

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 63-20-02-R01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 05.04.2021-18.08.2025
Belge Geçerlilik Tarihi / Document Validity Period : 63-20-02 (18.08.2020-18.08.2025) kodlu sertifikanın süresi boyunca geçerlidir./ Valid for the duration of the certificate with code 63-20-02 (18.08.2020-18.08.2025)
Firma Unvanı ve Adresi /
Company Name and Address : PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130
Ümraniye 34775 İstanbul / Türkiye
Ürün Adı /Modeller / Product Name / Models : SUVICOM SV-20
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Test Rapor No/ları / Test Report No : MNA Certificate no 63-20-02 (18.08.2020-18.08.2025)
Ürün Tipi / Product Type:
- EN ISO 13688 Koruyucu giyecekler - Genel özellikler / Protective clothing - General requirements
- EN 13034+ A1 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip PB 6-B) / Protective Clothing Against Liquid Chemicals (Type PB 6-B)
- EN 14126 Koruyucu Giyecekler - Patojen Organizmalara Karşı / Protective Clothing - Performance Requirements And Tests Methods For Protective Clothing Against Infective Agents
Ürünün Malzeme Bilgisi / Product Material Information: SUVICOM SV-20 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ SUVICOM SV-20 model products are manufactured using coated fabric.
Revizyon nedeni/ Reason for revision: Firma unvanı ve adresi revize edilmiştir./ Company name and address have been revised.

Volkan AKIN
05.04.2021
Karar Verici / Approver

Okan AKEL
05.04.2021
Şirket Müdürü / General manager



ATTACHMENTS (63-20-02-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 : SUVICOM SV-20

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	1
Wet Bacterial Penetration	1
Dry Microbial Penetration	1
Phi-X174 Bacteriophage	2

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: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.	
PPE TYPE: - EN ISO 13688 Protective clothing - General requirements - EN 14126 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents - EN 13034+ A1 Protective Clothing Against Liquid Chemicals (Type PB 6-B)	
MODEL: SUVICOM SV-20 PRODUCT SIZE: Standard	
PICTOGRAM AND PERFORMANCE LEVELS: EN ISO 13688 EN 13034+A1 (Type PB 6-B) EN 14126	
	
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.

MNA Laboratuvarları San. Tic.Ltd .Şti

Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul

Tel: 0216 574 07 08 Faks: 0216 575 13 31 www.mnalab.com

U-Form-002/Rev.04/12.03.2020

PRODUCT PICTURES

SUVICOM SV-20

DOCUMENTS IN THE TECHNICAL FILE

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

MNA Laboratuvarları San. Tic.Ltd .Şti

Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul

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MNA LABORATORIES ANALYSIS REPORT

Report No : 63-20-02	Date: 20.08.2020	Page: 1 / 7	Rev:
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Purpose of Analysis	: SPECIAL REQUEST	Brand	:
Sample Type	: BLUE PROTECTION GOWN	Model	:
Sample Send Org.	: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.	Sampler	: CUSTOMER
Manufacturer Name	: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.		
Analysis Date	: 07.08.2020		
Sample Quantity	: 25 pieces		
Other informations	:		

No	Tests	Results	Limit Value	Method	Evaluation	Physical Condition
1	Abrasion Resistance	10 (Cycle)	>10 Cycle	BS EN 14325 Part 4.4	PASS	NO DAMAGE
2		10 (Cycle)	>10 Cycle	BS EN 14325 Part 4.4		
3		10 (Cycle)	>10 Cycle	BS EN 14325 Part 4.4		
4		10 (Cycle)	>10 Cycle	BS EN 14325 Part 4.4		
5	Tear Resistance- Trapezoidal	50,30(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7	PERFORMANC E LEVEL:1	
6		56,96(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
7		59,43(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
8		62,28(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
9		77,39(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
10		17,35(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
11		17,15(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
12		18,47(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
13		17,37(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
14		18,61(Newton)	> 10 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
15	Puncture Resistance	5,33(Newton)	>5 N	EN 863+ BS EN 14325 Part 4.10	PERFORMANC E LEVEL:1	
16		5,68(Newton)	>5 N	EN 863+ BS EN 14325 Part 4.10		
17		5,78(Newton)	>5 N	EN 863+ BS EN 14325 Part 4.10		

MNA LABORATORIES ANALYSIS REPORT

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Sample Send Org.	: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.	Sampler	: CUSTOMER
Manufacturer Name	: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.		
Analysis Date	: 07.08.2020		
Sample Quantity	: 25 pieces		
Other informations	:		

