MANUFACTURER:

ALTEK YAPI MARKET SAN.TIC.LTD.STI.
Güzelevler Mah. Girne Bulv, Ceyhan Yolu 5. Km No:282/A, 01285 Yüreğir/Adana, Turkey

BASIC TYPE DESCRIPTION:

Article: TP63
code 1967
One-piece disposable coverall, with elasticated hood,waist and cuff, zip front opening covered by flap close by adhesive tape, and manufactured with serged seams and white nonwoven polypropylene fabric with polythylene film coating.



VARIATIONS DESCRIPTION:

No variations.

Category:
According to Regulation (EU) 2016/425

Category III PPE

STANDARDS:

EN ISO 13688:2013	Protective clothing – General requirements
EN 13034:2005+A1:2009	Protective clothing against liquid chemicals Type 6
EN ISO 13982-1:2004 +A1:2010	Protective clothing for use against solid particulates Type 5
EN ISO 14126:2003+AC:2004	Protective clothing against infective agents Types 3B, 4B, 5B, 6B
EN 1073-2:2002	Protective clothing against radioactive contamination

RISKS AGAINST WHICHTHE PPE IS INTENDED TO PROTECT:

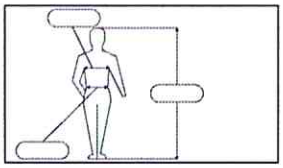
The design of protective clothing shall facilitate its correct positioning on the user, shall ensure that it remains in place for the foreseeable period of use and shall provide users with a level of comfort consistent with the level of protection required. The PPE furthermore, protects against:

EN 13034:2005+A1:2009	• Type 6 is intended to protect from exposure to a light spray, liquid aerosols or low pressure, low volume splashes, against which a complete liquid permeation barrier is not required i.e. when wearers are able to take timely adequate action when their clothing is contaminated. Type 6 protective clothing form the lowest level of chemical protection and are intended to protect from a potential exposure to small quantities of spray or accidental low volume splashes
EN ISO 13982-1:2011	• Type 5 is intended to be used for protection to the full body against airborne solid particulates
UNI EN ISO 14126:2004	• is intended to be used for protection against exposure to infective agents
UNI EN 1073-2:2003	• is intended to be used for protection against risks of exposure to particulate radioactive contamination

SIZES dimensions in centimeters

	S	M	L	XL	XXL	3XL
Length	165	167	169	174.5	176.5	177.5
Chest	115	117	123	126	130.0	128
Sleeve	76.5	77.5	79	81.5	82.5	85
Leg	77	78	78.5	79.5	80.5	81.5

SIZE DESIGNATION (EN 13688) dimensions in centimeters



	S	M	L	XL	XXL	3XL
Length	165	167	169	174.5	176.5	177.5
Chest	115	117	123	126	130.0	128
Sleeve	76.5	77.5	79	81.5	82.5	85
Leg	77	78	78.5	79.5	80.5	81.5

MATERIALS

Description	Colour	Composition	Weight	Supplier
Fabric	**White**	**100% PP + PE Film**	**60 g/m² ± 5%**	**ECOPLAST**

Certificates and/or Test Reports of materials are enclosed to this documentation.

The PPE has been designed and manufactured with materials and components used by our company for a long time for which do not know the harmful effects for health and safety.

The material shall not adversely affect the health or hygiene of the users in according to the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and subsequent amendments

CONFORMITY

During PPE manufacturing process, conformity is guaranteed by following design specifications and the following procedures:

Controls and test modalities:

Every phase of manufacturing is subject of control of the right execution of operations. Samples are taken statistically to verify the maintenance of product quality. Dimensional checks and product labelling are verified on finished garment.

Quality checks on raw materials:

- On a regular basis, the certificate of conformity is requested to raw materials suppliers

Quality checks during manufacturing process and final quality checks on product:

- Checking of the production process, checking of the correct way to carry out the procedures and correct way of assembly the components
- During the manufacturing process it is checked that all parts are correctly assembled.
- Checking of the correct positioning of marking.
- checking that CE marking is appropriate for the product type and it is positioned in the right place.
- Checking of seams strength.
- Seams are visually assessed and the strength is manually assessed
- Controlling of prototype correspondence.
- Verification that final product corresponds to the prototype object of the EU Type-Examination Certificate by means of type, construction, accessories position etc.

