

**CONFORMITY TO TYPE BASED ON INTERNAL  
PRODUCTON CONTROL PLUS SUPERVISED PRODUCT  
CHECK AT RANDOM INTERVALS  
(MODULE C2, ANNEX VII) (90-20-01-01)**

Report No : 90-20-01-01

Report Date : 22.04.2021

Application No : 90-20-01

**1. COMPANY INFORMATION:**

OLEY TIBBİ ÜRÜNLER VE MEDİKAL MALZEMELER SAN. TİC. LTD. ŞTİ.  
Parseller Mah. Menekşe Cad. Feyyaz Sok. No: 2 Ümraniye/ İSTANBUL/ TÜRKİYE  
Tel: 0 216 611 93 33  
Fax: 0 216 611 93 22

**2. PPE INFORMATION:**

Disposable non-sterile coverall.

**3. PPE TYPE IDENTIFICATION**

EN 13688 Protective clothing - General requirements  
EN 13034 Protective clothing against liquid chemicals (Type 6-B)  
EN ISO 13982-1 Protective clothing for use against solid particulates (Type 5-B)  
EN 14605+ A1 Protective clothing against liquid chemicals (Type 3-B, 4-B)  
EN 14126 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

**4. PPE PICTURES**



**5. PPE DIMENSIONS:**

OLEY 2311 model product has been found to be produced using S-M-L-XL-2XL size.

**6. PPE PRODUCT MATERIAL INFORMATION:**

- The product is made of coated fabric.

**7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS**

- Protective clothing doesn't contain any sharp or hard edges or rough surfaces.
- Wearer donned and removed without any difficulties and clothing fits perfectly.
- The clothing doesn't obstruct blood circulation in any part of the body.
- The clothing design at armholes and crotch are appropriately proportioned and positioned.
- Sufficient closure arrangements given in the clothing and all the closures systems functioning properly.
- The coverage of protection zones of protective material is maintained during movements as extreme as it is anticipated a user would make.
- Wearer doesn't observe any difficulties while standing, sitting, walking, stair climbing, raising both hands above the head and bending over and picking up a small objects.
- While movements the protective material covers body area sufficiently.
- No difficulties in putting on and removing other items of PPE such as gloves and boots.

**8. ANALYSIS AND EVALUATIONS:**

**EN ISO 13688**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
pH value	6,82	3,5 – 9,5	PASS

**EN 13034**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles	1	PASS
Tear resistance	33,41 N	2	PASS
Tensile strength	35,17 N	1	PASS
Puncture resistance	5,66 N	1	PASS
Repellency to liquids	H2SO4: 99,3 NaOH: 99,5	3 3	PASS
Resistance to penetration by liquids	H2SO4: 0,8 NaOH: 0,7	3 3	PASS
Resistance to penetration by spray liquid (spray test)	0 cm <sup>2</sup>	-	PASS
Seam Strength	50,41 N	2	PASS

**EN ISO 13982-1**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Total inward leakage	Ljmn82/90: 16,3 Ls8/10: 13,9 (%)	IL 82/90 <30% and TILS 8/10<15%	PASS
Flex Cracking resistance	500 cycles	1	PASS

**EN 14605+A1**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to penetration by jet liquid (jet test)	0cm <sup>2</sup>	-	PASS
Permeation	No leakage (%40 NaOH 30 min)	2	PASS

**EN 14126**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage)	3,5 kPa 0 (PFU/ml)	3	PASS
Resistance to wet bacterial penetration	%0,15	1	PASS
Resistance to penetration by biologically contaminant dust	2,03 (log cfu)	1	PASS

**9. DECISION PROPOSAL**

Analysis and examinations OLEY 2311 model coded personal protective equipment; EN 13688, EN 14605+A1, EN 14126, EN ISO 13982-1, EN 13034 are evaluated. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.

**10. ATTACHMENTS**

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports ( M-2021-00554)
- User Instruction

**CONTROLLER : VOLKAN AKIN**

**SING :**

**DATE : 22.04.2021**

