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2016/425/EU Personel Protective Equipment Regulation

TYPE PB 3B-PB 4B-PB-6B

TECHNICAL FILE

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I. PRODUCT DESCRIPTION

PRODUCT NAME **:** DISPOSABLE PROTECTIVE GOWN

PRODUCT TYPE **:**

EN ISO 13688 *Protective Clothing – General Requirements*

EN 13034+A1 *Protective Clothing Against Liquid Chemicals (Type 6-B)*

EN 14605+A1 *Protective Clothing Against Liquid Chemicals (Type PB 3-B, Type PB 4-B)*

EN 14126 *Protective Clothing – Performance Requirements And Test Methods For Protective Clothing Against Infective Agents*

MODEL NAME **:** SUVICOM SV-140

DESCRIPTION AND CONTENT: Protective gown, also known as protective clothing, disposable protective gown or antivirus gown. Protective gown is in the class of protective clothing used by medical personnel (doctors, nurses, public health personnel, cleaners, etc.) and people in a certain health area (patients, hospital visitors, people entering the infected area, etc.).

It consists of polypropylene fabric and polyethylene film lamination, polypropylene is 20 g / m^2 weight, contains 2 g adhesive and 18 g lamination. Blue disposable apron; Built for protection against light spray, liquid aerosol and airborne solid particles. It is without tape and stitched. It is for single use only. Shelf life is 2 years. It is not sterile. It can be stored in ambient conditions between -15 ° C and 30 ° C.

INSTRUCTIONS FOR USE

1.Wearing protective gown

1.1 Choose the suitable protective clothing model and size according to the place of use, personal size, chest circumference.

1.2 Read the instructions and notes before wearing and retain the instructions to view as needed.

1.3 Wear protective clothing in designated safety areas.

1.4 Wear safety shoes. Protective clothing should cover your ankles and upper parts of safety shoes.

1.5 Use appropriate face protection equipment correctly: protective masks and goggles, etc.

1.6 Wear protective gloves suitable for the needs of the environment.

1.7 Check the suitability of protective clothing: Before leaving the safe wearing area and entering the hazardous work area, the suitability of the protective clothing can be assessed by raising the arms, bending, squatting and other simple actions.

2. Removing protective gown

In the buffer zone between the contaminated zone and the semi-contaminated zone:

Take off the disposable gown and roll it to the middle → Take off the outer gloves → Take off the goggles →

Enter the buffer zone between the semi-contaminated zone and the clean zone:

Take off the protective gown→ Take off the gloves → Take off the mask and be careful not to touch the outer surface of the mask → disinfect your hands → Enter the clean area, after washing and changing the clothes, you can return to the living area.

3. Precautions for protective gown

Proper training, use and maintenance of protective gown is essential for safety. In any case, please verify that the product is complete, the place of use, that it is wearing correctly, that it has always been worn during exposure and, if necessary, replace it.

Before use, if you need to wear other safety protective equipment (mask, goggles, etc.), the user should read the product instructions carefully to make sure that the protective equipment is matched properly.

After use, in the process of removing protective gown, wash your hands or disinfect hands in all aspects of the process to avoid pollution. Except for the above protective items, the protective mirror to be sterilized, other disposable items should be placed in a designated waste bin for central collection.

AREA OF USE

Protective gown is designed to protect against harmful substances and contamination. It is mainly used against dry particles and less dangerous splashes and sprays. It is the user's responsibility to determine the suitability of protective suits. Protective gown may be contaminated during removal; In such case, it should be removed immediately in order to prevent contamination to the user.

LIMITATIONS

In order to fully meet the requirements of EN 14126 for Type 3/4 and 5/6 suits, when using the protective gown with other personal protective equipment, all closures such as front pats, wrists, neck should be completely closed.

The user should choose suitable size protective clothing for unlimited mobility against the detected risk.

The user is responsible for the suitability of the type of protection required and the correct combination of protective clothing accessories and auxiliary equipment.

After contamination, wear or damage, protective clothing should be removed and disposed of as quickly as possible.

Ensure the integrity of protective clothing before being worn.

The possibility of thermal stress in very hot environments should be taken into account.

Thermal stress can be reduced or eliminated by using the appropriate underwear or ventilation system.

Excessive heat or cold can adversely affect the performance of the protective suit.

Protective clothing should not be used in environments where harmful chemicals that have not been tested are likely to be present.

Although it provides limited protection against various chemicals, attention should be paid to the physical protection levels in Type 3, Type 4 and Type 6 tests.

The user should also wear suitable chemical protective gloves, boots and respiratory protection.

Gloves must have elastic wrists.

STORAGE AND DISPOSAL

It is recommended to keep it dry, protected from light and away from heat sources, in its packaging.
Restrictions on disposal depend entirely on the contamination situation during use.
The manufacturer does not accept any responsibility for improper use and disposal.

EXPIRATION

It is recommended to use within 2 years from the date of manufacture given by the manufacturer.

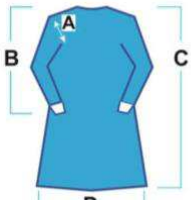
WARNINGS

• In cases where there are solid airborne particles, it is recommended to close the zipper and wrap the ends of the sleeves and leggings with adhesive tape.

II. DESIGN

DESIGN

PRODUCT MODELS : SUVICOM SV-140, DISPOSIBLE PROTECTIVE GOWN
S, M, L, XL, 2XL, 3XL, 4XL SIZES



	XS	S	M	L	XL	2XL	3XL
A	59	61	62	63	64	65	66
B	54	56	59	60	62	64	66
C	113	117	125	132	140	150	131
D	144	146	148	150	152	154	156

III. BASIC HEALTH AND SAFETY REQUIREMENTS

Basic Health and Safety Requirements that the Product Meets

S.No	MUST REQUIREMENTS	RELATED STANDARD	EXPLANATION
1 2	General Principles It is mandatory to apply the basic health and safety requirements set out in this annex. Obligations regarding essential health and safety requirements apply only where there is a relevant risk for the PPE in question.	TS EN 14126 +A1 TS EN 14605+A1	*Situations that may endanger the health and safety of individuals and the measures taken were determined in the Risk Assessment prepared in accordance with the TS EN 14971: 2020 standard and included in the technical file. In addition, the precautions to be taken are specified on the product label. Within the scope of TS EN 14971: 2020 Standard A.2.9 article, the risks of the product are also determined for after-sales.*
3 4 5 1 1.1 1.1. 1.1.1	Basic health and safety requirements should be interpreted and applied in a way that takes technical and economic considerations into account in order to protect health and safety at the highest level during design and manufacture. The manufacturer must carry out a risk assessment to identify the risks prevailing in the PPE. Then it will design and manufacture by taking this evaluation into account. When designing PPE, manufacturing and drawing up instructions, the manufacturer must anticipate not only the intended use of PPE, but also reasonable and predictable use cases. Wherever possible, the health and safety of people other than the user will also be ensured. General Features Required in All PPE PPE should provide adequate protection against all risks encountered during their intended use. Design Principles Ergonomics PPE should be designed and manufactured in such a way as to protect the user at the highest possible level during use in the foreseeable conditions and in the intended direction while performing the work involving risk.	TS EN 14126 +A1	*Controls are made during the production phase and records are kept. Risks have been eliminated as much as possible, and necessary alarms and precautions for unavoidable situations are detailed on the product label.*
1.1.2 1.1.2.1. 1.1.2.2.	Protection Levels and Classes The Highest Level of Protection Possible The most appropriate level of protection to be considered during design is the point at which the effectiveness of PPE begins to decrease when exposed to the risk arising from the use of PPE or during the execution of work under normal conditions. Suitable Protection Classes for Different Risk Levels In the design of PPE, appropriate protection classifications should be taken into account in cases where predictable usage conditions differ, such as distinguishing different levels of the same risk factor.	TS EN 14126 +A1	*There is a risk possibility at every stage, starting from obtaining the raw material until the finished product is delivered to the user, therefore, input and process controls are carried out.*

