

Notified Body Number: 2841

Report No : 24-20-01-R01-01

Report Date : 16.09.2020

Application No : 24-20-01

1. COMPANY INFORMATION:

STERİL SAĞLIK ÜRÜNLERİ- ZEYNEL ABİDİN SAVRUN
Ziyapaşa Mah. 67132 Sok. Gülmen Apt. Asma kat D:1 Seyhan/ ADANA
Tel: +90 542 236 58 78
Fax: +90 322 453 62 17

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:

CA-403 model coverall has been found to be produced using S-M-L-XL-2XL-3XL-4XL size.

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECKS AT RANDOM INTERVALS
(MODULE C2, ANNEX VII)**

6. PPE PRODUCT MATERIAL INFORMATION:

The coverall 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	6,91	3,5 – 9,5	PASS

EN 13034

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles	Class 1	PASS
Tear resistance	41,19 N	Class 3 (>40N)	PASS
Tensile strength	41,4 N	Class 1 (>30N)	PASS
Puncture resistance	7,61 N	Class 1 (>5N)	PASS
Repellency to liquids	H2SO4:96 NaOH:96	Class 3 (>90N) Class 3 (>90N)	PASS
Resistance to penetration by liquids	H2SO4:0,5 NaOH:0,5	Class 3 (<1%) Class 3 (<1%)	PASS
Seam Strength	63,72	Class 2 (>50N)	PASS

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECKS AT RANDOM INTERVALS
(MODULE C2, ANNEX VII)**

EN ISO 13982-1

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Flex Cracking resistance	500 cycles	1	PASS

EN 14605+A1

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Permeation	No leakage (%40 NaOH 30 min)	2 (>30 min)	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	%0,13	1	PASS
Resistance to penetration by biologically contaminant dust	2,05(log cfu)	1	PASS

9. DECISION PROPOSAL

Analysis and examinations CA-403 model coded personal protective coverall; EN 13688, EN 14605+A1, EN ISO 13982-1, EN 13034+A1 , EN 14126 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

CONTROLLER : VOLKAN AKIN**SING :****DATE : 16.09.2020**