18	Puncture Resistance	5,82 (Newton)		>5 N	EN 863+ BS EN 14325 Part 4.10	PERFORMANC E LEVEL:1
19	Resistance to liquids- Sulphuric acid	Penetration	0 (%)	<1%	EN ISO 6530+ BS EN 14325 Part4.12,13	PERFORMANC E LEVEL:3
		Repellency	98 (%)	>90%	EN ISO 6530+ BS EN 14325 Part4.12,13	
		Absorption	- (%)		EN ISO 6530+ BS EN 14325 Part4.12,13	
20	Resistance to liquids- Sodium Hydroxide	Penetration	0 (%)	<1%	EN ISO 6530+ BS EN 14325 Part4.12,13	PERFORMANC E LEVEL:3
		Repellency	99 (%)	>90%	EN ISO 6530+ BS EN 14325 Part4.12,13	
		Absorption	- (%)		EN ISO 6530+ BS EN 14325 Part4.12,13	
21	Wet Bacterial Penetration (1. sample)	1. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		2. plate	1 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		3. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		4. plate	3 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		5. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		6. plate	- (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		%Penetration	0,08 (%)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
22	Wet Bacterial Penetration (2. sample)	1. plate	4 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	

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Sample Type	: BLUE PROTECTION GOWN	Model	:
Sample Send Org.	: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.	Sampler	: CUSTOMER
Manufacturer Name	: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.		
Analysis Date	: 07.08.2020		
Sample Quantity	: 25 pieces		
Other informations	:		

22	Wet Bacterial Penetration (2. sample)	2. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		3. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		4. plate	6 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		5. plate	5 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		6. plate	- (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		%Penetration	0,16 (%)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
23	Wet Bacterial Penetration (3. sample)	1. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		2. plate	4 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		3. plate	7 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		4. plate	8 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		5. plate	5 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		6. plate	- (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		%Penetration	0,22 (%)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		

**MNA LABORATORIES
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Purpose of Analysis : SPECIAL REQUEST **Brand** :
Sample Type : BLUE PROTECTION GOWN **Model** :
Sample Send Org. : PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. **Sampler** : CUSTOMER
Manufacturer Name : PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
Analysis Date : 07.08.2020
Sample Quantity : 25 pieces
Other informations :

24	Wet Bacterial Penetration (4. sample)	1. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		2. plate	6 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		3. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		4. plate	8 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		5. plate	1 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		6. plate	- (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		%Penetration	0,16 (%)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
25	Wet Bacterial Penetration (5. sample)	1. plate	1 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		2. plate	6 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		3. plate	5 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		4. plate	7 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		5. plate	8 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		6. plate	- (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		

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Purpose of Analysis	: SPECIAL REQUEST	Brand	:
Sample Type	: BLUE PROTECTION GOWN	Model	:
Sample Send Org.	: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.	Sampler	: CUSTOMER
Manufacturer Name	: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.		
Analysis Date	: 07.08.2020		
Sample Quantity	: 25 pieces		
Other informations	:		

25	Wet Bacterial Penetration (5. sample)	%Penetration	0,23 (%)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2		
		Total Penetration%	0,17 (%)	t<15 Dakika	ISO 22610:2018 + TS EN 14126 Part4.1.4.2	PERFORMANC E LEVEL:1	
26	Seam Strength	35,66(Newton)	>30 N	EN ISO 13935-2		PERFORMANC E LEVEL:1	
27		36,49(Newton)	>30 N	EN ISO 13935-2			
28		32,38(Newton)	>30 N	EN ISO 13935-2			
29		38,57(Newton)	>30 N	EN ISO 13935-2			
30		30,53(Newton)	>30 N	EN ISO 13935-2			
31		33,19(Newton)	>30 N	EN ISO 13935-2			
32	Tensile Strength	32,35(Newton)	>30 N	ISO 13934-1		PERFORMANC E LEVEL:1	
33		34,29(Newton)	>30 N	ISO 13934-1			
34		34,02(Newton)	>30 N	ISO 13934-1			
35		32,32(Newton)	>30 N	ISO 13934-1			
36		33,24(Newton)	>30 N	ISO 13934-1			
37		62,67(Newton)	>30 N	ISO 13934-1			
38		68,43(Newton)	>30 N	ISO 13934-1			
39		69,55(Newton)	>30 N	ISO 13934-1			
40		67,32(Newton)	>30 N	ISO 13934-1			
41		68,54(Newton)	>30 N	ISO 13934-1			

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Purpose of Analysis : SPECIAL REQUEST **Brand** :
Sample Type : BLUE PROTECTION GOWN **Model** :
Sample Send Org. : PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. **Sampler** : CUSTOMER
Manufacturer Name : PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
Analysis Date : 07.08.2020
Sample Quantity : 25 pieces
Other informations :