1.2. **1.2.1.** **1.2.1.1** **1.2.1.2** **1.2.1.3**	PPE Does Not Cause Danger By Itself Absence of Disturbing Factors and Other Risks Arising from the Structure of PPE PPE should be designed and manufactured in such a way that it does not cause dangers and other disturbing factors that may arise from its structure during its use under foreseeable conditions. Made from suitable material PPE material and parts, including those resulting from deterioration, must not adversely affect the health and safety of the user. Compliance of PPE's User Contact Surface Any PPE element that touches or is likely to come into contact with the user when worn, should not be hard enough to cause irritation or injury, and should not have sharp edges and protrusions. PPE does not prevent the user The limitations caused by the PPE to the posture and movement of the body and the loss of sensitivity to the sensory organs should be minimized and the PPE should not cause movements that may be dangerous for the user or other persons.	TS EN 14126 +A1	*All risks that may endanger the safety of the user, which may occur under normal use conditions, are specified in the Risk Assessment section.*
1.3. **1.3.1** **1.3.2.** **1.3.3.** **1.3.4**	Comfort and Efficiency Compliance of PPE to the User's Body Structure PPE should be designed and produced in such a way that the user can easily stand in the correct position on the user and remain in place during the foreseen usage period, taking into account the movements and posture of the body during work. For this purpose, it should be ensured that PPE can be used in the most effective way by ensuring the suitability of the user's body structure with the help of adjustable and attached systems or by producing in different body sizes. Lightness and Durability PPE should be manufactured as light as possible so as not to reduce its durability and functionality. PPE should be able to withstand the effect of ambient conditions under the stipulated conditions of use, which must be fulfilled in order to provide adequate protection against the risks specified in article 4 of this Annex and apart from additional requirements for certain risks. Compatibility of Different PPE Types or Classes Designed to be Used Simultaneously If the same manufacturer introduces different types and classes of PPE models to the market in order to ensure that parts of the body close to each other are protected against these risks in case of multiple risks at the same time, they must be compatible with each other. Protective Clothing with Detachable Protector Protective clothing with detachable protection together constitutes personal protective equipment and should be evaluated together during the conformity assessment procedures.	TS EN 14126 +A1	*Proper conditions and storage environment are provided for each batch of products produced to prevent damage during transportation and storage. Product storage conditions are detailed on the product label.*
1.4.	Information to be Provided by the Manufacturer The manufacturer must give the name and address of the manufacturer or authorized representative of the product, as well as the user		*Manufacturer and authorized representative contact information, all details about security and necessary storage, use, cleaning, maintenance and transportation information for the user, service life,*

	manual containing the following issues, together with the PPE it has put on the market: a) Information on storage, use, cleaning, maintenance, repair and disinfection (cleaning, maintenance and anti-infection agents recommended by the manufacturer should not harm the user or PPE when used in accordance with the instructions given in the user manual), b) Performance results recorded in technical tests applied to measure the class or level of protection provided by the PPE in question, c) Features of accessories and spare parts suitable for the said PPE, ç) Suitable protection classes for different risk levels and corresponding usage limits, d) The useful life or expiry date of PPE or its specific parts, e) Packaging type suitable for transportation, f) Meaning of the signs (see Article 2.12.), g) The risk that PPE is designed to protect ğ) References of harmonized standards, if any, h) The title, address and identity number of the notified body or organizations involved in the conformity assessment procedures of PPE. ı) Reference numbers and dates of the relevant harmonized standard or standards or other technical references used i) Website address where the EU Declaration of Conformity can be accessed The information in the above mentioned articles (ğ), (h), (ı) and (i) does not need to be included in the user manual where the EU Declaration of Conformity accompanies the product. This information must be understandable, precise and in Turkish or, if it is placed on the market in another member country, in the official language or languages of that member country.	TS EN 14126 +A1	*explanations of the symbols on the product, etc. information is specified in labels and user manuals.*

2.	Common Additional Requirements for Certain Types or Classes of PPE		
2.1.	Adjustable PPE If PPE has adjustable systems, these systems should be designed and manufactured in a way to prevent an incorrect adjustment without the knowledge of the user under the foreseen conditions of use.	TS EN 14126 +A1	*There are necessary explanations and symbols about the storage and use of the product on the product labels and in the product user manual. The duration of use of the product has been explained in the technical file.*
2.2.	PPE Covering the Body Part to be Protected PPE covering the body part to be protected should be designed and produced in a way that minimizes the sweating that occurs during use. If this cannot be done, PPE should have equipment to absorb perspiration.		
2.3.	Face, Eye and Respiratory Tract PPE Restrictions caused by PPE used for face, eyes and respiratory tracts in the user's field of vision should be minimized. The optical neutrality degree of the visual systems of this type of PPE should be compatible with the user, relatively long-term or demanding work. If necessary, it should be reinforced with protective material by preventing the formation of fog. PPE models to be used by those who have to wear prescription glasses or contact lenses should be compatible with prescription glasses or contact lenses.		
2.4.	Lifetime of PPE If it is known that the function of a new PPE decreases significantly over time, the date of manufacture and, if possible, the expiry date should be clearly stated on each piece of PPE and its changeable parts, without causing any misunderstanding, and this information should also be included on the packaging of the PPE.		*The duration of use of the product is explained on the product packaging.*
2.5.	PPE Carrying the Risk of Getting Stuck on Surrounding Objects During Use If PPE carries the risk of getting caught by moving objects in the foreseen conditions of use and thus poses a danger to the user, it should have a low crush resistance that eliminates the danger by allowing any part to break in case of being stuck.		
2.6.	PPE Used in Explosive Atmospheres PPE to be used in explosive environments should be designed and manufactured in a way that will not create electricity, static electricity, arcs or sparks that may cause explosive mixtures to ignite.	TS EN 14126 +A1	*N/A*
2.7.	PPE for Quick Attaching and / or Removal or Emergency Use These PPE types should be designed and manufactured to minimize the time required for insertion and / or removal. The parts of the PPE that are used to properly attach or remove them should be in a structure that allows the user to attach or remove them with a quick and easy process.	TS EN 14605+A	*No risk has been observed with other substances and materials that have been contacted under normal conditions of use. The product can be easily put on and taken off by the user.*

2.8.	PPE Used in Very Dangerous Situations The user manual presented together with the PPE used in very dangerous situations and prepared by the manufacturer should contain the necessary data especially for the specialists who are trained to interpret them and ensure the correct application of the PPE by the user. In addition, in the user's manual, the method to be followed to ensure that the PPE is correctly adjusted and functional should be specified. If PPE has an alarm system that activates when it does not provide the normal level of protection, this system should be designed and placed in such a way that it can be easily noticed by the user depending on the usage conditions of the PPE.	TS EN 14126 +A1	NOT APPLIED The product is not designed for use in dangerous situations and has an alarm system.
2.9.	PPE With Elements That Can Be Installed Or Removed By The User PPE elements that can be attached and removed by the user for the purpose of replacement should be designed and manufactured in such a way that they can be easily mounted, removed and adjusted without using any tools.		General information is given on the product labels and in the user manual.
2.10.	PPE Connected Externally to Another Complementary Device If PPE has a complementary system that can be connected with another, the joining mechanism should be designed and manufactured in a way that allows it to be attached only to the appropriate device.	TS EN 14126 +A1	*N/A*
2.11.	PPE Containing a Fluid Circulation System In case PPE has a fluid circulation system, this system should be selected or designed in such a way that it will provide sufficient fluid supply around all of the body parts to be protected and will not be affected by the user's posture or body movements under the foreseen usage conditions.		N/A
2.12.	PPE Carrying One or More Descriptive Signs Related to Health and Safety Indirectly or Directly The descriptive signs affixed to the PPE, directly or indirectly related to health and safety, should be in the form of warning signs (pictograms or ideograms) appropriate to the message they want to convey. They must be perfectly visible and legible and fully retain the understandable state of the PPE during the anticipated lifespan. In addition, these signs should be understandable, precise and complete to avoid any misunderstanding. In particular, if these marks contain a written phrase or word, they must be in the official language or languages of the country in which the device will be used. If the PPE is so small that all or part of the required marks cannot be placed, then the relevant explanatory information must be found on the packaging and in the user manual.	TS EN 14126 +A1	*General information is given on the product labels and in the user manual.*
2.13.	PPE Providing Visibility to the User Wearable PPE to be used in conditions where the visibility of the user is required should have one or more equipment with photometric and colorimetric properties, emitting or reflecting visible light of sufficient intensity, placed in an appropriate position.		NOT APPLIED The product is not a product designed to be visible to the user.

2.14.	PPE Used Against Multiple Risks PPE designed to protect the user against more than one possible risk at the same time should be designed and manufactured to meet the basic requirements of each of these risks.	TS EN 14126 +A1	Products are manufactured under controlled conditions. *N/A*
3. **3.1.** **3.1.1.**	Additional Requirements for Certain Risks Protection Against Mechanical Effects Falling or Throwing Parts Crashing and Colliding with an Obstacle PPE suitable for these types of hazards should have a level of shock absorption to prevent damage (breakage, puncture, crushing, etc.) of the protected part in order to prevent injury that may occur as a result of impact. This type of PPE should, on the one hand, provide the highest possible level of protection, on the other hand, the weight and dimensions of the shock absorbing equipment should be at a level that will not prevent effective use during the foreseen usage period.	TS EN 14126 +A1	NOT APPLIED The product is not designed to protect against falling or flying parts hitting it and colliding with an obstacle.
3.1.2. **3.1.2.1.** **3.1.2.2.** **3.1.3.**	Falls Prevention of Falls Occurring as a Result of Slipping The outer sole of the shoe designed to prevent slipping should be designed and manufactured or reinforced with additional elements to provide sufficient adhesion, taking into account the condition and structure of the surface to be pressed. Prevention of Falls from Height PPE should include a fastening system that can be connected to a secure external anchorage point and a body harness to prevent falls from heights or falls from heights. While the braking force does not reach the limit value that will cause the user to fall in case of physical damage or rupture or tearing of any PPE element, it should be designed and produced in a way that minimizes the vertical fall distance in order to prevent the users from colliding with obstacles under the foreseen conditions of use. This type of PPE should also ensure that, after braking, the user remains in an appropriate position where he can await assistance if needed. The user manual should indicate all relevant information, in particular: a) Requirements for a safe external anchorage point and the minimum vertical distance below the user, b) Equipping the body harness and properly securing a secure external anchorage point. Mechanical Vibration PPE designed to prevent the effects of mechanical vibration should have the capacity to provide a sufficient reduction in harmful vibration components in the part of the body that is at risk.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to prevent falls caused by slipping. NOT APPLIED The product is not a product designed to prevent falls from heights. NOT APPLIED The product is not a product designed to protect against mechanical vibrations.
3.2.	Protecting Any Part of the Body Against Static Pressure PPE designed to protect against static compressive stress of any part of the body should be capable of reducing the pressure effect sufficiently to prevent chronic complaints and serious injury.	TS EN 14126 +A1	NOT APPLIED The product is not designed to protect against static stress.

