



Notified Body Number: 2841

# EU Type-Examination Certificate

**Certificate No** : 115-21-04-R01  
**Certification Date / Certificate Validity Date** : 02.09.2021-12.07.2026  
**Document Validity Period** : 5 Years  
**Company Name and Address** : CARINE EUROPE GmbH  
Ammannstraße 12, 86167 Augsburg, Germany  
**Product Name / Models** : CRN400-PGA-HC  
**Directive** : 2016/425 REGULATION  
**Module / Category** : MODULE B / CATEGORY III  
**Test Report No** : MNA M-2021-01245, BUTEKOM 2021-1273

**Product Type:**

- 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-PGA-HC model products are manufactured using coated fabric.

**Reason for revision:** Model name has been revised.

**Volkan AKIN**

02.09.2021

Approver

**Okan AKEL**

02.09.2021

General manager



MNA Laboratuvarları San. Tic.Ltd .Şti  
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**ATTACHMENTS (115-21-04-R01)**

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

**Model : CRN400-PGA-HC**

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type PB 3-B, Type PB 4-B
Abrasion Resistance	1
Tear Resistance (Trapezoidal)	3
Tensile Strength	1
Puncture Resistance	1
Liquid Repellency	NaOH: 3, H <sub>2</sub> SO <sub>4</sub> : 3
Resistance To Penetration By Liquid	NaOH: 3, H <sub>2</sub> SO <sub>4</sub> : 3
Flex Cracking Resistance	1
Seam Strength	2
Permeation by Liquids	NaOH: 2
Wet Bacterial Penetration	6
Dry Microbial Penetration	3
Phi-X174 Bacteriophage	6
Synthetic Blood	6
Half Decay Time (t <sub>50</sub> , s)	2,83

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

MARKING
<b>MANUFACTURER:</b> AYDAĞ TEDAVİ VE SAĞLIK HİZMETLERİ SAN. VE TİC. A.Ş.
<b>PPE TYPE:</b> <ul style="list-style-type: none"><li>- EN ISO 13688:2013 Protective clothing - General requirements</li><li>- EN 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)</li><li>- EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents</li><li>- EN 1149-5: 2018 Protective clothing - Electrostatic properties</li></ul>
<b>MODEL:</b> CRN400-PGA-HC
Material: 63 g/qm +/- 5 % 41 g/qm SMMS (Spunbond/Meltblown/Meltblown/Spunbond) 20 g/qm PE Film 2 g/qm Hotmelt
<b>PRODUCT SIZE:</b> Standard



**ATTACHMENTS (115-21-04-R01)****PICTOGRAM AND PERFORMANCE LEVELS:**

EN ISO 13688:2013

EN 14605:2005+A1:2009 (Type 3-B, 4-B)

EN 14126:2003

EN 1149-5: 2018



NB 2841

"Flammable material. Keep away from fire."

Type PB 3-B, Type PB 4-B

"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**

CRN400-PGA-HC

**DOCUMENTS IN THE TECHNICAL FILE**

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

**Report No** : 115-21-04-R01

**Report Date** : 02.09.2021

**Application No** : 115-21-04

**1. COMPANY INFORMATION:**

CARINE EUROPE GmbH

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**2. PPE INFORMATION:**

Disposable non-sterile hood.

