

Notified Body Number: 2841

Report No : 24-20-02-01

Report Date : 20.11.2020

Application No : 24-20-02-01

1. COMPANY INFORMATION:

STERİL SAĞLIK ÜRÜNLERİ- ZEYNEL ABİDİN SAVRUN

Ziyapaşa Mah. 67132 Sok. Gülmen Apt. Asma kat D:1 Seyhan/ ADANA

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2. PPE INFORMATION:

Disposable non-sterile gown.

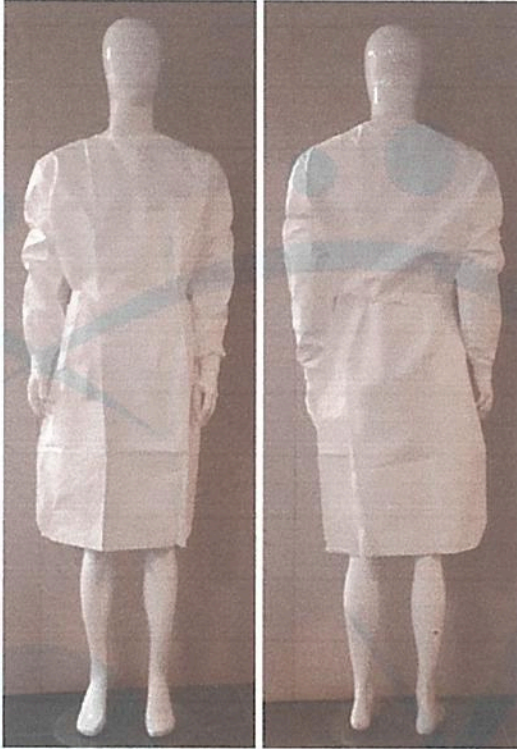
3. PPE TYPE IDENTIFICATION

EN 13688 Protective clothing - General requirements

EN 13034 Protective clothing against liquid chemicals (Type PB 6-B)

EN 14126 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

4. PPE PICTURES



SSU-904

5. PPE DIMENSIONS:

SSU-904 model gown has been found to be produced using S-M-L-XL-2XL-3XL size.

Notified Body Number: 2841

6. PPE PRODUCT MATERIAL INFORMATION:

The gown 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	6,51	3,5 – 9,5	PASS

EN 13034

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles	1	PASS
Tear resistance	37,76 N	2	PASS
Tensile strength	33,12 N	1	PASS
Puncture resistance	5,32 N	1	PASS
Repellency to liquids	H2SO4: 97.6 NaOH: 98,7	3 3	PASS
Resistance to penetration by liquids	H2SO4: 0,9 NaOH: 0,8	3 3	PASS
Seam Strength	77,77 N	2	PASS

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	2,09 (log cfu)	1	PASS

9. DECISION PROPOSAL

Analysis and examinations SSU-904 model coded personal protective equipment; EN 13688, 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 : ERHAN ÜSTÜNEL

SING :

DATE : 20.11.2020