3.3.	Protection Against Mechanical Injuries PPE material and other parts designed to protect body parts against superficial injuries such as peeling, punctures, cuts and pinching should be selected, designed and assembled in such a way that they are sufficiently durable under the stipulated conditions of use.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to protect against mechanical injury.
3.4. **3.4.1.**	Protection in Liquid Media Prevention of Choking PPE designed to prevent suffocation; After falling into the liquid environment, the user who may be unconscious and very tired should return to the surface as soon as possible and without harm to health and remain in a position that allows the user to breathe on the water. PPE must be made of fully or partially self-floating / buoyant material or must be inflated with gas or breath, manually or automatically. This type of PPE, in the foreseen conditions of use; a) It must be capable of withstanding the effects of contact with the liquid medium and the natural environmental factors of this environment, without preventing its comfortable use, b) Inflatable PPE should be able to inflate fully and in a short time. Where required by some foreseen conditions of use, PPE of certain types should have one or more additional features specified below. a) If it has inflatable feature, necessary equipment for inflation and a device with a light or sound signal should be available when necessary, b) It should have a device that provides connection to the body so that the user can be pulled out of the liquid environment. c) In situations that require entering the liquid environment or have the risk of falling into it, the user should be suitable for use during the whole working period in jobs that are likely to work by wearing PPE.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to prevent suffocation.
3.4.2.	Buoyancy Aids Safe when worn, depending on the anticipated usage conditions, they are equipment that provide support in the water and effectively stay on the water. In the foreseen conditions of use, such PPE should not restrict the user's mobility; in particular, it must enable the user to swim or save other persons or make movements away from danger.		NOT APPLIED The product is not a buoyancy aid product.
3.5.	Protection from the Harmful Effects of Noise PPEs designed to prevent the harmful effects of noise should reduce the noise that the user is exposed to, in a way not to exceed the limit values specified in the Regulation on the Protection of Employees from Noise Related Risks published in the Official Gazette dated 28/8/2013 and numbered 28721. All PPE should have labels indicating the level of noise reduction, if this is not possible, the labels should be attached to the packaging of the PPE.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to protect against the harmful effects of noise.

3.6.	Protection Against Heat and / or Fire PPE designed to protect the whole or a part of the body against the harmful effects of heat and / or fire must have thermal insulation capacity and mechanical durability in accordance with the prescribed usage conditions.		NOT APPLIED The product is not a product designed to protect against the harmful effects of heat and / or fire.
3.6.1.	Material of PPE and Other Elements PPE and other elements that provide protection against radiant and conventional heat should have sufficient heat conduction coefficient and at the same time be made of materials of sufficient strength that will not cause sudden flammability and burning. In places where the outer surfaces of the materials and components from which PPE is made should be reflective; The reflective power should be suitable for the density of the radiant heat flow in the infrared range. In high-temperature environments, PPE produced for short-term use and the material and other elements on which PPE, which is likely to splash hot products such as molten material, are made, in addition to normal protection, the stored heat is greatly It should also have sufficient thermal capacity to hold the part. This type of PPE material and other elements should also have sufficient mechanical shock absorption (see Article 3.1.). PPE material and other components that are likely to come into contact with a naked flame and materials used in the manufacture of fire extinguishing equipment, besides normal protection, must have a degree of non-flammability, thermal or arc heat protection that corresponds to the risk class in the stipulated conditions of use. These materials should not melt when exposed to flame and should not contribute to the spread of the flame.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to protect against the harmful effects of heat and / or fire.
3.6.2.	Ready-to-use PPE In the foreseen conditions of use; a) The amount of heat transmitted by the PPE to the user should be low enough to prevent the accumulation of heat in the body parts at risk during wearing, from reaching the limit or pain threshold that will harm health in any way. b) PPE should prevent leakage of liquid and vapor when necessary and should not cause burns when it comes into contact with the user. PPE with a cooling system based on absorption of the heat in the environment through liquid substance evaporation or solid substance sublimation; volatile substances released from this system should be designed in such a way that they are thrown out of the preservative and not towards the user. Respirators to be used in combination with a PPE should be able to fully perform the protection task expected from them under the prescribed conditions of use. In high temperature environments, the user manual, which should be given with PPE for short-term use, should contain all the necessary information to determine the maximum permissible level of heat exposure transmitted to the user by the device, especially when used for the intended purpose.		NOT APPLIED The product is not a product designed to protect against the harmful effects of heat and / or fire.

3.7.	Cold Protection PPE designed to protect part or all of the body against the effects of cold should have mechanical endurance and thermal insulation capacity in accordance with the anticipated usage conditions.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to protect against the effects of cold.
3.7.1.	Material of PPE and Other Elements PPE material and other elements suitable for protection against cold must have a low thermal conductivity coefficient required by the stipulated conditions of use. The flexible parts and other elements in PPE to be used in low temperature environments should have the required degree of flexibility in order for the user to take the appropriate position and make his movements easily. The material and other elements of the PPE to be used against large amounts of splashes from cold materials should also have sufficient mechanical shock absorption (see Article 3.1.).		NOT APPLIED The product is not a product designed to protect against the effects of cold.
3.7.2.	Ready-to-Use PPE In the foreseen conditions of use; a) The heat flow transmitted from the PPE to the user during the period of wearing should be low in all circumstances, at a level that does not harm the health and does not reach the pain threshold, in any case, the cold accumulation that will occur in any part of the body that needs to be protected, including the tips of the fingers and toes. b) PPE should prevent the infiltration of rain water and similar liquids as much as possible, contact of cold protective surfaces with the user should not cause any injury. Respirator to be used in combination with protective PPE against cold, should fully perform the protection task expected from it under the prescribed conditions of use. User manual given with PPE produced for short-term use in low temperature environments; It should also contain all necessary information regarding the maximum permissible level of cold exposure transmitted by the device to the user.		NOT APPLIED The product is not a product designed to protect against the effects of cold.

3.8.	Protection Against Electric Shock		NOT APPLIED
3.8.1.	Insulation Equipment PPE designed to protect the whole or a part of the body against the effects of electric current should be insulated sufficiently against the voltages that the user may be exposed to under the most adverse conditions foreseen. In order to achieve this purpose, the material and other elements of this type of PPE should be tested under conditions suitable for the voltages that may be encountered in real working environments and the amount of leakage current passing through the protective surface should be measured. The material of PPE and other elements should be selected, designed and combined so that the measured value is below the maximum allowed value corresponding to the tolerance threshold value in all circumstances. In the type of PPE to be used in the work done in the live or potential electrical installation and in their packaging; In particular, there should be signs indicating the date of manufacture, serial number, appropriate voltage of use and / or protection class. In addition, on the outer surface of this type of PPE, an empty space should be left to write the starting date and the periodic test and control dates to be made respectively. In the user's manual, the frequency and type of dielectric tests that should be done especially during the lifetime and the purposes for which such PPE will be used should be specified.	TS EN 14126 +A1	The product is not an insulating equipment.
3.8.2.	Conductive Equipment PPE used in high voltage live lines should be designed and produced to ensure that there is no potential difference between the installation that the user and the user intervened with.	TS EN 14126 +A1	NOT APPLIED The product is not conductive equipment.