Control of large-scale manufacturing

Through a periodical analysis it is verified that each PPE sample is compliant with the approved type and with essential health and safety requirements.

DISPOSAL:

If the product has not been contaminated, it should be treated as a generic textile waist.
If contamination occurred, it has to be treated as a special waist and dispose accordingly to national laws.

Performance of whole suit

Test	Requirement	Result /Class/Conformity
Resistance to liquid penetration Spray test type 6 (EN ISO 17491-4 met. A – EN 13034)		Pass
Resistance to aerosol penetration Inward leakage type 5 (EN ISO 13982-2 – EN ISO 13982)	$IL_{82/90} \leq 30\%$ $TILS_{8/10} \leq 15\%$	Pass
Nominal protection factor (EN ISO 13982-2 – EN 1073-2)	Classe 3: TIL_E % 0,3; TIL_A % 0,2; Fpn 500 Classe 2: TIL_E % 3; TIL_A % 2; Fpn 50 Classe 1: TIL_E % 30; TIL_A % 20; Fpn 5	Class 1
Practical performance tests (EN 1073-2)		Pass
Seams: strength (EN ISO 13935-2)	Class 6: > 500 N Class 5: > 300 N Class 4: > 125 N Class 3: > 75 N Class 2: > 50 N Class 1: > 30 N	Class 3

Performance of fabric

Test	Requirement		Result/Class/Conformity	
Resistance to penetration to liquid (EN ISO 6530 – EN 13034)	Class 3: < 1% Class 2: < 5% Class 1: < 10%		H_2SO_4 30%:	class 3
			NaOH 10%:	class 3
			o-xilene:	NC
			Butan-1-ol:	NC
Repellency to liquid (EN ISO 6530 – EN 13034)	class 3: > 95% class 2: > 90% class 1: > 80%		H_2SO_4 30%:	class 3
			NaOH 10%:	class 3
			o-xilene:	NC
			Butan-1-ol:	NC
Abrasion Resistance (EN 530 - method 2)	Class 6	> 2000 cycles	Class 4	
	Class 5	> 1500 cycles		
	Class 4	> 1000 cycles		
	Class 3	> 500 cycles		
	Class 2	> 100 cycles		
	Class 1	> 10 cycles		
Trapezoidal tear resistance (EN ISO 9073-4 – EN 1073-2)	Class 6	> 150 N	Class 3	
	Class 5	> 80 N		
	Class 4	> 40 N		
	Class 3	> 20 N		
	Class 2	> 10 N		
	Class 1	> 2 N		
Trapezoidal tear resistance (EN ISO 9073-4)	Class 6	> 150 N	Class 2	
	Class 5	> 100 N		
	Class 4	> 60 N		
	Class 3	> 40 N		
	Class 2	> 20 N		
	Class 1	> 10 N		
Tensile strength (EN ISO 13934-1)	Class 6	> 1000 N	Class 2	
	Class 5	> 500 N		
	Class 4	> 250 N		
	Class 3	> 100 N		
	Class 2	> 60 N		
	Class 1	> 30 N		
Puncture resistance (EN 863 - EN 1073-2)	Class 6	> 250 N	Class 2	
	Class 5	> 150 N		
	Class 4	> 100 N		
	Class 3	> 50 N		
	Class 2	> 10 N		
Puncture resistance (EN 863 - EN 13034)	Class 6	> 250 N	Class 2	
	Class 5	> 150 N		
	Class 4	> 100 N		
	Class 3	> 50 N		
	Class 2	> 10 N		
	Class 1	> 5 N		
Flex cracking resistance (EN 7854)	Class 6	> 100 000 c.	Class 6	
	Class 5	> 40 000 c.		
	Class 4	> 15 000 c.		
	Class 3	> 5 000 c.		
	Class 2	> 2 500 c.		
	Class 1	> 1 000 c.		
Blocking resistance (EN 25978 - EN 1073-2)			Pass	
Ignition and flammability (EN 13274-4 - EN 1073-2)			Pass	

