

# EU Type-Examination Certificate

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| <b>Certificate No</b>                                 | : 115-21-08  |
| <b>Certification Date / Certificate Validity Date</b> | : 12.07.2021-12.07.2026  |
| <b>Document Validity Period</b>                       | : 5 Years  |
| <b>Company Name and Address</b>                       | : CARINE EUROPE GmbH<br>Ammannstraße 12, 86167 Augsburg, Germany |
| <b>Product Name / Models</b>                          | : CRM400-IGA-100   |
| <b>Directive</b>                                      | : 2016/425 REGULATION  |
| <b>Module / Category</b>                              | : MODULE B / CATEGORY III  |
| <b>Test Report No</b>                                 | : MNA M-2021-01244, BUTEKOM 2021-1273                            |

**Product Type:**

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

**Volkan AKIN**  
12.07.2021  
Approver



**Okan AKEL**  
12.07.2021  
General manager



**PICTOGRAM AND PERFORMANCE LEVELS:**

EN ISO 13688:2013

EN 1149-5: 2018

EN 14126:2003

EN 13034:2005+A1:2009 (Type 6-B)



NB 2841

Type PB 6-B

“Flammable material. Keep away from fire.”

“Do not re-use”

MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

**PRODUCT PICTURES**

CRM400-IGA-100

**DOCUMENTS IN THE TECHNICAL FILE**

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Technical Report

Report No : 115-21-08

Report Date : 12.07.2021

Application No : 115-21-08

**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.



## 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<br>EN ISO 3071 | 7,32   | 3,5 – 9,5         | PASS       |

### EN 13034:2005+A1:2009

| TEST   | RESULT   | PERFORMANCE LEVEL | EVALUATION |
|--|--|-------------------|------------|
| Abrasion resistance<br>BS EN 14325 Part 4.4            | >10 cycles<br>>10 cycles<br>>10 cycles<br>>10 cycles   | 1 (>10 cycle)     | PASS       |
| Tear resistance<br>EN ISO 9073-4+ BS EN 14325 Part 4.7 | 62,91 (Newton)<br>59,52 (Newton)<br>53,33 (Newton)<br>50,11 (Newton)<br>23,64 (Newton)<br>15,64 (Newton)<br>59,80 (Newton)<br>17,55 (Newton)<br>19,44 (Newton)<br>21,82 (Newton) | 1 (>10N)          | PASS       |
| Tensile strength<br>ISO 13934-1                        | 31,43 (Newton)<br>32,49 (Newton)<br>33,30 (Newton)<br>31,49 (Newton)<br>36,87 (Newton)<br>54,98 (Newton)<br>57,50 (Newton)<br>51,34 (Newton)                                     | 1 (>30N)          | PASS       |

## TECHNICAL EVALUATION REPORT (115-21-08)

|   |  |                      |      |
|---|--|----------------------|------|
|   | 54,92 (Newton)<br>57,43 (Newton)                                 |                      |      |
| Puncture resistance<br>EN 863+ BS EN 14325 Part 4.10                          | 5,84 (Newton)<br>5,69 (Newton)<br>5,27 (Newton)<br>5,62 (Newton) | 1 (>5N)              | PASS |
| Repellency to liquids<br>EN ISO 6530+ BS EN 14325 Part 4.12,13                | H <sub>2</sub> SO <sub>4</sub> : 98,4<br>NaOH: 99,0              | 3 (>90N)<br>3 (>90N) | PASS |
| Resistance to penetration by liquids<br>EN ISO 6530+ BS EN 14325 Part 4.12,13 | H <sub>2</sub> SO <sub>4</sub> : 0,9<br>NaOH: 0,8                | 3 (<1%)<br>3 (<1%)   | PASS |
| Seam Strength<br>EN ISO 13935-2   | 79,46 (Newton)<br>72,16 (Newton)<br>73,41 (Newton)               | 2 (>50N)             | PASS |

## EN 14126:2003

| TEST  | RESULT     | PERFORMANCE LEVEL | EVALUATION |
|---|------------|-------------------|------------|
| Penetration by blood borne pathogens (Bacteriophage)<br>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)<br>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 <sup>2</sup> | 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 <sup>8</sup>                           | 2,0x10 <sup>8</sup>                         | < 1                  | No penetration             |
| Sample 2 |                              |                |                                     | 2,6x10 <sup>8</sup>                           | 2,2x10 <sup>8</sup>                         | < 1                  | No penetration             |
| Sample 3 |                              |                |                                     | 2,6x10 <sup>8</sup>                           | 2,1x10 <sup>8</sup>                         | < 1                  | No penetration             |

| TEST  | RESULT                   | PERFORMANCE LEVEL | EVALUATION |
|---|--------------------------|-------------------|------------|
| Resistance to wet bacterial penetration<br>ISO 22610:2018 + EN 14126 Part 4.1.4.2 | Total penetration 0,25 % | 1 (t< 15 min)     | PASS       |

| Plates                | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 |
|-----------------------|----------|----------|----------|----------|----------|
| Plate 1               | 6        | 5        | 3        | 6        | 4        |
| Plate 2               | 6        | 4        | 5        | 4        | 6        |
| Plate 3               | 4        | 6        | 4        | 6        | 2        |
| Plate 4               | 5        | 5        | 4        | 6        | 7        |
| Plate 5               | 6        | 7        | 6        | 5        | 4        |
| Penetration (%)       | 0,27     | 0,27     | 0,22     | 0,27     | 0,23     |
| Total Penetration (%) | 0.25     |          |          |          |          |

| TEST   | RESULT       | PERFORMANCE LEVEL                  | EVALUATION |
|--|--------------|------------------------------------|------------|
| Resistance to penetration by biologically contaminant dust<br>BS EN ISO 22612+ EN 14126 Part 4.1.4.4 | 2,05 log cfu | 1 ( $2 < \log \text{cfu} \leq 3$ ) | PASS       |

**EN 1149-5: 2018**

| TEST                            | RESULT | PERFORMANCE LEVEL       | EVALUATION |
|---------------------------------|--------|-------------------------|------------|
| Half decay time ( $t_{50}$ , s) | 2,67   | $T_{50} < 4 \text{ sn}$ | PASS       |

**9. DECISION PROPOSAL**

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. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

CONTROLLER : VOLKAN AKIN

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DATE : 12.07.2021