3.9.	Radiation Protection		NOT APPLIED
3.9.1.	Non-Ionizing Radiation PPE designed to protect the eye from acute or chronic damages caused by non-ionizing radiation sources should be capable of absorbing or reflecting the vast majority of the light energy emitted at harmful wavelengths. However, it should not adversely affect the distinction of colors, perception of details and the passage of harmless light in the visual range required by the stipulated conditions of use. In order to achieve this goal, protective glasses must be designed and manufactured in such a way that, for each harmful wavelength, the light energy that can reach the user's eye through the filter minimizes the intensity of illumination and in no way exceeds the maximum permissible exposure value. In addition, under the foreseen conditions of use, the properties of the glasses should not be deteriorated or lost by the effect of the emitted rays. In all types of glasses offered to the market, the protection factor number corresponding to the spectral distribution curve of the transmittance factor must be found. Glasses to be used for the same type of radiation sources will be classified according to the levels of protection factors. In the user manual; In particular, the permeability curve that will enable the selection of the most suitable PPE should be given, taking into account the conditions of use according to the distance from the source and the spectral distribution of the energy emitted at this distance. The relevant protection factor number must be attached to all types of filter glasses by the manufacturer.	TS EN 14126 +A1	The product is not a product that protects from non-ionizing radiation.
3.9.2.	Ionizing Radiation		
3.9.2.1	Protection from Outdoor Radioactive Pollution The material and other elements of PPE designed to protect the whole or part of the body from radioactive powders, gases, liquids or their mixture should be selected, designed and combined in a way that effectively prevents the infiltration of radioactive contaminants under the prescribed conditions of use. Depending on the nature or condition of these contaminants, the required sealing should be provided by the impermeability of the protective surface and / or by any other suitable means, such as pressure application and normal ventilation designed to prevent the re-diffusion of these contaminants. None of the radiation purification measures applied to PPE should prevent the reuse of such equipment within the anticipated lifetime.	TS EN 14126 +A1	NOT APPLIED The product is not a product that provides protection from external radioactive pollution.
3.9.2.2	Limited Protection Against External Radioactive Radiation PPEs used to completely protect the user from external radioactive radiation or to reduce the effect of the radiation sufficiently if this cannot be achieved, should primarily be designed to resist weak electron radiation such as beta or weak photon radiation such as X, gamma. The material and other elements of this class of PPE should be selected or designed and combined to provide the protection level required by the anticipated usage conditions without causing an increase in the exposure time by obstructing the user's movements or standing position. (See Article 1.3.2.)		NOT APPLIED The product is not a product that provides protection against external radioactive radiation.

	PPE should have a mark indicating the appropriate material type and equivalent thickness for the envisaged usage conditions.		
3.10.	Protection from Hazardous Substances and Mixtures and Harmful Biological Agents		NOT APPLIED
3.10.1	Protection of Respiratory System PPE designed for the protection of respiratory tracts should be capable of providing breathable air to the user in case of exposure to contaminated ambient air and / or insufficient oxygen in the environment. Breathable air supplied to the user through PPE; It should be obtained by appropriate methods such as filtering the dirty air with protective tools or devices or providing clean air from a source through a piping system. The material and other elements of this class of PPE should be selected or designed and combined in a hygienic manner that will provide the user with adequate breathing during wearing under the prescribed conditions of use. The impermeability of the parts protecting the face, the pressure drop during breathing and the cleaning capacity of the filters should be capable of protecting the ingress of contaminants in the environment, the health and hygiene of the user. PPE should contain the manufacturer's identification mark and details indicating the features of such equipment; This information, together with the user manual, should enable the correct use of PPE by the user by trained and qualified persons. In cases where filter devices are used, the storage life of the filters should also be specified in the user manual, if these devices are preserved in their original packaging without ever being used.	TS EN 14126 +A1	The product is not a product designed for respiratory protection.
3.10.2	Skin and Eye Protection The protective surfaces of PPE produced to protect the whole or part of the body surface from contact with hazardous substances and mixtures or harmful biological agents should be capable of preventing the passage or leakage of such substances to the user under the foreseen conditions of use. For this purpose, the materials and other elements of this class of PPE should be selected or designed and combined in a way that ensures a complete sealing as possible so that they can be used throughout the day when necessary. In cases where the tightness cannot be fully achieved, the wearing time should be limited. PPE should be subjected to standard tests based on efficiency for classification purposes in cases where certain hazardous substances and mixtures with high leakage power or harmful biological agents are in question due to their structures and foreseen conditions of use and these limit the protection period provided by PPE. PPE that is accepted to be in accordance with the specifications specified in the tests should contain information showing the names of the substances used in the tests or, if this cannot be done, their codes and corresponding standard protection periods. In particular, the user manual should include a description of the codes, a detailed description of the standard tests, if necessary, and all the necessary information to determine the maximum allowable period of use under the various stipulated conditions of use.	TS EN 14126 +A1	*The product is designed and manufactured to prevent the contact of hazardous substances and mixtures to the user during use. No substance leaks into the body during the use of the product.* *The materials used in the production of the product are designed and manufactured to ensure impermeability throughout its life. Necessary explanations, usage instructions and service life are clearly stated in the user manual and product labels.*

3.11.	Diving Equipment In particular, respirators should make it possible to provide the user with a breathable gas mixture, taking into account the maximum immersion depth and under the envisaged conditions of use. If required by the stipulated conditions of use, diving equipment should be equipped with the following equipment: a) A set of clothing to protect the user from the pressure caused by the immersion depth (see 3.2.) and / or cold (see 3.7.), b) An alarm system designed to immediately notify the user that the supply of respirable gas mixture is about to be interrupted (see Article 2.8.2), c) A life-saving clothing set that will enable the user to resurface (see 3.4.1.).	TS EN 14126 +A1	NOT APPLIED The product is not diving equipment.

IV. RISK ANALYSIS

RISK ANALYSIS REPORT			
RISK ASSESSMENT			
EFFECT		**PROBABILITY**	
DEVASTATING	5	OFTEN	5
IMPORTANT	4	LIKELY	4
MIDDLE	3	FAR	3
SMALL	2	IMPOSSIBLE	2
INSIGNIFICANT	1	EXCEPTIONAL	1

RISK = EFFECT * PROBABILITY

EFFECT		**PROBABILITY**				
E	ASSESSMENT	**O1**	**O2**	**O3**	**O4**	**O5**
E1	1	**1*1=1**	**1*2=2**	**1*3=3**	**1*4=4**	**1*5=5**
E2	2	**2*1=2**	**2*2=4**	**2*3=6**	**2*4=8**	**2*5=10**
E3	3	**3*1=3**	**3*2=6**	**3*3=9**	**3*4=12**	**3*5=15**
E4	4	**4*1=4**	**4*2=8**	**4*3=12**	**4*4=16**	**4*5=20**
E5	5	**5*1=5**	**5*2=10**	**5*3=15**	**5*4=20**	**5*5=25**

Green Zone; Acceptable Risk Zone (ARZ)

Blue Zone; Acceptable Zone Provided That Precaution Is Taken (AZPTPIT)

Red Zone; Unacceptable Risk Zone (URZ)

RISK ANALYSIS TABLE								
Risk	**Before Precautions**			**Hedging Method**	**After Precautions**			**Situation After Taking Action**
	Effect	**Probability**	**Effect*Probability**		**Effect**	**Probability**	**Effect*Probability**	
Damage in the structure of the product due to the use of the expired product	5	4	20	The shelf life of the product is indicated on the product label (2 years).	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.
Failure to provide protection as a result of multiple use of the product	5	4	20	The presence of a warning in the product manual and on the product label that the product is for single use only.	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.
Damage in the structure of the product as a result of exposure to direct sunlight.	5	4	20	Presence of "Protect from sunlight" warning on the product label and user manual.	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.
Using products with torn packaging	5	4	20	Indication of a warning about not using damaged packaged products on the product label and in the user manual.	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.
Contamination (contamination, burning, etc.) as a result of using damaged products.	5	4	20	Indication of a warning about not using damaged products on the product label and in the user manual	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.

CONCLUSION: As a result of the risk assessment, the existing risks were reduced to an acceptable level. Necessary warnings for risks are indicated on the label. The substances in the structure of the product do not pose a risk to the user's health. The product has been found to be adequate in terms of performance and reliable for use.

V. LABELING

Explanation of Symbols Used on the Label

PODIMA MEDICAL	**(Manufacturer (Manufactured by)** **PODIMA MEDIKAL VE TEKSTIL SAN. TIC. LTD. STI.** **YUKARI DUDULLU MAHALLESI BAYRAK CADDESI NO: 30 DAIRE: 130/131 UMRANIYE 34775 ISTANBUL / TURKIYE** Tel. : +902165405881 / +90532421985 www.podimamedikal.com info@podimamedikal.com

LOT No


Production Date


Whole body protection according to Chemical Protective Clothing standards set by the European Union EN 13982-1 (Type 5), EN 13034 (Type 6).


Keep away from flame and heat


Read the user manual


Do not iron


Do not dry clean


Do not wash


Complies with 89/686 / PPE directive


Do not use bleach.


Do not tumble dry.