EN ISO 13688:2013

Test	Requirement	Result /Class/Conformity
pH (EN 340 – ISO 3071)	3.5 > pH > 9.5	
Amines (EN 340 – ISO 3071)		Pass

EN 14126:2003+AC:2004			
Test	**Requirement**		**Result /Class/Conformity**
Resistance to penetration by blood-borne phatogens - phi-x174 bacteriophage test - ISO 16603/16604	Class 6	20 kPa	Class 6
	Class 5	14 kPa	
	Class 4	7 kPa	
	Class 3	3,5 kPa	
	Class 2	1,75 kPa	
	Class 1	0 kPa	
Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids - ISO 22610 (test microorganism: staphylococcus aureus)	Class 6	t > 75	Class 6
	Class 5	60 < t ≤ 75	
	Class 4	45 < t ≤ 60	
	Class 3	30 < t ≤ 45	
	Class 2	15 < t ≤ 30	
	Class 1	≤ 15 min	
Resistance to penetration by contaminated liquid aerosols - ISO DIS 22611 (test microorganism: staphylococcus aureus)	Class 3	log > 5	Class 3
	Class 2	3 < log ≤ 5	
	Class 1	1 < log ≤ 3	
Resistance to penetration by contaminated solid particles - EN ISO 22612 (test microorganism: spores of Bacillus subtilis)	Class 3	≤ 1	Class 3
	Class 2	1 < log ufc ≤ 2	
	Class 1	2 < log ufc ≤ 3	

EXHAUSTIVE LIST OF ESSENTIAL REQUIREMENTS OF HEALTH AND SAFETY

(Annex II of Regulation (UE) 2016/425)

Clauses of Regulation (UE) 2016/425 Annex II		Clause of standard **EN ISO 13688:2013**
1.2.1	Absence of inherent risks and other nuisance factors	5.3
1.2.1.1	Suitable constituent materials	4.2
1.2.1.2	Satisfactory surface condition of all PPE parts in contact with the user	4.4
1.4	Manufacturer's instructions and information	8
2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	6, 7

Clauses of Regulation (UE) 2016/425 Annex II		Clause of standard **EN 13034**
1.1.1	Ergonomics	5.2
1.2.1	Absence of inherent risks and other nuisance factors	4.1
1.2.1.1	Suitable constituent materials	4.1
1.2.1.3	Maximum permissible user impediment	5.1, 5.2
1.3.2	Lightness and strength	4.1, 4.2.2
1.3.3	Compatibility of different types of PPE intended for simultaneous use	7
1.4	Manufacturer's instructions and information	7
2.4	PPE subject to ageing	5.1, 7
2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	6, 7
3.10.2	Protection against cutaneous and ocular contact	4.1, 4.2.1, 5.1, 5.2

