

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

Certificate No : 115-21-08-01
Certification Date / Certificate Validity Date : 13.08.2021-13.08.2022
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Company Name and Address : CARINE EUROPE GmbH
Ammannstraße 12, 86167 Augsburg, Germany
Product Name / Models : CRM400-IGA-100
Directive : 2016/425 REGULATION
Module / Category : MODULE C2 / CATEGORY III
Test Report No : MNA M-2021-01319
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: CRM400-IGA-100 model products are manufactured using coated fabric.

Erhan ÜSTÜNEL

13.08.2021

Approver



Okan AKEL

13.08.2021

General manager



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1. COMPANY INFORMATION:

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2. PPE INFORMATION:

Disposable non-sterile gown.

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



CRM400-IGA-100

5. PPE DIMENSIONS:

CRM400-IGA-100 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	7,21	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	55,23 (Newton) 53,12 (Newton) 56,87 (Newton) 49,08 (Newton) 22,12 (Newton) 18,76 (Newton) 45,67 (Newton) 44,21 (Newton) 21,44 (Newton) 19,43 (Newton)	1 (>10N)	PASS
Tensile strength ISO 13934-1	33,12 (Newton) 35,76 (Newton) 31,54 (Newton) 37,43 (Newton) 37,66 (Newton) 55,77 (Newton) 54,65 (Newton) 54,12 (Newton)	1 (>30N)	PASS

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	54,43 (Newton) 57,56 (Newton)		
Puncture resistance EN 863+ BS EN 14325 Part 4.10	5,56 (Newton) 5,54 (Newton) 5,23 (Newton) 5,21 (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: 0,8	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	77,21 (Newton) 75,34 (Newton) 72,77 (Newton)	2 (>50N)	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	40	2,6x10 ⁸	2,0x10 ⁸	< 1	No penetration
Sample 2				2,6x10 ⁸	2,2x10 ⁸	< 1	No penetration
Sample 3				2,6x10 ⁸	2,1x10 ⁸	< 1	No penetration

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration ISO 22610:2018 + EN 14126 Part 4.1.4.2	See below table	1 (t< 15 min)	PASS

Plates	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Plate 1	5	3	5	5	4
Plate 2	4	3	7	4	6
Plate 3	4	6	6	3	3
Plate 4	6	5	4	4	4
Plate 5	3	6	5	5	6
Penetration (%)	0,22	0,23	0,27	0,21	0,23
Total Penetration (%)	0,23				

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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	2,02 log cfu	1 ($2 < \log \text{cfu} \leq 3$)	PASS

9. DECISION

Analysis and examinations CRM400-IGA-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 : 13.08.2021