Single use only

VI. HARMONIZED STANDARDS

HARMONIZED STANDARDS

EN ISO 13688
Protective Clothing – General Requirements

EN 13034+A1
Protective Clothing Against Liquid Chemicals (Type 6-B)

EN 14605+A1
Protective Clothing Against Liquid Chemicals (Type PB 3-B, Type PB 4-B)

EN 14126
Protective Clothing – Performance Requirements And Test Methods For Protective Clothing Against Infective Agents

2016/425/EU Personel Protective Equipment Regulation

TYPE PB-6B

TECHNICAL FILE

PODIMA MEDIKAL VE TEKSTIL SAN. TIC. LTD. STI.
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Tel. : +902165405881 / +90532421985
www.poimamedikal.com
info@podimamedikal.com

I.

PRODUCT DESCRIPTION

PRODUCT NAME **:** DISPOSABLE PROTECTIVE GOWN

PRODUCT TYPE **:**

EN ISO 13688 *Protective Clothing – General Requirements*

EN 13034+A1 *Protective Clothing Against Liquid Chemicals (Type 6-B)*

MODEL NAME **:** SUVICOM SV-180

DESCRIPTION AND CONTENT: Protective gown, also known as protective clothing, disposable protective gown or antivirus gown. Protective gown is in the class of protective clothing used by medical personnel (doctors, nurses, public health personnel, cleaners, etc.) and people in a certain health area (patients, hospital visitors, people entering the infected area, etc.).

It consists of SS / Polypropylene fabric and weighs 40 g / m^2. Blue disposable apron; It is produced for protection against liquid chemicals. It is without tape and stitched. It is for single use only. Shelf life is 2 years. It is not sterile. It can be stored in ambient conditions between -15 ° C and 30 ° C.

INSTRUCTIONS FOR USE

1.Wearing protective gown

1.1 Choose the suitable protective clothing model and size according to the place of use, personal size, chest circumference.

1.2 Read the instructions and notes before wearing and retain the instructions to view as needed.

1.3 Wear protective clothing in designated safety areas.

1.4 Wear safety shoes. Protective clothing should cover your ankles and upper parts of safety shoes.

1.5 Use appropriate face protection equipment correctly: protective masks and goggles, etc.

1.6 Wear protective gloves suitable for the needs of the environment.

1.7 Check the suitability of protective clothing: Before leaving the safe wearing area and entering the hazardous work area, the suitability of the protective clothing can be assessed by raising the arms, bending, squatting and other simple actions.

2. Removing protective gown

In the buffer zone between the contaminated zone and the semi-contaminated zone:

Take off the disposable gown and roll it to the middle → Take off the outer gloves → Take off the goggles →

Enter the buffer zone between the semi-contaminated zone and the clean zone:

Take off the protective gown→ Take off the gloves → Take off the mask and be careful not to touch the outer surface of the mask → disinfect your hands → Enter the clean area, after washing and changing the clothes, you can return to the living area.

3. Precautions for protective gown

Proper training, use and maintenance of protective gown is essential for safety. In any case, please verify that the product is complete, the place of use, that it is wearing correctly, that it has always been worn during exposure and, if necessary, replace it.

Before use, if you need to wear other safety protective equipment (mask, goggles, etc.), the user should read the product instructions carefully to make sure that the protective equipment is matched properly.

After use, in the process of removing protective gown, wash your hands or disinfect hands in all aspects of the process to avoid pollution. Except for the above protective items, the protective mirror to be sterilized, other disposable items should be placed in a designated waste bin for central collection.

AREA OF USE

Protective gown is designed to protect against harmful substances and contamination. It is mainly used against dry particles and less dangerous splashes and sprays. It is the user's responsibility to determine the suitability of protective suits. Protective gown may be contaminated during removal; In such case, it should be removed immediately in order to prevent contamination to the user.

LIMITATIONS

The user should choose suitable size protective clothing for unlimited mobility against the detected risk.
The user is responsible for the suitability of the type of protection required and the correct combination of protective clothing accessories and auxiliary equipment.
After contamination, wear or damage, protective clothing should be removed and disposed of as quickly as possible.
Ensure the integrity of protective clothing before being worn.
The possibility of thermal stress in very hot environments should be taken into account.
Thermal stress can be reduced or eliminated by using the appropriate underwear or ventilation system.
Excessive heat or cold can adversely affect the performance of the protective suit.
Protective clothing should not be used in environments where harmful chemicals that have not been tested are likely to be present.
Although it provides limited protection against various chemicals, attention should be paid to the physical protection levels in Type 6 tests.
The user should also wear suitable chemical protective gloves, boots and respiratory protection.
Gloves must have elastic wrists.

STORAGE AND DISPOSAL

It is recommended to keep it dry, protected from light and away from heat sources, in its packaging.
Restrictions on disposal depend entirely on the contamination situation during use.
The manufacturer does not accept any responsibility for improper use and disposal.

EXPIRATION

It is recommended to use within 2 years from the date of manufacture given by the manufacturer.

WARNINGS

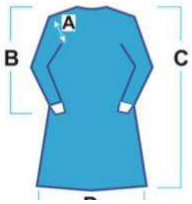
• In cases where there are solid airborne particles, it is recommended to close the zipper and wrap the ends of the sleeves and leggings with adhesive tape.

II. DESIGN

DESIGN

PRODUCT MODELS : SUVICOM SV-180, DISPOSIBLE PROTECTIVE GOWN

S, M, L, XL, 2XL, 3XL, 4XL SIZES



	XS	S	M	L	XL	2XL	3XL
A	59	61	62	63	64	65	66
B	54	56	59	60	62	64	66
C	113	117	125	132	140	150	131
D	144	146	148	150	152	154	156

III. BASIC HEALTH AND SAFETY REQUIREMENTS

Basic Health and Safety Requirements that the Product Meets

S.No	MUST REQUIREMENTS	RELATED STANDARD	EXPLANATION
1 2	General Principles It is mandatory to apply the basic health and safety requirements set out in this annex. Obligations regarding essential health and safety requirements apply only where there is a relevant risk for the PPE in question.	TS EN 14126 +A1 TS EN 14605+A1	*Situations that may endanger the health and safety of individuals and the measures taken were determined in the Risk Assessment prepared in accordance with the TS EN 14971: 2020 standard and included in the technical file. In addition, the precautions to be taken are specified on the product label. Within the scope of TS EN 14971: 2020 Standard A.2.9 article, the risks of the product are also determined for after-sales.*
3 4 5 1 1.1 1.1. 1.1.1	Basic health and safety requirements should be interpreted and applied in a way that takes technical and economic considerations into account in order to protect health and safety at the highest level during design and manufacture. The manufacturer must carry out a risk assessment to identify the risks prevailing in the PPE. Then it will design and manufacture by taking this evaluation into account. When designing PPE, manufacturing and drawing up instructions, the manufacturer must anticipate not only the intended use of PPE, but also reasonable and predictable use cases. Wherever possible, the health and safety of people other than the user will also be ensured. General Features Required in All PPE PPE should provide adequate protection against all risks encountered during their intended use. Design Principles Ergonomics PPE should be designed and manufactured in such a way as to protect the user at the highest possible level during use in the foreseeable conditions and in the intended direction while performing the work involving risk.	TS EN 14126 +A1	*Controls are made during the production phase and records are kept. Risks have been eliminated as much as possible, and necessary alarms and precautions for unavoidable situations are detailed on the product label.*
1.1.2 1.1.2.1. 1.1.2.2.	Protection Levels and Classes The Highest Level of Protection Possible The most appropriate level of protection to be considered during design is the point at which the effectiveness of PPE begins to decrease when exposed to the risk arising from the use of PPE or during the execution of work under normal conditions. Suitable Protection Classes for Different Risk Levels In the design of PPE, appropriate protection classifications should be taken into account in cases where predictable usage conditions differ, such as distinguishing different levels of the same risk factor.	TS EN 14126 +A1	*There is a risk possibility at every stage, starting from obtaining the raw material until the finished product is delivered to the user, therefore, input and process controls are carried out.*

