



Notified Body Number: 2841

EU Type-Examination Certificate

Certificate No : 115-21-06-R01
Certification Date / Certificate Validity Date : 02.09.2021-01.09.2026
Document Validity Period : 5 Years
Company Name and Address : CARINE EUROPE GmbH
Ammannstraße 12, 86167 Augsburg, Germany
Product Name / Models : CRN400-PGA-HC-100
Directive : 2016/425 REGULATION
Module / Category : MODULE B / CATEGORY III
Test Report No : MNA M-2021-01246, 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-HC-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 (115-21-06-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-100

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type PB 6-B
Abrasion Resistance	1
Tear Resistance (Trapezoidal)	2
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)	2,53

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-HC-100
Material: 63 g/qm +/- 5 % 41 g/qm SMMS (Spunbond/Meltblown/Meltblown/Spunbond) 20 g/qm PE Film 2 g/qm Hotmelt
PRODUCT SIZE: Standard

ATTACHMENTS (115-21-06-R01)**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."

"Do not re-use"

Type PB 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-PGA-HC-100

DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 115-21-06-R01
Report Date : 02.09.2021
Application No : 115-21-06

1. COMPANY INFORMATION:

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

2. PPE INFORMATION:

Disposable non-sterile hood.

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-HC-100

5. PPE DIMENSIONS:

CRN400-PGA-HC-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	7,07	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	33,81 (Newton) 36,52 (Newton) 34,77 (Newton) 39,65 (Newton) 38,28 (Newton) 98,17 (Newton) 95,74 (Newton) 91,01 (Newton) 97,04 (Newton) 95,17 (Newton)	2 (>20N)	PASS
Tensile strength ISO 13934-1	94,66 (Newton) 90,24 (Newton) 90,09 (Newton) 87,73 (Newton) 89,55 (Newton) 42,31 (Newton) 42,69 (Newton) 43,31 (Newton) 40,43 (Newton) 40,89 (Newton)	1 (>30N)	PASS

Puncture resistance EN 863+ BS EN 14325 Part 4.10	6,49 (Newton) 6,82 (Newton) 7,31 (Newton) 6,29 (Newton)	1 (>5N)	PASS
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H ₂ SO ₄ : 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 ₂ SO ₄ : 0,6 NaOH: 0,5	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	76,81 (Newton) 75,19 (Newton) 72,01 (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	2,6x10 ⁸	2,3x10 ⁸	< 1	No penetration
Sample 2				2,6x10 ⁸	2,3x10 ⁸	< 1	No penetration
Sample 3				2,6x10 ⁸	2,4x10 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	0,53 log cfu	3 (log cfu≤1)	PASS

EN 1149-5: 2018

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Half decay time (t ₅₀ , s)	2,53	T ₅₀ < 4 sn	PASS



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MNA LABORATUVARLARI

TECHNICAL EVALUATION REPORT (115-21-06-R01)

9. DECISION PROPOSAL

Analysis and examinations CRN400-PGA-HC-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