

Report No : 90-21-01-01-R02

Report Date : 19.03.2021

Application No : 90-21-01-01

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

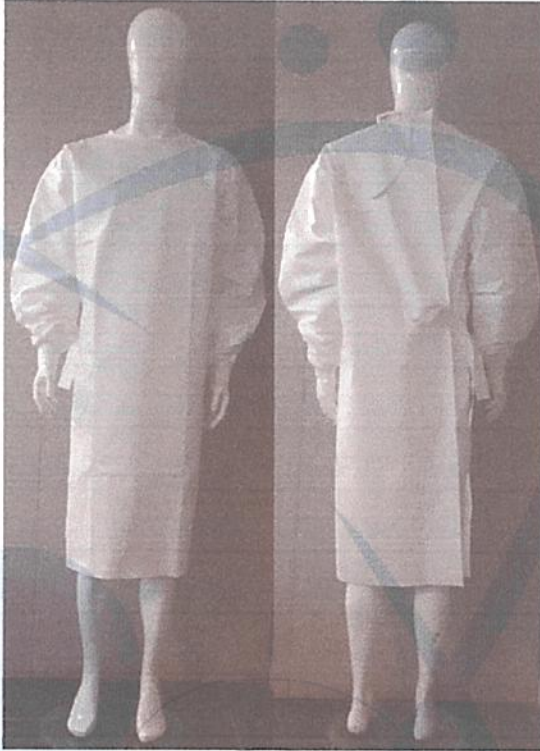
2. PPE INFORMATION:

Disposable non-sterile gown.

3. PPE TYPE IDENTIFICATION

EN ISO 13688: 2013 Protective clothing - General requirements
EN 13034: 2005+A1: 2009 Protective Clothing Against Liquid Chemicals (Type PB 6-B)
EN 14605: 2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)
EN 14126: 2003 Protective Clothing - Performance Requirements And Tests Methods For Protective Clothing Against Infective Agents

4. PPE PICTURES



5. PPE DIMENSIONS:

BGM01 model product has been found to be produced using standart size.

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTON CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (90-21-01-01-R02)**

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 13688:2013

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
pH value	6,85	3,5 – 9,5	PASS

EN 13034:2005+A1:2009

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles >10 cycles >10 cycles >10 cycles	1 (>10 cycle)	PASS
Tear resistance	80,17 79,59 87,66 62,13 82,67 46,39 45,76 46,55 57,21 46,98	3 (>40N)	PASS
Tensile strength	36,70 40,66 43,81 41,43 44,32	1 (>30N)	PASS

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	88,79 87,52 85,65 68,96 89,77		
Puncture resistance	7,11 7,43 7,09 7,12	1 (>5N)	PASS
Repellency to liquids	H2SO4: 98,6 NaOH: 99,2	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids	H2SO4: 0,6 NaOH: 0,4	3 (<1%) 3 (<1%)	PASS
Seam Strength	77,32 70,32 74,32 71,43 79,41 70,65	2 (>50N)	PASS

EN 14605:2005+A1:2009

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

EN 14126:2003

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage)	0 (PFU/ml) See the table below	3 (3,5 kPa)	PASS

Sample	Material Compatibility Ratio	Thickness (mm)	Mass per unit area g/m ²	Starting Bacteriophage Challenge Titer PFU/ml	Ending Bacteriophage Challenge Titer PFU/ml	Penetration (PFU/ml)	Visible Liquid Penetration
Sample 1	0,9	0,20	60	2.6x10 ⁸	2,3x10 ⁸	< 1	No penetration
Sample 2				2.6x10 ⁸	2,5x10 ⁸	< 1	No penetration
Sample 3				2.6x10 ⁸	2,5x10 ⁸	< 1	No penetration

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TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration	Total penetration 0,23 % See the table below	1 (t≤15 min)	PASS

Plates	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Plate 1	5	3	5	5	4
Plate 2	4	3	7	4	6
Plate 3	4	6	6	3	3
Plate 4	6	5	4	4	4
Plate 5	3	6	5	5	6
Penetration (%)	0,22	0,23	0,27	0,21	0,23
Total Penetration (%)	0.23				

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Dry microbial penetration	2,02 log cfu	1 (2<log cfu≤3)	PASS

9. DECISION

Analysis and examinations BGM01 model coded personal protective equipment; EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14126:2003, EN 14605: 2005+A1:2009 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
- User Instruction

Reason for revision : The missing table has been added.

CONTROLLER : VOLKAN AKIN

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DATE : 19.03.2021

