

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

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| <i>Certificate No</i> | : 115-21-02-01-R01 |
| <i>Certification Date / Certificate Validity Date</i> | : 02.09.2021-13.08.2022 |
| <i>Document Validity Period</i> | : 1 Year |
| <i>Company Name and Address</i> | : CARINE EUROPE GmbH Ammannstraße 12, 86167 Augsburg, Germany |
| <i>Product Name / Models</i> | : CRN400-PCA-100 |
| <i>Directive</i> | : 2016/425 REGULATION |
| <i>Module / Category</i> | : <i>MODULE C2 / CATEGORY III</i> |
| <i>Test Report No</i> | : MNA M-2021-01313 |
| <i>Product Type:</i> | |

- 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-PCA-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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**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (115-21-02-01-R01)**

Notified Body Number: 2841

Report No : 115-21-02-01-R01

Report Date : 02.09.2021

Application No : 115-21-02-01

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 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



CRN400-PCA-100

5. PPE DIMENSIONS:

CRN400-PCA-100 model product has been found to be produced using S-M-L-XL-2XL-3XL-4XL 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 EN ISO 3071 | 7,15 | 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 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 | 40,12 (Newton) 47,40 (Newton) 46,24 (Newton) 44,67 (Newton) 47,51 (Newton) 88,52 (Newton) 90,39 (Newton) 87,45 (Newton) 91,04 (Newton) 92,14 (Newton) | 3 (>40N) | PASS |
| Tensile strength ISO 13934-1 | 40,08 (Newton) 41,49 (Newton) 43,74(Newton) 40,10 (Newton) 43,86 (Newton) 92,22 (Newton) | 1 (>30N) | PASS |

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| | 91,33 (Newton) 89,40 (Newton) 91,30 (Newton) 92,56 (Newton) | | |
| Puncture resistance EN 863+ BS EN 14325 Part 4.10 | 6,98 (Newton) 8,40 (Newton) 7,29 (Newton) 8,60 (Newton) | 1 (>5N) | PASS |
| Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13 | H ₂ SO ₄ : 99,0 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: 0,5 | 3 (<1%) 3 (<1%) | PASS |
| Seam Strength EN ISO 13935-2 | 69,71 (Newton) 62,50 (Newton) 65,88 (Newton) 69,39 (Newton) 70,12 (Newton) 71,65 (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 | 1,1 | 0,20 | 60 | 2,5x10 ⁸ | 2,4x10 ⁸ | < 1 | No penetration |
| Sample 2 | | | | 2,5x10 ⁸ | 2,5x10 ⁸ | < 1 | No penetration |
| Sample 3 | | | | 2,5x10 ⁸ | 2,3x10 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 | 0,47 log cfu | 3 (log cfu≤1) | PASS |

9. DECISION

Analysis and examinations CRN400-PCA-100 model coded personal protective equipment; EN ISO 13688:2013, EN 14605:2005+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
SINGATURE :
DATE : 02.09.2021