1.2. **1.2.1.** **1.2.1.1** **1.2.1.2** **1.2.1.3**	PPE Does Not Cause Danger By Itself Absence of Disturbing Factors and Other Risks Arising from the Structure of PPE PPE should be designed and manufactured in such a way that it does not cause dangers and other disturbing factors that may arise from its structure during its use under foreseeable conditions. Made from suitable material PPE material and parts, including those resulting from deterioration, must not adversely affect the health and safety of the user. Compliance of PPE's User Contact Surface Any PPE element that touches or is likely to come into contact with the user when worn, should not be hard enough to cause irritation or injury, and should not have sharp edges and protrusions. PPE does not prevent the user The limitations caused by the PPE to the posture and movement of the body and the loss of sensitivity to the sensory organs should be minimized and the PPE should not cause movements that may be dangerous for the user or other persons.	TS EN 14126 +A1	*All risks that may endanger the safety of the user, which may occur under normal use conditions, are specified in the Risk Assessment section.*
1.3. **1.3.1** **1.3.2.** **1.3.3.** **1.3.4**	Comfort and Efficiency Compliance of PPE to the User's Body Structure PPE should be designed and produced in such a way that the user can easily stand in the correct position on the user and remain in place during the foreseen usage period, taking into account the movements and posture of the body during work. For this purpose, it should be ensured that PPE can be used in the most effective way by ensuring the suitability of the user's body structure with the help of adjustable and attached systems or by producing in different body sizes. Lightness and Durability PPE should be manufactured as light as possible so as not to reduce its durability and functionality. PPE should be able to withstand the effect of ambient conditions under the stipulated conditions of use, which must be fulfilled in order to provide adequate protection against the risks specified in article 4 of this Annex and apart from additional requirements for certain risks. Compatibility of Different PPE Types or Classes Designed to be Used Simultaneously If the same manufacturer introduces different types and classes of PPE models to the market in order to ensure that parts of the body close to each other are protected against these risks in case of multiple risks at the same time, they must be compatible with each other. Protective Clothing with Detachable Protector Protective clothing with detachable protection together constitutes personal protective equipment and should be evaluated together during the conformity assessment procedures.	TS EN 14126 +A1	*Proper conditions and storage environment are provided for each batch of products produced to prevent damage during transportation and storage. Product storage conditions are detailed on the product label.*
1.4.	Information to be Provided by the Manufacturer The manufacturer must give the name and address of the manufacturer or authorized representative of the product, as well as the user		*Manufacturer and authorized representative contact information, all details about security and necessary storage, use, cleaning, maintenance and transportation information for the user, service life,*

	manual containing the following issues, together with the PPE it has put on the market: a) Information on storage, use, cleaning, maintenance, repair and disinfection (cleaning, maintenance and anti-infection agents recommended by the manufacturer should not harm the user or PPE when used in accordance with the instructions given in the user manual), b) Performance results recorded in technical tests applied to measure the class or level of protection provided by the PPE in question, c) Features of accessories and spare parts suitable for the said PPE, ç) Suitable protection classes for different risk levels and corresponding usage limits, d) The useful life or expiry date of PPE or its specific parts, e) Packaging type suitable for transportation, f) Meaning of the signs (see Article 2.12.), g) The risk that PPE is designed to protect ğ) References of harmonized standards, if any, h) The title, address and identity number of the notified body or organizations involved in the conformity assessment procedures of PPE. ı) Reference numbers and dates of the relevant harmonized standard or standards or other technical references used i) Website address where the EU Declaration of Conformity can be accessed The information in the above mentioned articles (ğ), (h), (ı) and (i) does not need to be included in the user manual where the EU Declaration of Conformity accompanies the product. This information must be understandable, precise and in Turkish or, if it is placed on the market in another member country, in the official language or languages of that member country.	TS EN 14126 +A1	*explanations of the symbols on the product, etc. information is specified in labels and user manuals.*

2.	Common Additional Requirements for Certain Types or Classes of PPE		
2.1.	Adjustable PPE If PPE has adjustable systems, these systems should be designed and manufactured in a way to prevent an incorrect adjustment without the knowledge of the user under the foreseen conditions of use.	TS EN 14126 +A1	*There are necessary explanations and symbols about the storage and use of the product on the product labels and in the product user manual. The duration of use of the product has been explained in the technical file.*
2.2.	PPE Covering the Body Part to be Protected PPE covering the body part to be protected should be designed and produced in a way that minimizes the sweating that occurs during use. If this cannot be done, PPE should have equipment to absorb perspiration.		
2.3.	Face, Eye and Respiratory Tract PPE Restrictions caused by PPE used for face, eyes and respiratory tracts in the user's field of vision should be minimized. The optical neutrality degree of the visual systems of this type of PPE should be compatible with the user, relatively long-term or demanding work. If necessary, it should be reinforced with protective material by preventing the formation of fog. PPE models to be used by those who have to wear prescription glasses or contact lenses should be compatible with prescription glasses or contact lenses.		
2.4.	Lifetime of PPE If it is known that the function of a new PPE decreases significantly over time, the date of manufacture and, if possible, the expiry date should be clearly stated on each piece of PPE and its changeable parts, without causing any misunderstanding, and this information should also be included on the packaging of the PPE.		*The duration of use of the product is explained on the product packaging.*
2.5.	PPE Carrying the Risk of Getting Stuck on Surrounding Objects During Use If PPE carries the risk of getting caught by moving objects in the foreseen conditions of use and thus poses a danger to the user, it should have a low crush resistance that eliminates the danger by allowing any part to break in case of being stuck.		
2.6.	PPE Used in Explosive Atmospheres PPE to be used in explosive environments should be designed and manufactured in a way that will not create electricity, static electricity, arcs or sparks that may cause explosive mixtures to ignite.	TS EN 14126 +A1	*N/A*
2.7.	PPE for Quick Attaching and / or Removal or Emergency Use These PPE types should be designed and manufactured to minimize the time required for insertion and / or removal. The parts of the PPE that are used to properly attach or remove them should be in a structure that allows the user to attach or remove them with a quick and easy process.	TS EN 14605+A	*No risk has been observed with other substances and materials that have been contacted under normal conditions of use. The product can be easily put on and taken off by the user.*

2.8.	PPE Used in Very Dangerous Situations The user manual presented together with the PPE used in very dangerous situations and prepared by the manufacturer should contain the necessary data especially for the specialists who are trained to interpret them and ensure the correct application of the PPE by the user. In addition, in the user's manual, the method to be followed to ensure that the PPE is correctly adjusted and functional should be specified. If PPE has an alarm system that activates when it does not provide the normal level of protection, this system should be designed and placed in such a way that it can be easily noticed by the user depending on the usage conditions of the PPE.	TS EN 14126 +A1	NOT APPLIED The product is not designed for use in dangerous situations and has an alarm system.
2.9.	PPE With Elements That Can Be Installed Or Removed By The User PPE elements that can be attached and removed by the user for the purpose of replacement should be designed and manufactured in such a way that they can be easily mounted, removed and adjusted without using any tools.	TS EN 14126 +A1	General information is given on the product labels and in the user manual. *N/A*
2.10.	PPE Connected Externally to Another Complementary Device If PPE has a complementary system that can be connected with another, the joining mechanism should be designed and manufactured in a way that allows it to be attached only to the appropriate device.		N/A
2.11.	PPE Containing a Fluid Circulation System In case PPE has a fluid circulation system, this system should be selected or designed in such a way that it will provide sufficient fluid supply around all of the body parts to be protected and will not be affected by the user's posture or body movements under the foreseen usage conditions.		*General information is given on the product labels and in the user manual.*
2.12.	PPE Carrying One or More Descriptive Signs Related to Health and Safety Indirectly or Directly The descriptive signs affixed to the PPE, directly or indirectly related to health and safety, should be in the form of warning signs (pictograms or ideograms) appropriate to the message they want to convey. They must be perfectly visible and legible and fully retain the understandable state of the PPE during the anticipated lifespan. In addition, these signs should be understandable, precise and complete to avoid any misunderstanding. In particular, if these marks contain a written phrase or word, they must be in the official language or languages of the country in which the device will be used. If the PPE is so small that all or part of the required marks cannot be placed, then the relevant explanatory information must be found on the packaging and in the user manual.	TS EN 14126 +A1	
2.13.	PPE Providing Visibility to the User Wearable PPE to be used in conditions where the visibility of the user is required should have one or more equipment with photometric and colorimetric properties, emitting or reflecting visible light of sufficient intensity, placed in an appropriate position.		NOT APPLIED The product is not a product designed to be visible to the user.

2.14.	PPE Used Against Multiple Risks PPE designed to protect the user against more than one possible risk at the same time should be designed and manufactured to meet the basic requirements of each of these risks.	TS EN 14126 +A1	Products are manufactured under controlled conditions. *N/A*
3. **3.1.** **3.1.1.**	Additional Requirements for Certain Risks Protection Against Mechanical Effects Falling or Throwing Parts Crashing and Colliding with an Obstacle PPE suitable for these types of hazards should have a level of shock absorption to prevent damage (breakage, puncture, crushing, etc.) of the protected part in order to prevent injury that may occur as a result of impact. This type of PPE should, on the one hand, provide the highest possible level of protection, on the other hand, the weight and dimensions of the shock absorbing equipment should be at a level that will not prevent effective use during the foreseen usage period.	TS EN 14126 +A1	NOT APPLIED The product is not designed to protect against falling or flying parts hitting it and colliding with an obstacle.
3.1.2. **3.1.2.1.** **3.1.2.2.** **3.1.3.**	Falls Prevention of Falls Occurring as a Result of Slipping The outer sole of the shoe designed to prevent slipping should be designed and manufactured or reinforced with additional elements to provide sufficient adhesion, taking into account the condition and structure of the surface to be pressed. Prevention of Falls from Height PPE should include a fastening system that can be connected to a secure external anchorage point and a body harness to prevent falls from heights or falls from heights. While the braking force does not reach the limit value that will cause the user to fall in case of physical damage or rupture or tearing of any PPE element, it should be designed and produced in a way that minimizes the vertical fall distance in order to prevent the users from colliding with obstacles under the foreseen conditions of use. This type of PPE should also ensure that, after braking, the user remains in an appropriate position where he can await assistance if needed. The user manual should indicate all relevant information, in particular: a) Requirements for a safe external anchorage point and the minimum vertical distance below the user, b) Equipping the body harness and properly securing a secure external anchorage point. Mechanical Vibration PPE designed to prevent the effects of mechanical vibration should have the capacity to provide a sufficient reduction in harmful vibration components in the part of the body that is at risk.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to prevent falls caused by slipping. NOT APPLIED The product is not a product designed to prevent falls from heights. NOT APPLIED The product is not a product designed to protect against mechanical vibrations.
3.2.	Protecting Any Part of the Body Against Static Pressure PPE designed to protect against static compressive stress of any part of the body should be capable of reducing the pressure effect sufficiently to prevent chronic complaints and serious injury.	TS EN 14126 +A1	NOT APPLIED The product is not designed to protect against static stress.

