown have marking with the following information on the single PPE package / PPE itself;</p> <ul style="list-style-type: none"> <li>• Name / trademark of the manufacturer, type and model of PPE</li> <li>• Size of the gown</li> <li>• Applied product standards (EN ISO 13034:2005+A1:2009)</li> <li>• Pictograms for protection against chemicals, invitation to read manufacturer's instructions</li> <li>• Shelf life and date of manufacturing</li> </ul> <p>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 gown is for single use, the markings for re-use cleaning or disinfection is discarded.</p> <p>Ref: Technical File PPE Marking section.</p>
<p><i>Article 7</i></p>	<p>EHSR Ref 1.3.3, 2.4, 2.12;</p> <p>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;</p> <ul style="list-style-type: none"> <li>• Name / trademark of the manufacturer, its address, or the authorised representative for EU community</li> <li>• Type of protection against chemicals (Type PB [6]). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, mask and visor / face shield).</li> <li>• Size of the gown and model name</li> <li>• The standard code / name with the published year</li> <li>• The statement that the gown 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)</li> <li>• Pictogram and information that the PPE is non-reusable also the shelf life is mentioned</li> <li>• Instructions for use, controls before use, how to wear / unwear, limitations, instructions for storage conditions, complementary, instructions for disposal</li> <li>• The statement on the light spray test results</li> <li>• Statement for warning the user on flammability, to keep away of fire</li> </ul> <p>The above user information text is available in Turkish</p> <p>Ref Technical File, User Information Sheet</p>





**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, the instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.





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

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

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

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

**3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS**

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

**3.10.2. Protection against cutaneous and ocular contact**

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

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

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



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

**EN 14126:2003 + AC:2004 Standard Requirements Evaluation**

EHSR Ref 1.3.2;

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

EHSR Ref 1.1.2.2, 3.10.2;

Evaluation of the performance requirements against penetration by infactive agents;

The gown 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 gown material withstands and do not allow any penetration of bacteria under 20kPa hydrostatic pressure and is classified as **Class 6** according to Table 1 given in 4.1.4.1 Clause of this standard,
- The gown 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 gown 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 allows penetration in first cycle of 15 minutes and classified as **Class 1** 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 gown is tested for its resistance to penetration by contaminated solid particles according to ISO 22612:2005 testing standard. The laboratory environmental conditions and the test setup parameters were inline with the standard requirements. The laboratory results indicates that the tested 10 specimens the arithmetic mean of penetration results is smaller than 2 log cfu. The tested sample is classified as **Class 2** 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 Property	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 < 15 min	Class 1	To be Classified
EN ISO 22612 - Resistance to penetration by contaminated solid particles	Penetration 1 < log cfu ≤ 2	Class 2	To be Classified

Ref: Laboratory Test Report 2





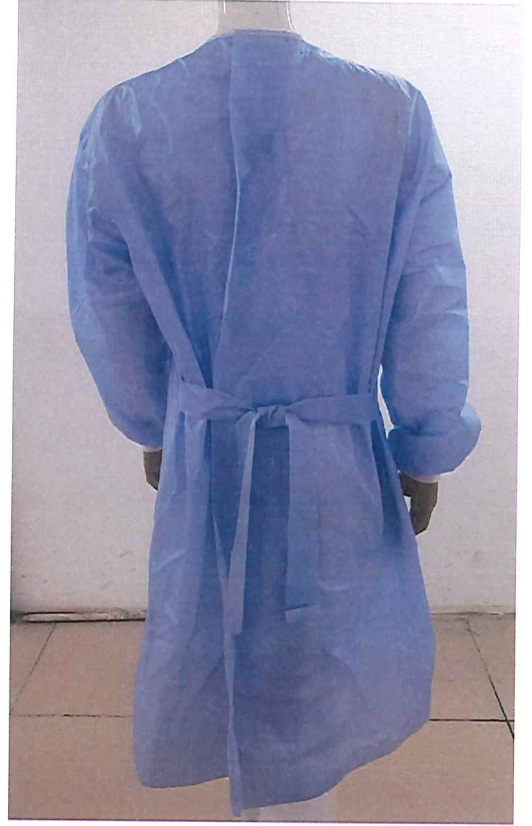
**EN 14126:2003 + AC:2004 Standard Requirements Evaluation**

Article 4.2	<p>EHSR Ref 1.3.2;</p> <p>The seam strength is evaluated and classified based on the test report as shown below;</p> <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 gown. The lowest Class is given among all kinds of seams</td><td>Class 1</td><td>To be Classified</td></tr></table> <p>Ref: Laboratory Test Report 1</p>	Property of Material EN 14325:2018	Result Classification		Requirement of EN EN 14126	5.5 Seam Strength	Refer to the strength values for seams at different parts of gown. The lowest Class is given among all kinds of seams	Class 1	To be Classified
Property of Material EN 14325:2018	Result Classification		Requirement of EN EN 14126						
5.5 Seam Strength	Refer to the strength values for seams at different parts of gown. The lowest Class is given among all kinds of seams	Class 1	To be Classified						
Article 4.3	<p>EHSR Ref 1.3.1, 3.10.2;</p> <p>The PPE under evaluation conforms the relevant requirements of EN ISO 13688 standard. The requirements of the gown with respect to health and safety, ageing and sizing are evaluated in EN ISO 13688 section of this report.</p>								
Article 5	<p>EHSR Ref 2.12;</p> <p>The marking requiremnts for protective clothing against chemicals are evaluated in the relevant section of this report. Additionally;</p> <p>Each piece of gown have marking with the following information on the single PPE package / PPE itself;</p> <ul style="list-style-type: none"><li>Applied product standards (EN 14126:2003+AC:2004)</li><li>Type marking of the PPE as Type PB [6]-B</li><li>the pictogram “protection against biological hazard”</li></ul> <p>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.</p> <p>Ref: Technical File PPE Marking section.</p>								
Article 6	<p>EHSR Ref 1.4;</p> <p>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;</p> <ul style="list-style-type: none"><li>Name / trademark of the manufacturer, its address, or the authorised representative for EU community</li><li>Type of protection against chemicals (Type PB [6]-B). The information also includes a reminder for wearing necessary additional PPE in order to achieve a full body protection (i.e boots, gloves, mask and visor / face shield).</li><li>The standard number (EN 14126)</li><li>The performance levels identified with the tests against infactive agents</li><li>Pictogram and information that the PPE is non-reusable also the shelf life is mentioned</li><li>Instructions for use, controls before use, how to wear / unwear, limitations, instructions for storage conditions, complemantary, instructions for disposal</li></ul> <p>The above user information text is available in Turkish Ref Technical File, User Information Sheet</p>								





**Sample Photo**



PPE Experts contributed to this report:

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Osman CAMCI



Approval  
Suat KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director