



Notified Body Number: 2841

EU Type-Examination Certificate

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



MNA Laboratuvarları San. Tic.Ltd .Şti
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ATTACHMENTS (115-21-08)

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 : CRM400-IGA-100

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type PB 6-B
Abrasion Resistance	1
Tear Resistance (Trapezoidal)	1
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	1
Dry Microbial Penetration	1
Phi-X174 Bacteriophage	6
Synthetic Blood	6
Half Decay Time (t ₅₀ , s)	2,67

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:

- EN ISO 13688:2013 Protective clothing - General requirements
- EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
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MODEL: CRM400-IGA-100

Material: 45 g/qm +/- 5 %

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

18 g/qm PE Film

2 g/qm Hotmelt

PRODUCT SIZE: S, M, L, XL, 2XL, 3XL, 4XL

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

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:

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 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 EN ISO 3071	7,32	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	62,91 (Newton) 59,52 (Newton) 53,33 (Newton) 50,11 (Newton) 23,64 (Newton) 15,64 (Newton) 59,80 (Newton) 17,55 (Newton) 19,44 (Newton) 21,82 (Newton)	1 (>10N)	PASS
Tensile strength ISO 13934-1	31,43 (Newton) 32,49 (Newton) 33,30 (Newton) 31,49 (Newton) 36,87 (Newton) 54,98 (Newton) 57,50 (Newton) 51,34 (Newton)	1 (>30N)	PASS

	54,92 (Newton) 57,43 (Newton)		
Puncture resistance EN 863+ BS EN 14325 Part 4.10	5,84 (Newton) 5,69 (Newton) 5,27 (Newton) 5,62 (Newton)	1 (>5N)	PASS
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H ₂ SO ₄ : 98,4 NaOH: 99,0	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: 0,8	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	79,46 (Newton) 72,16 (Newton) 73,41 (Newton)	2 (>50N)	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	40	2,6x10 ⁸	2,0x10 ⁸	< 1	No penetration
Sample 2				2,6x10 ⁸	2,2x10 ⁸	< 1	No penetration
Sample 3				2,6x10 ⁸	2,1x10 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 0,25 %	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				



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MNA LABORATUVARLARI

TECHNICAL EVALUATION REPORT (115-21-08)

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to penetration by biologically contaminant dust 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

SING :

DATE : 12.07.2021