Notified Body Number: 2841

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTON CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (123-20-02-01)

Report No : 123-20-02-01

Report Date : 09.03.2021

Application No : 123-20-02-01

1. COMPANY INFORMATION:

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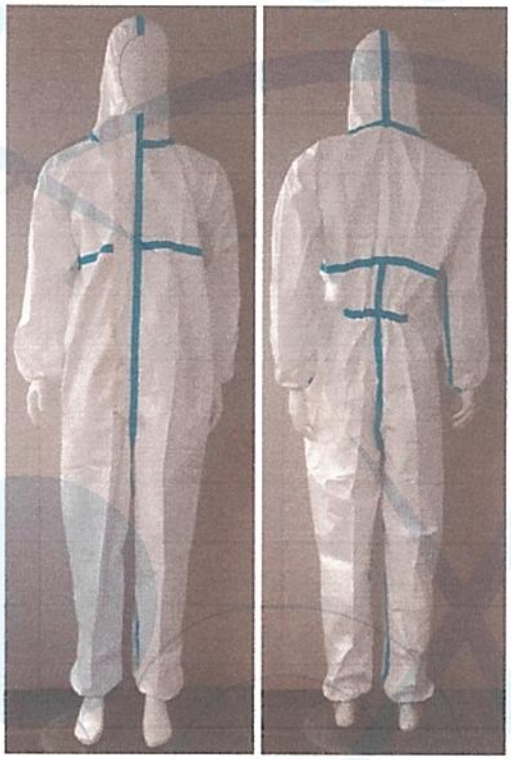
2. PPE INFORMATION:

Disposable non-sterile coverall.

3. PPE TYPE IDENTIFICATION

EN ISO 13688:2013 Protective clothing - General requirements
EN 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type 3-B, Type 4-B)
EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN 13034:2005+A1:2009 Protective Clothing Against Liquid Chemicals (Type 6-B)
EN ISO 13982-1: 2004+A1:2010 Protective Clothing For Use Against Solid Particulates (Type 5-B)
EN 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



5. PPE DIMENSIONS:

DCOVER DC-TB model coverall has been found to be produced using S-M-L-XL-2XL-3XL 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 13688:2013

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

EN 13034:2005+A1:2009, EN 14605:2005+A1:2009, EN ISO 13982-1: 2004+A1:2010

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles >10 cycles >10 cycles >10 cycles	1 (>10 cycle)	PASS
Tear resistance	36,79 39,86 40,41 42,55 38,64 110,87 108,62	2 (>20N)	PASS

	100,09 101,82 105,06		
Tensile strength	94,36 98,14 97,52 93,67 91,83 40,71 43,53 42,22 43,17 43,05	1 (>30N)	PASS
Puncture resistance	8,02 7,74 9,55 8,51	1 (>5N)	PASS
Repellency to liquids	H2SO4: 98,8 NaOH: 99,1	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids	H2SO4: 0,7 NaOH: 0,5	3 (<1%) 3 (<1%)	PASS
Seam Strength	74,23 78,54 60,36 62,11 54,21 53,06 51,40 72,01 61,02	1 (>30N)	PASS
Resistance to penetration by spray liquid (spray test)	0 cm^2	3 times the maximum calibration stain	PASS
Resistance to penetration by jet of liquid (jet test)	0 cm^2	3 times the maximum calibration stain	PASS
Flex cracking resistance	>500 cycles	1(>500 cycle)	PASS
Permeation	No leakage (%40 NaOH 30 min)	2 (>30 min)	PASS
Total inward leakage	Ljmn: 15,0 - Ls: 11,3 (%) See the table below	Ljmn≤30 - Ls≤15	PASS

		% Total Inward Leakage										
		Subject 1 Sample 1	Subject 1 Sample 2	Subject 2 Sample 1	Subject 2 Sample 2	Subject 3 Sample 1	Subject 3 Sample 2	Subject 4 Sample 1	Subject 4 Sample 2	Subject 5 Sample 1	Subject 5 Sample 2	Average
Standing still	Knee	12,4	9,0	9,2	12,9	11,2	12,2	13,2	13,2	7,8	4,1	10,5
	Waist	11,2	11,3	12,2	10,9	7,4	5,6	5,6	10,1	5,5	5,9	8,6
	Chest	12,1	11,3	7,8	11,5	6,3	5,5	11,1	11,0	8,3	6,9	9,2
Walking	Knee	9,1	6,8	1,1	9,2	9,8	11,4	12,1	12,1	10,4	13,8	9,6
	Waist	7,6	8,0	4,4	6,7	11,0	11,1	13,6	10,9	11,2	13,5	9,8
	Chest	12,3	10,3	11,3	6,5	10,5	5,7	10,3	9,7	12,4	12,1	10,1
Squatting	Knee	9,1	10,1	11,0	8,2	10,5	11,4	12,8	8,5	12,8	12,5	10,7
	Waist	10,7	8,5	19,3	8,1	17,0	12,3	11,4	17,0	13,5	12,5	13,0
	Chest	16,9	21,4	14,0	16,0	13,4	16,7	12,5	15,0	15,4	13,4	15,5
	Average	11,3	10,7	10,0	10,0	10,8	10,2	11,4	11,9	10,8	10,5	10,8

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	1,0	0,20	60	2.7x10^8	2,6x10^8	< 1	No penetration
Sample 2				2.7x10^8	2,5x10^8	< 1	No penetration
Sample 3				2.7x10^8	2,3x10^8	< 1	No penetration

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration	Total penetration 0,19 % See the table below	1 (t≤15 min)	PASS

Plates	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Plate 1	3	3	2	4	6
Plate 2	4	4	4	3	4
Plate 3	5	3	2	4	4
Plate 4	6	5	4	3	5
Plate 5	3	2	5	5	3
Penetration (%)	0,21	0,17	0,17	0,19	0,22
Total Penetration (%)	0.19				

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

9. DECISION

Analysis and examinations DCOVER DC-TB model coded personal protective equipment; EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14605:2005+A1:2009, EN ISO 13982-1: 2004+A1:2010, EN 14126:2003, EN 1149-5: 2018 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

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DATE : 09.03.2021