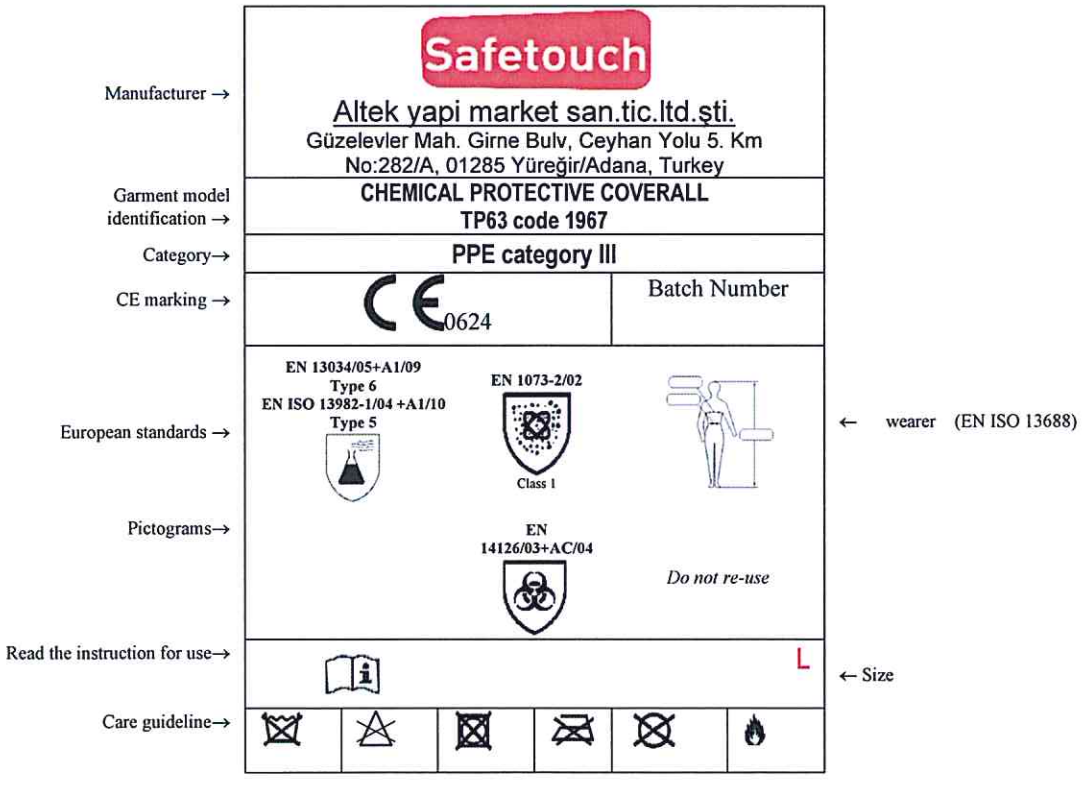
Clauses of Regulation (UE) 2016/425 Annex II		Clause of standard **EN ISO 13982-1**
1.1.1	Ergonomics	4.3.2
1.1.2.1	Optimum level of protection	4.3.1, 4.3.2
1.2.1.1	Suitable constituent materials	4.1
1.2.1.2	Satisfactory surface condition of all PPE parts in contact with the user	4.3.1
1.2.1.3	Maximum permissible user impediment	4.3.2
1.3.1	Adaptation of PPE to user morphology	4.3
1.3.2	Lightness and strength	4.1, 4.2
1.3.3	Compatibility of different types of PPE intended for simultaneous use	4.3, 6
1.4	Manufacturer's instructions and information	5, 6
2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	5, 6
3.10.2	Protection against cutaneous and ocular contact	4.2.1, 4.3.2

Clauses of Regulation (UE) 2016/425 Annex II		Clause of standard **EN 14126**
1.1.2.2	Classes of protection appropriate to different levels of risk	4.1.4
1.3.1	Adaptation of PPE to user morphology	4.3
1.3.2	Lightness and strength	4.1.2, 4.2
1.4	Manufacturer's instructions and information	6
2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	5
3.10.2	Protection against cutaneous and ocular contact	4.3, 4.1.4

Clauses of Regulation (UE) 2016/425 Annex II		Clause of standard **EN 1073-2**
1.1.1	Ergonomics	4
1.1.2.1	Optimum level of protection	4
1.1.2.2	Classes of protection appropriate to different levels of risk	4.2, 4.3, 4.4
1.2.1	Absence of inherent risks and other nuisance factors	4
1.3.1	Adaptation of PPE to user morphology	4.1.1, 4.1.2
1.3.2	Lightness and strength	4.1.2, 4.4
1.3.3	Compatibility of different types of PPE intended for simultaneous use	4.1.4, 4.1.2
1.4	Manufacturer's instructions and information	7
2.2	PPE enclosing the parts of the body to be protected	4.1.2
2.4	PPE subject to ageing	6.7
3.9.2.1	Protection against external radioactive contamination	4, 6, 7

LABEL (Example):

Marking and manufacturer's information are in the official language of the state of destination
Numbers are not smaller than 2 mm and pictograms are not smaller than 10 mm, they are black on white background.
The various components of CE marking must have the same vertical dimension, which may be not less than 5 mm.
The CE marking must be affixed to each piece of manufactured PPE so as to be visible, legible and indelible throughout the expected life of the PPE
It is not provided the manufacturer address on label but on "Manufacturer's instructions and information" included with the product



Care guideline

					
Do not wash	Do not dry	Do not bleach	Do not iron	Do not dry clean	Flammable fabric