

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

Certificate No : F15-21-05-01-R01
Certification Date / Certificate Validity Date : 02.09.2021-13.08.2022
Document Validity Period : 1 Year
Company Name and Address : CARINE EUROPE GmbH
Ammannstraße 12, 86167 Augsburg, Germany
Product Name / Models : CRN400-PGA-LSC
Directive : 2016/425 REGULATION
Module / Category : MODULE C2 / CATEGORY III
Test Report No : MNA M-2021-01316
Product Type:

- 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 1149-5:2018 Protective clothing - Electrostatic properties

Product Material Information: CRN400-PGA-LSC model products are manufactured using coated fabric.
Reason for revision: Model name has been revised.

Erhan ÜSTÜNEL

02.09.2021

Approver



Okan AKEL

02.09.2021

General manager



Report No : 115-21-05-01-R01

Report Date : 02.09.2021

Application No : 115-21-05-01

1. COMPANY INFORMATION:

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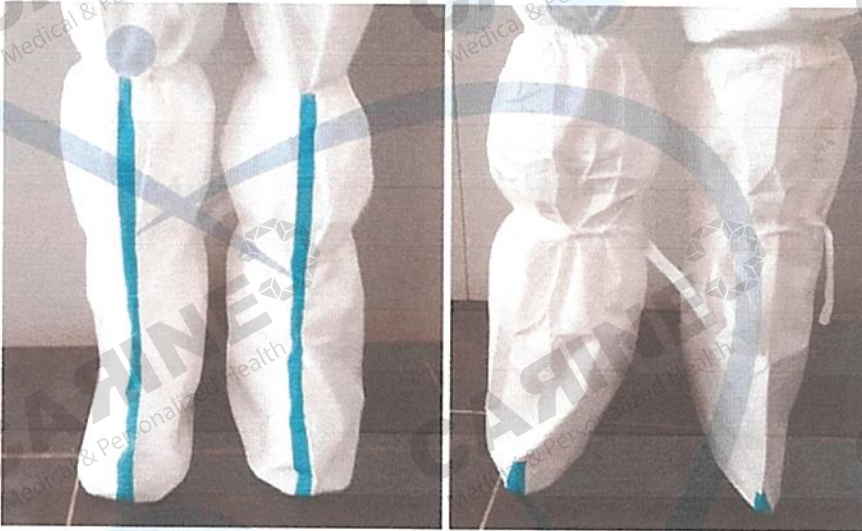
2. PPE INFORMATION:

Disposable non-sterile overboot.

3. PPE TYPE IDENTIFICATION

EN ISO 13688:2013 Protective clothing - General requirements
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
EN 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



CRN400-PGA-LSC

5. PPE DIMENSIONS:

CRN400-PGA-LSC model product has been found to be produced using standard size.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of coated fabric.

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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 EN ISO 3071	6,89	3,5 – 9,5	PASS

EN 14605:2005+A1:2009

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance BS EN 14325 Part 4.4	>10 cycles >10 cycles >10 cycles >10 cycles	1 (>10 cycle)	PASS
Tear resistance EN ISO 9073-4+ BS EN 14325 Part 4.7	34,56 (Newton) 36,49 (Newton) 31,77 (Newton) 38,02 (Newton) 34,19 (Newton) 91,43 (Newton) 92,12 (Newton) 89,89 (Newton) 92,40 (Newton) 90,11 (Newton)	2 (>20N)	PASS
Tensile strength ISO 13934-1	82,90 (Newton) 81,34 (Newton) 84,44 (Newton) 82,10 (Newton) 80,80 (Newton) 41,35 (Newton) 42,11 (Newton) 43,95 (Newton) 42,39 (Newton) 40,67 (Newton)	1 (>30N)	PASS

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Puncture resistance EN 863+ BS EN 14325 Part 4.10	6,84 (Newton) 7,12 (Newton) 7,34 (Newton) 7,09 (Newton)	1 (>5N)	PASS
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H ₂ SO ₄ : 98,9 NaOH: 99,2	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H ₂ SO ₄ : 0,8 NaOH: 0,6	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	79,89 (Newton) 70,26 (Newton) 73,24 (Newton)	2 (>50N)	PASS
Resistance to penetration by spray liquid (spray test) BS EN ISO 17491-4	0 cm ²	3 times the maximum calibration stain	PASS
Resistance to penetration by jet of liquid (jet test) BS EN ISO 17491-3	0 cm ²	3 times the maximum calibration stain	PASS
Flex cracking resistance EN ISO 7854+ BS EN 14325 Part 4.5	>50000 cycles	6 (>50000 cycle)	PASS
Permeation ISO 6529	No leakage (%40 NaOH 30 min)	2 (>30 min)	PASS

EN 14126:2003

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage) BS ISO 16604+ EN 14126 Part 4.1.4.1	0 (PFU/ml) See the table below	6 (20 kPa)	PASS
Penetration by blood and body fluids (Synthetic blood) BS ISO 16603+ EN 14126 Part 4.1.4.1	0 (PFU/ml)	6 (20 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	2,8x10 ⁸	2,7x10 ⁸	< 1	No penetration
Sample 2				2,8x10 ⁸	2,5x10 ⁸	< 1	No penetration
Sample 3				2,8x10 ⁸	2,5x10 ⁸	< 1	No penetration

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
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Resistance to wet bacterial penetration ISO 22610:2018 + EN 14126 Part 4.1.4.2	Total penetration 0 %	6 (t>75 min)	PASS
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TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to penetration by biologically contaminant dust BS EN ISO 22612+ EN 14126 Part 4.1.4.4	0,41 log cfu	3 (log cfu≤1)	PASS

9. DECISION

Analysis and examinations CRN400-PGA-LSCmodel coded personal protective equipment; EN ISO 13688:2013, EN 14605:2005+A1:2009, EN 14126:2003, EN 1149-5: 2018 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.

CONTROLLER : ERHAN ÜSTÜNEL

SIGNATURE :

DATE : 02.09.2021