**3. PPE TYPE IDENTIFICATION**

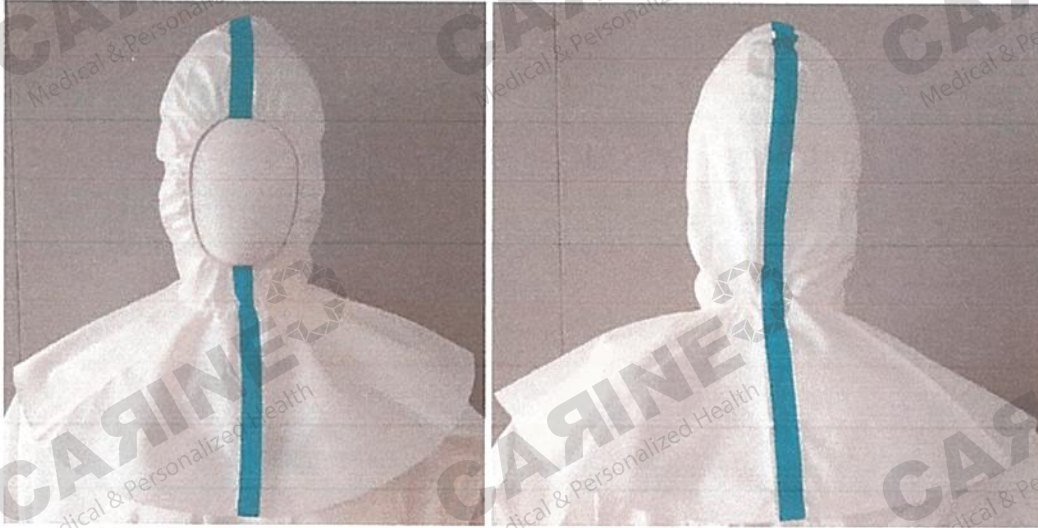
EN ISO 13688:2013 Protective clothing - General requirements

EN 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 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-PGA-HC

**5. PPE DIMENSIONS:**

CRN400-PGA-HC model product has been found to be produced using standard 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	6,99	3,5 – 9,5	PASS

#### EN 14605:2005+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	40,33 (Newton) 44,09 (Newton) 41,23 (Newton) 43,66 (Newton) 40,19 (Newton) 99,66 (Newton) 93,81 (Newton) 98,49 (Newton) 97,79 (Newton) 95,69 (Newton)	3 (>40N)	PASS
Tensile strength ISO 13934-1	39,98 (Newton) 37,81 (Newton) 38,88 (Newton) 40,11 (Newton) 40,59 (Newton) 100,30 (Newton) 101,56 (Newton) 104,89 (Newton) 106,44 (Newton) 99,52 (Newton)	1 (>30N)	PASS
Puncture resistance EN 863+ BS EN 14325 Part 4.10	8,04 (Newton) 6,69 (Newton)	1 (>5N)	PASS

	7,45 (Newton) 6,91 (Newton)		
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H <sub>2</sub> SO <sub>4</sub> : 98,7 NaOH: 99,1	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H <sub>2</sub> SO <sub>4</sub> : 0,9 NaOH: 0,6	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	74,55 (Newton) 78,09 (Newton) 76,11 (Newton)	2 (>50N)	PASS
Resistance to penetration by spray liquid (spray test) BS EN ISO 17491-4	0 cm <sup>2</sup>	3 times the maximum calibration stain	PASS
Resistance to penetration by jet of liquid (jet test) BS EN ISO 17491-3	0 cm <sup>2</sup>	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 <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	60	2,5x10 <sup>8</sup>	2,3x10 <sup>8</sup>	< 1	No penetration
Sample 2				2,5x10 <sup>8</sup>	2,4x10 <sup>8</sup>	< 1	No penetration
Sample 3				2,5x10 <sup>8</sup>	2,5x10 <sup>8</sup>	< 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 (>75 min)	PASS

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION



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TECHNICAL EVALUATION REPORT (115-21-04-R01)

Resistance to penetration by biologically contaminant dust BS EN ISO 22612+ EN 14126 Part 4.1.4.4	0,38 log cfu	3 (log cfu $\leq$ 1)	PASS
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EN 1149-5: 2018

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Half decay time ( $t_{50}$ , s)	2,83	$T_{50} < 4 \text{ sn}$	PASS

### 9. DECISION PROPOSAL

Analysis and examinations CRN400-PGA-HC model coded personal protective equipment; EN ISO 13688:2013, EN 14605:2005+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

SING :

DATE : 02.09.2021