3.3.	Protection Against Mechanical Injuries PPE material and other parts designed to protect body parts against superficial injuries such as peeling, punctures, cuts and pinching should be selected, designed and assembled in such a way that they are sufficiently durable under the stipulated conditions of use.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to protect against mechanical injury.
3.4. **3.4.1.** **3.4.2.**	Protection in Liquid Media Prevention of Choking PPE designed to prevent suffocation; After falling into the liquid environment, the user who may be unconscious and very tired should return to the surface as soon as possible and without harm to health and remain in a position that allows the user to breathe on the water. PPE must be made of fully or partially self-floating / buoyant material or must be inflated with gas or breath, manually or automatically. This type of PPE, in the foreseen conditions of use; a) It must be capable of withstanding the effects of contact with the liquid medium and the natural environmental factors of this environment, without preventing its comfortable use, b) Inflatable PPE should be able to inflate fully and in a short time. Where required by some foreseen conditions of use, PPE of certain types should have one or more additional features specified below. a) If it has inflatable feature, necessary equipment for inflation and a device with a light or sound signal should be available when necessary, b) It should have a device that provides connection to the body so that the user can be pulled out of the liquid environment. c) In situations that require entering the liquid environment or have the risk of falling into it, the user should be suitable for use during the whole working period in jobs that are likely to work by wearing PPE. Buoyancy Aids Safe when worn, depending on the anticipated usage conditions, they are equipment that provide support in the water and effectively stay on the water. In the foreseen conditions of use, such PPE should not restrict the user's mobility; in particular, it must enable the user to swim or save other persons or make movements away from danger.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to prevent suffocation. NOT APPLIED The product is not a buoyancy aid product.
3.5.	Protection from the Harmful Effects of Noise PPEs designed to prevent the harmful effects of noise should reduce the noise that the user is exposed to, in a way not to exceed the limit values specified in the Regulation on the Protection of Employees from Noise Related Risks published in the Official Gazette dated 28/8/2013 and numbered 28721. All PPE should have labels indicating the level of noise reduction, if this is not possible, the labels should be attached to the packaging of the PPE.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to protect against the harmful effects of noise.

3.6.	Protection Against Heat and / or Fire PPE designed to protect the whole or a part of the body against the harmful effects of heat and / or fire must have thermal insulation capacity and mechanical durability in accordance with the prescribed usage conditions.		NOT APPLIED The product is not a product designed to protect against the harmful effects of heat and / or fire.
3.6.1.	Material of PPE and Other Elements PPE and other elements that provide protection against radiant and conventional heat should have sufficient heat conduction coefficient and at the same time be made of materials of sufficient strength that will not cause sudden flammability and burning. In places where the outer surfaces of the materials and components from which PPE is made should be reflective; The reflective power should be suitable for the density of the radiant heat flow in the infrared range. In high-temperature environments, PPE produced for short-term use and the material and other elements on which PPE, which is likely to splash hot products such as molten material, are made, in addition to normal protection, the stored heat is greatly It should also have sufficient thermal capacity to hold the part. This type of PPE material and other elements should also have sufficient mechanical shock absorption (see Article 3.1.). PPE material and other components that are likely to come into contact with a naked flame and materials used in the manufacture of fire extinguishing equipment, besides normal protection, must have a degree of non-flammability, thermal or arc heat protection that corresponds to the risk class in the stipulated conditions of use. These materials should not melt when exposed to flame and should not contribute to the spread of the flame.	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to protect against the harmful effects of heat and / or fire.
3.6.2.	Ready-to-use PPE In the foreseen conditions of use; a) The amount of heat transmitted by the PPE to the user should be low enough to prevent the accumulation of heat in the body parts at risk during wearing, from reaching the limit or pain threshold that will harm health in any way. b) PPE should prevent leakage of liquid and vapor when necessary and should not cause burns when it comes into contact with the user. PPE with a cooling system based on absorption of the heat in the environment through liquid substance evaporation or solid substance sublimation; volatile substances released from this system should be designed in such a way that they are thrown out of the preservative and not towards the user. Respirators to be used in combination with a PPE should be able to fully perform the protection task expected from them under the prescribed conditions of use. In high temperature environments, the user manual, which should be given with PPE for short-term use, should contain all the necessary information to determine the maximum permissible level of heat exposure transmitted to the user by the device, especially when used for the intended purpose.		NOT APPLIED The product is not a product designed to protect against the harmful effects of heat and / or fire.

3.7.	Cold Protection PPE designed to protect part or all of the body against the effects of cold should have mechanical endurance and thermal insulation capacity in accordance with the anticipated usage conditions. Material of PPE and Other Elements	TS EN 14126 +A1	NOT APPLIED The product is not a product designed to protect against the effects of cold.
3.7.1.	PPE material and other elements suitable for protection against cold must have a low thermal conductivity coefficient required by the stipulated conditions of use. The flexible parts and other elements in PPE to be used in low temperature environments should have the required degree of flexibility in order for the user to take the appropriate position and make his movements easily. The material and other elements of the PPE to be used against large amounts of splashes from cold materials should also have sufficient mechanical shock absorption (see Article 3.1.).		NOT APPLIED The product is not a product designed to protect against the effects of cold.
3.7.2.	Ready-to-Use PPE In the foreseen conditions of use; a) The heat flow transmitted from the PPE to the user during the period of wearing should be low in all circumstances, at a level that does not harm the health and does not reach the pain threshold, in any case, the cold accumulation that will occur in any part of the body that needs to be protected, including the tips of the fingers and toes. b) PPE should prevent the infiltration of rain water and similar liquids as much as possible, contact of cold protective surfaces with the user should not cause any injury. Respirator to be used in combination with protective PPE against cold, should fully perform the protection task expected from it under the prescribed conditions of use. User manual given with PPE produced for short-term use in low temperature environments; It should also contain all necessary information regarding the maximum permissible level of cold exposure transmitted by the device to the user.		NOT APPLIED The product is not a product designed to protect against the effects of cold.

3.8.	Protection Against Electric Shock		NOT APPLIED
3.8.1.	Insulation Equipment PPE designed to protect the whole or a part of the body against the effects of electric current should be insulated sufficiently against the voltages that the user may be exposed to under the most adverse conditions foreseen. In order to achieve this purpose, the material and other elements of this type of PPE should be tested under conditions suitable for the voltages that may be encountered in real working environments and the amount of leakage current passing through the protective surface should be measured. The material of PPE and other elements should be selected, designed and combined so that the measured value is below the maximum allowed value corresponding to the tolerance threshold value in all circumstances. In the type of PPE to be used in the work done in the live or potential electrical installation and in their packaging; In particular, there should be signs indicating the date of manufacture, serial number, appropriate voltage of use and / or protection class. In addition, on the outer surface of this type of PPE, an empty space should be left to write the starting date and the periodic test and control dates to be made respectively. In the user's manual, the frequency and type of dielectric tests that should be done especially during the lifetime and the purposes for which such PPE will be used should be specified.	TS EN 14126 +A1	The product is not an insulating equipment.
3.8.2.	Conductive Equipment PPE used in high voltage live lines should be designed and produced to ensure that there is no potential difference between the installation that the user and the user intervened with.	TS EN 14126 +A1	NOT APPLIED The product is not conductive equipment.

