

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

Certificate No : 115-21-03-01-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-PCA-200
Directive : 2016/425 REGULATION
Module / Category : MODULE C2 / CATEGORY III
Test Report No : MNA M-2021-01314
Product Type:

- EN ISO 13688:2013 *Protective clothing - General requirements*
- 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 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-PCA-200 model products are manufactured using coated fabric.
Reason for revision: Model name has been revised.

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02.09.2021

Approver



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02.09.2021

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Notified Body Number: 2841

Report No : 115-21-03-01-R01

Report Date : 02.09.2021

Application No : 115-21-03-01

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 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



CRN400-PCA-200

5. PPE DIMENSIONS:

CRN400-PCA-200 model product has been found to be produced using S-M-L-XL-2XL-3XL-4XL size.

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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 EN ISO 3071	7,32	3,5 – 9,5	PASS

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

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	35,43 (Newton) 33,63 (Newton) 37,77 (Newton) 32,21 (Newton) 95,32 (Newton) 98,35 (Newton) 90,98 (Newton) 93,22 (Newton) 92,55 (Newton) 38,64 (Newton)	2 (>20N)	PASS
Tensile strength ISO 13934-1	44,22 (Newton) 43,65 (Newton) 38,72 (Newton) 43,35 (Newton) 45,98 (Newton) 89,71 (Newton) 97,14 (Newton) 95,21 (Newton) 92,24 (Newton)	1 (>30N)	PASS

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	93,77 (Newton)		
Puncture resistance EN 863+ BS EN 14325 Part 4.10	6,78 (Newton) 7,89 (Newton) 6,43 (Newton) 7,91 (Newton)	1 (>5N)	PASS
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H ₂ SO ₄ : 99,2 NaOH: 99,1	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: 0,7	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	66,22 (Newton) 68,53 (Newton) 62,27 (Newton) 66,54 (Newton) 65,76 (Newton) 67,28 (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
Flex cracking resistance EN ISO 7854+ BS EN 14325 Part 4.5	>50000 cycles	6 (>50000 cycle)	PASS
Total inward leakage ISO 13982-2	Ljmn,82/90: 15,0 Ls,8/10: 11,5 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	9,6	8,8	14,1	10,5	7,5	7,6	6,1	6,1	9,9	9,1	8,9
	Waist	13,7	13,9	9,9	13,3	9,4	10,0	7,4	10,0	7,3	7,9	10,3
	Chest	12,2	13,8	10,0	18,8	8,1	7,3	13,6	12,2	10,3	9,0	11,5
Walking	Knee	11,4	8,8	2,5	11,5	12,0	10,1	9,8	17,1	12,6	16,7	11,3
	Waist	10,1	10,2	6,1	8,6	13,4	9,9	10,1	13,3	13,5	10,0	10,5
	Chest	15,2	12,5	13,8	8,8	12,8	7,7	12,8	11,9	10,2	9,8	11,5
Squatting	Knee	11,4	12,5	13,4	10,2	12,8	14,3	7,1	10,6	10,6	10,1	11,3
	Waist	13,9	10,6	10,8	10,0	12,7	15,3	10,1	11,4	16,1	10,1	12,1
	Chest	13,5	11,2	9,8	10,1	15,0	9,8	14,1	16,7	9,0	15,0	12,4
	Average	12,3	11,4	10,0	11,3	11,5	10,2	10,1	12,1	11,1	10,8	11,1

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)	0 (PFU/ml)	6 (20 kPa)	PASS

BS ISO 16603+ EN 14126 Part 4.1.4.1			
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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	2,6x10 ⁸	2,2x10 ⁸	< 1	No penetration
Sample 2				2,6x10 ⁸	2,5x10 ⁸	< 1	No penetration
Sample 3				2,6x10 ⁸	2,6x10 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

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to penetration by biologically contaminant dust BS EN ISO 22612+ EN 14126 Part 4.1.4.4	0,37 log cfu	3 (log cfu≤1)	PASS

9. DECISION

Analysis and examinations CRN400-PCA-200 model coded personal protective equipment; EN ISO 13688:2013, EN 13034:2005+A1:2009, EN ISO 13982-1: 2004+A1:2010, 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