



Notified Body Number: 2841

EU Type-Examination Certificate

Certificate No	: 115-21-07-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-LSC-100
Directive	: 2016/425 REGULATION
Module / Category	: MODULE B / CATEGORY III
Test Report No	: MNA M-2021-01247, 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: CRN400-PGA-LSC-100 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 (115-21-07-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-LSC-100

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type PB 6-B
Abrasion Resistance	1
Tear Resistance (Trapezoidal)	3
Tensile Strength	1
Puncture Resistance	1
Liquid Repellency	NaOH: 3, H ₂ SO ₄ : 3
Resistance To Penetration By Liquid	NaOH: 3, H ₂ SO ₄ : 3
Seam Strength	2
Wet Bacterial Penetration	6
Dry Microbial Penetration	3
Phi-X174 Bacteriophage	6
Synthetic Blood	6
Half Decay Time (t ₅₀ , s)	2,91

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.
PPE TYPE: <ul style="list-style-type: none">- 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
MODEL: CRN400-PGA-LSC-100
Material: 63 g/qm +/- 5 % 41 g/qm SMMS (Spunbond/Meltblown/Meltblown/Spunbond) 20 g/qm PE Film 20 g/qm Hotmelt
PRODUCT SIZE: Standard

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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

“Flammable material. Keep away from fire.”

Type PB 6-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-LSC-100

DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 115-21-07-R01
Report Date : 02.09.2021
Application No : 115-21-07

1. COMPANY INFORMATION:

CARINE EUROPE GmbH
Ammannstraße 12, 86167 Augsburg, Germany
Tel: +49 821 45560525
Fax: +49 821 45560524
Mail: info@carine-medical.com

2. PPE INFORMATION:

Disposable non-sterile overboot.

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



CRN400-PGA-LSC-100

5. PPE DIMENSIONS:

CRM400-PGA-LSC-100 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	7,09	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	44,01 (Newton) 47,97 (Newton) 44,69 (Newton) 48,31 (Newton) 47,05 (Newton) 100,01 (Newton) 102,24 (Newton) 103,25 (Newton) 98,89 (Newton) 96,49 (Newton)	3 (>40N)	PASS
Tensile strength ISO 13934-1	39,71 (Newton) 41,77 (Newton) 47,23 (Newton) 40,33 (Newton) 41,09 (Newton) 99,05 (Newton) 98,34 (Newton) 94,58 (Newton) 98,78 (Newton) 99,98 (Newton)	1 (>30N)	PASS
Puncture resistance EN 863+ BS EN 14325 Part 4.10	7,18 (Newton) 6,08 (Newton)	1 (>5N)	PASS

	7,54 (Newton) 7,33 (Newton)		
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 : 0,9 NaOH: 0,6	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	67,09 (Newton) 70,11 (Newton) 73,78 (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

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	60	2,8x10 ⁸	2,8x10 ⁸	< 1	No penetration
Sample 2				2,8x10 ⁸	2,7x10 ⁸	< 1	No penetration
Sample 3				2,8x10 ⁸	2,5x10 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
Resistance to penetration by biologically contaminant dust BS EN ISO 22612+ EN 14126 Part 4.1.4.4	0,45 log cfu	3 (log cfu≤1)	PASS

EN 1149-5: 2018

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Half decay time (t ₅₀ , s)	2,91	T ₅₀ < 4 sn	PASS



MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ.

MNA LABORATUVARLARI

TECHNICAL EVALUATION REPORT (115-21-07-R01)

9. DECISION PROPOSAL

Analysis and examinations CRN400-PGA-LSC-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

SING :

DATE : 02.09.2021