3.9.	Radiation Protection		NOT APPLIED
3.9.1.	Non-Ionizing Radiation PPE designed to protect the eye from acute or chronic damages caused by non-ionizing radiation sources should be capable of absorbing or reflecting the vast majority of the light energy emitted at harmful wavelengths. However, it should not adversely affect the distinction of colors, perception of details and the passage of harmless light in the visual range required by the stipulated conditions of use. In order to achieve this goal, protective glasses must be designed and manufactured in such a way that, for each harmful wavelength, the light energy that can reach the user's eye through the filter minimizes the intensity of illumination and in no way exceeds the maximum permissible exposure value. In addition, under the foreseen conditions of use, the properties of the glasses should not be deteriorated or lost by the effect of the emitted rays. In all types of glasses offered to the market, the protection factor number corresponding to the spectral distribution curve of the transmittance factor must be found. Glasses to be used for the same type of radiation sources will be classified according to the levels of protection factors. In the user manual; In particular, the permeability curve that will enable the selection of the most suitable PPE should be given, taking into account the conditions of use according to the distance from the source and the spectral distribution of the energy emitted at this distance. The relevant protection factor number must be attached to all types of filter glasses by the manufacturer.	TS EN 14126 +A1	The product is not a product that protects from non-ionizing radiation.
3.9.2.	Ionizing Radiation		
3.9.2.1	Protection from Outdoor Radioactive Pollution The material and other elements of PPE designed to protect the whole or part of the body from radioactive powders, gases, liquids or their mixture should be selected, designed and combined in a way that effectively prevents the infiltration of radioactive contaminants under the prescribed conditions of use. Depending on the nature or condition of these contaminants, the required sealing should be provided by the impermeability of the protective surface and / or by any other suitable means, such as pressure application and normal ventilation designed to prevent the re-diffusion of these contaminants. None of the radiation purification measures applied to PPE should prevent the reuse of such equipment within the anticipated lifetime.	TS EN 14126 +A1	NOT APPLIED The product is not a product that provides protection from external radioactive pollution.
3.9.2.2	Limited Protection Against External Radioactive Radiation PPEs used to completely protect the user from external radioactive radiation or to reduce the effect of the radiation sufficiently if this cannot be achieved, should primarily be designed to resist weak electron radiation such as beta or weak photon radiation such as X, gamma. The material and other elements of this class of PPE should be selected or designed and combined to provide the protection level required by the anticipated usage conditions without causing an increase in the exposure time by obstructing the user's movements or standing position. (See Article 1.3.2.)		NOT APPLIED The product is not a product that provides protection against external radioactive radiation.

	PPE should have a mark indicating the appropriate material type and equivalent thickness for the envisaged usage conditions.		
3.10.	Protection from Hazardous Substances and Mixtures and Harmful Biological Agents		NOT APPLIED
3.10.1	Protection of Respiratory System PPE designed for the protection of respiratory tracts should be capable of providing breathable air to the user in case of exposure to contaminated ambient air and / or insufficient oxygen in the environment. Breathable air supplied to the user through PPE; It should be obtained by appropriate methods such as filtering the dirty air with protective tools or devices or providing clean air from a source through a piping system. The material and other elements of this class of PPE should be selected or designed and combined in a hygienic manner that will provide the user with adequate breathing during wearing under the prescribed conditions of use. The impermeability of the parts protecting the face, the pressure drop during breathing and the cleaning capacity of the filters should be capable of protecting the ingress of contaminants in the environment, the health and hygiene of the user. PPE should contain the manufacturer's identification mark and details indicating the features of such equipment; This information, together with the user manual, should enable the correct use of PPE by the user by trained and qualified persons. In cases where filter devices are used, the storage life of the filters should also be specified in the user manual, if these devices are preserved in their original packaging without ever being used.	TS EN 14126 +A1	The product is not a product designed for respiratory protection.
3.10.2	Skin and Eye Protection The protective surfaces of PPE produced to protect the whole or part of the body surface from contact with hazardous substances and mixtures or harmful biological agents should be capable of preventing the passage or leakage of such substances to the user under the foreseen conditions of use. For this purpose, the materials and other elements of this class of PPE should be selected or designed and combined in a way that ensures a complete sealing as possible so that they can be used throughout the day when necessary. In cases where the tightness cannot be fully achieved, the wearing time should be limited. PPE should be subjected to standard tests based on efficiency for classification purposes in cases where certain hazardous substances and mixtures with high leakage power or harmful biological agents are in question due to their structures and foreseen conditions of use and these limit the protection period provided by PPE. PPE that is accepted to be in accordance with the specifications specified in the tests should contain information showing the names of the substances used in the tests or, if this cannot be done, their codes and corresponding standard protection periods. In particular, the user manual should include a description of the codes, a detailed description of the standard tests, if necessary, and all the necessary information to determine the maximum allowable period of use under the various stipulated conditions of use.	TS EN 14126 +A1	*The product is designed and manufactured to prevent the contact of hazardous substances and mixtures to the user during use. No substance leaks into the body during the use of the product.* *The materials used in the production of the product are designed and manufactured to ensure impermeability throughout its life. Necessary explanations, usage instructions and service life are clearly stated in the user manual and product labels.*

3.11.	Diving Equipment In particular, respirators should make it possible to provide the user with a breathable gas mixture, taking into account the maximum immersion depth and under the envisaged conditions of use. If required by the stipulated conditions of use, diving equipment should be equipped with the following equipment: a) A set of clothing to protect the user from the pressure caused by the immersion depth (see 3.2.) and / or cold (see 3.7.), b) An alarm system designed to immediately notify the user that the supply of respirable gas mixture is about to be interrupted (see Article 2.8.2), c) A life-saving clothing set that will enable the user to resurface (see 3.4.1.).	TS EN 14126 +A1	NOT APPLIED The product is not diving equipment.

IV. RISK ANALYSIS

RISK ANALYSIS REPORT			
RISK ASSESSMENT			
EFFECT		**PROBABILITY**	
DEVASTATING	5	OFTEN	5
IMPORTANT	4	LIKELY	4
MIDDLE	3	FAR	3
SMALL	2	IMPOSSIBLE	2
INSIGNIFICANT	1	EXCEPTIONAL	1

RISK = EFFECT * PROBABILITY

EFFECT		**PROBABILITY**				
E	ASSESSMENT	**O1**	**O2**	**O3**	**O4**	**O5**
E1	1	**1*1=1**	**1*2=2**	**1*3=3**	**1*4=4**	**1*5=5**
E2	2	**2*1=2**	**2*2=4**	**2*3=6**	**2*4=8**	**2*5=10**
E3	3	**3*1=3**	**3*2=6**	**3*3=9**	**3*4=12**	**3*5=15**
E4	4	**4*1=4**	**4*2=8**	**4*3=12**	**4*4=16**	**4*5=20**
E5	5	**5*1=5**	**5*2=10**	**5*3=15**	**5*4=20**	**5*5=25**

Green Zone; Acceptable Risk Zone (ARZ)

Blue Zone; Acceptable Zone Provided That Precaution Is Taken (AZPTPIT)

Red Zone; Unacceptable Risk Zone (URZ)

RISK ANALYSIS TABLE								
Risk	**Before Precautions**			**Hedging Method**	**After Precautions**			**Situation After Taking Action**
	Effect	**Probability**	**Effect*Probability**		**Effect**	**Probability**	**Effect*Probability**	
Damage in the structure of the product due to the use of the expired product	5	4	20	The shelf life of the product is indicated on the product label (2 years).	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.
Failure to provide protection as a result of multiple use of the product	5	4	20	The presence of a warning in the product manual and on the product label that the product is for single use only.	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.
Damage in the structure of the product as a result of exposure to direct sunlight.	5	4	20	Presence of "Protect from sunlight" warning on the product label and user manual.	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.
Using products with torn packaging	5	4	20	Indication of a warning about not using damaged packaged products on the product label and in the user manual.	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.
Contamination (contamination, burning, etc.) as a result of using damaged products.	5	4	20	Indication of a warning about not using damaged products on the product label and in the user manual	5	1	5	Thanks to the warning of the user through the product label, the probability of occurrence of the risk was reduced from 4 to 1 and the risk was reduced to an acceptable level.

CONCLUSION: As a result of the risk assessment, the existing risks were reduced to an acceptable level. Necessary warnings for risks are indicated on the label. The substances in the structure of the product do not pose a risk to the user's health. The product has been found to be adequate in terms of performance and reliable for use.

V. LABELING

Explanation of Symbols Used on the Label

PODIMA MEDICAL	**(Manufacturer (Manufactured by)** **PODIMA MEDIKAL VE TEKSTIL SAN. TIC. LTD. STI.** **YUKARI DUDULLU MAHALLESI BAYRAK CADDESI NO: 30 DAIRE: 130/131 UMRANIYE 34775 ISTANBUL / TURKIYE** Tel. : +902165405881 / +90532421985 www.podimamedikal.com info@podimamedikal.com

LOT **LOT No** **Production Date**

Whole body protection according to Chemical Protective Clothing standards set by the European Union EN 13982-1 (Type 5), EN 13034 (Type 6).

Keep away from flame and heat

Read the user manual

Do not iron

Do not dry clean

Do not wash

CE Complies with 89/686 / PPE directive

Do not use bleach.

Do not tumble dry.

TEK KULLANIMLIK Single use only

VI. HARMONIZED STANDARDS

HARMONIZED STANDARDS

EN ISO 13688
Protective Clothing – General Requirements

EN 13034+A1
Protective Clothing Against Liquid Chemicals (Type PB 6-B)