



Notified Body Number: 2841

# EU Type-Examination Certificate

**Certificate No** : 115-21-01-R01  
**Certification Date / Certificate Validity Date** : 02.09.2021-12.07.2026  
**Document Validity Period** : 5 Years  
**Company Name and Address** : CARINE EUROPE GmbH  
Ammannstr. 12, 86167 Augsburg, Germany  
**Product Name / Models** : CRN400-PCA-300  
**Directive** : 2016/425 REGULATION  
**Module / Category** : MODULE B / CATEGORY III  
**Test Report No** : MNA M-2021-01242, BUTEKOM 2021-1273  
**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 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-300 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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U-Form-002/Rev.04/12.03.2021



**ATTACHMENTS (115-21-01-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-PCA-300**

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type 3-B, Type 4-B, Type 5-B, Type 6-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)	2,80

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**

**MANUFACTURER:** AYDAĞ TEDAVİ VE SAĞLIK HİZMETLERİ SAN. VE TİC. A.Ş.  
CARINE Europe GmbH

**PPE 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 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

**MODEL:** CRN400-PCA-300

Material: 63 g/qm +/- 5 %

41 g/qm SMMS (Spunbond/Meltblown/Meltblown/Spunbond)

20 g/qm PE Film

2 g/qm Hotmelt

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**PRODUCT SIZE:** S, M, L, XL, 2XL, 3XL, 4XL**PICTOGRAM AND PERFORMANCE LEVELS:**

EN ISO 13688:2013

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

EN 14126:2003

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

EN ISO 13982-1: 2004+A1:2010 (Type 5-B)

EN 1149-5: 2018

"Flammable material. Keep away from fire."

"Do not re-use"



NB 2841

Type 3-B, Type 4-B, Type 5-B, Type 6-B

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-PCA-300

**DOCUMENTS IN THE TECHNICAL FILE**

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

Report No : 115-21-01-R01

Report Date : 02.09.2021

Application No : 115-21-01

**1. COMPANY INFORMATION:**

CARINE Europe GmbH, Ammannstr. 12, 86167 Augsburg, Germany

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Mail: info@carine-medical.com

**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 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-300

**5. PPE DIMENSIONS:**

CRN400-PCA-300 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	7,07	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	94,44 (Newton) 95,43 (Newton) 87,03 (Newton) 43,73 (Newton) 43,79 (Newton) 45,48 (Newton) 75,51 (Newton) 80,64 (Newton) 46,28 (Newton) 41,84 (Newton)	3 (>40N)	PASS
Tensile strength ISO 13934-1	43,57 (Newton) 46,36 (Newton) 41,48 (Newton) 119,97 (Newton) 106,33 (Newton) 103,91 (Newton) 46,23 (Newton) 98,58 (Newton)	1 (>30N)	PASS

Puncture resistance EN 863+ BS EN 14325 Part 4.10	117,38 (Newton) 40,71 (Newton) 8,42 (Newton) 7,71 (Newton) 9,29 (Newton) 9,64 (Newton)	1 (>5N)	PASS
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H <sub>2</sub> SO <sub>4</sub> : 98,1 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: 0,5	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	123,37 (Newton) 127,47 (Newton) 117,61 (Newton) 125,93 (Newton) 62,24 (Newton) 66,07 (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
Total inward leakage ISO 13982-2	Ljmn,82/90:12,6 Ls,8/10:10,9 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	7,5	8,8	7,5	11,3	9,6	10,7	10,6	8,2	13,9	9,2	9,7
	Waist	10,0	8,5	10,7	9,3	10,1	10,8	10,7	8,4	12,2	10,7	10,2
	Chest	10,6	9,7	6,0	9,7	12,4	3,5	10,1	9,4	11,6	11,5	9,5
Walking	Knee	12,2	7,6	9,7	7,5	8,1	9,8	10,6	10,6	13,7	10,5	10,0
	Waist	11,6	6,2	9,4	10,7	9,4	9,5	12,2	9,3	9,3	11,4	9,9
	Chest	10,6	10,1	9,7	14,1	9,0	3,7	8,6	8,8	11,5	11,1	9,7
Squatting	Knee	12,2	8,4	9,4	7,5	9,0	9,6	10,2	14,8	11,8	12,6	10,6
	Waist	9,2	6,8	13,0	6,5	9,8	10,7	9,8	15,9	12,6	11,5	10,6
	Chest	7,2	7,7	12,5	13,8	11,8	10,3	10,8	13,5	8,9	9,9	10,6
Average		10,1	8,2	9,8	10,0	9,9	8,7	10,4	11,0	11,7	10,9	10,1



**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) 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	1,1	0,20	60	2,6x10 <sup>8</sup>	2,5x10 <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>	2,5x10 <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 (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	0,35 log cfu	3 (log cfu≤1)	PASS

**EN 1149-5: 2018**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Half decay time (t <sub>50</sub> , s)	2,80	T <sub>50</sub> < 4 sn	PASS

**9. DECISION PROPOSAL**

Analysis and examinations CRN400-PCA-300 model coded personal protective equipment; EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14605:2005+A1:2009, EN ISO 13982-1: 2004+A1:2010, 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

