

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

Certificate No : 115-21-07-01-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-100
Directive : 2016/425 REGULATION
Module / Category : MODULE C2 / CATEGORY III
Test Report No : MNA M-2021-01318
Product Type:

- EN ISO 13688:2013 *Protective clothing - General requirements*
- EN 13034:2005+A1:2009 *Protective Clothing Against Liquid Chemicals (Type 6-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-100 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





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Application No : 115-21-07-01

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 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 PB 6-B)

EN 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



CRN400-PGA-LSC-100

5. PPE DIMENSIONS:

CRN400-PGA-LSC-100 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	7,14	3,5 – 9,5	PASS

EN 13034:2005+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	44,33 (Newton) 45,42 (Newton) 43,97 (Newton) 48,75 (Newton) 46,17 (Newton) 99,54 (Newton) 102,17 (Newton) 103,66 (Newton) 99,98 (Newton) 97,44 (Newton)	3 (>40N)	PASS
Tensile strength ISO 13934-1	41,14 (Newton) 42,65 (Newton) 47,35 (Newton) 40,64 (Newton) 44,55 (Newton) 98,53 (Newton) 97,43 (Newton) 94,55 (Newton) 98,96 (Newton) 99,87 (Newton)	1 (>30N)	PASS

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Puncture resistance EN 863+ BS EN 14325 Part 4.10	7,35 (Newton) 6,44 (Newton) 7,24 (Newton) 7,76 (Newton)	1 (>5N)	PASS
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H ₂ SO ₄ : 99,1 NaOH: 99,0	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H ₂ SO ₄ : 0,9 NaOH: 0,8	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	66,24 (Newton) 68,65 (Newton) 73,61 (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

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)	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	2,8x10 ⁸	< 1	No penetration
Sample 2				2,8x10 ⁸	2,7x10 ⁸	< 1	No penetration
Sample 3				2,8x10 ⁸	2,5x10 ⁸	< 1	No penetration

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration ISO 22610:2018 + EN 14126 Part 4.1.4.2	Total penetration 0 %	6 (t>75 min)	PASS
Resistance to penetration by biologically contaminant dust BS EN ISO 22612+ EN 14126 Part 4.1.4.4	0,36 log cfu	3 (log cfu≤1)	PASS

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9. DECISION

Analysis and examinations CRN400-PGA-LSC-100 model coded personal protective equipment; EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14126:2003, EN 1149-5: 2018 standards 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.

CONTROLLER : ERHAN ÜSTÜNEL**SIGNATURE** :**DATE** : 02.09.2021