42	Dry Microbial Penetration	2,04 (log cfu)	2<log cfu<3	BS EN ISO 22612+ TS EN 14126 Part4.1.4.4	PERFORMANC E LEVEL:1	
43		0 (PFU/ml)	1,75 kPa	BS ISO 16604+ TS EN 14126 Part4.1.4.1		
44	Penetration by Blood Borne Pathogens- Bacteriophage	0 (PFU/ml)	1,75 kPa	BS ISO 16604+ TS EN 14126 Part4.1.4.1	PERFORMANC E LEVEL:2	
45		0 (PFU/ml)	1,75 kPa	BS ISO 16604+ TS EN 14126 Part4.1.4.1		
46	Determination of pH *	6,41	3.5 < Result < 9.5	EN 420 + A1 Part 4.3.2 TS EN ISO 3071	PASS	

SAMPLE PLACE

**MNA LABORATORIES
ANALYSIS REPORT**

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Manufacturer Name : PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
Analysis Date : 07.08.2020
Sample Quantity : 25 pieces
Other informations :

Operating as an experimental laboratory, MNA Laboratories have been accredited by TÜRKAK with AB-1183-T and TS EN ISO / IEC 17025: 2017 standard. Turkish Accreditation Agency (TÜRKAK) signed a multilateral agreement with the European Accreditation Association (EA) on the recognition of test reports and a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC).

* Analysis is under accreditation.

Note :

1. No part of this analysis report can be used alone or separately, and may not be partially copied or reproduced, used to third parties and as a means of advertising without the written permission of the laboratory.
2. Analysis results are valid for the above mentioned sample sent by MNA Laboratory company / institution / person. It may not represent the whole.
3. Unsigned and unsealed reports are invalid.
4. This analysis report cannot be used in judicial-administrative procedures and for advertising purposes.
5. Results are valid for the sample as received.
6. The decision rule is the rule that determines how measurement uncertainty is taken into account when specifying the PASS density to a specified specification. According to the TLM-052 Decision Rule Implementation instruction, the Decision Rule Implementation Method selected in agreement with CUSTOMER is clearly stated in the report.
7. Limit Values are determined by taking from analysis methods.
8. The laboratory is not responsible if the information provided by the CUSTOMER affects the validity of the results.
9. Test and / or measurement results, expanded measurement uncertainties (if any) and test methods are given in the following pages, which are the supplementary part of this certificate.
10. Water Repellency Determination Hydrostatic Pressure Determination TS ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13965-2 (Strength Test Device E / N: 50) Analysis and resistance to liquid chemical permeation TS EN 659 -A1 Part 3.18 (Liquid Chemical Transfer Device E / N: 107) Analysis is carried out in the conditioning room and ISO 139 PART 3.2 conditions (23 ± 2 ° C temperature and 50 ± 4% relative humidity) are applied for ambient conditions.
11. List of phthalates analyzed is below.
Di-iso-nonyl phthalate (DINP), CAS number: 28553-12-0 or 68515-48-0
Di- (2-ethylhexyl) phthalate (DEHP), CAS number: 117-81-7
Di-n-octyl phthalate (DNOP), CAS number: 117-84-0
Di-iso-decyl phthalate (DIDP), CAS number: 26761-40-0 or 68515-49-1
Butyl benzyl phthalate (BBP), CAS number: 85-68-7
Di-butyl phthalate (DBP), CAS number: 84-74-2

Selin GERGİN

Sample Reception and
Reporting Officer

Erhan ÜSTÜNEL

PPE Lab. Responsible

Confirmed

20.08.2020

Volkan AKIN

Laboratory Manager

Report No : 63-20-02-R01-01

Report Date : 20.04.2021

Application No : 63-20-02-R01-01

1. COMPANY INFORMATION:

PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130 Ümraniye 34775 İstanbul / Türkiye

Tel: +905333221100

Mail: info@podimabilisim.com

2. PPE INFORMATION:

Disposable non-sterile gown.

3. PPE TYPE IDENTIFICATION

EN 13688 Protective clothing - General requirements

EN 13034 Protective clothing against liquid chemicals (Type PB 6-B)

EN 14126 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

4. PPE PICTURES



SUVICOM SV-20

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (63-20-02-R01-01)**

5. PPE DIMENSIONS:

SUVICOM SV-20 model product has been found to be produced using standart 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

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
pH value	6,89	3,5 – 9,5	PASS

EN 13034

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles	1	PASS
Tear resistance	42,38 N	3	PASS
Tensile strength	50,26 N	1	PASS
Puncture resistance	5,91 N	1	PASS
Repellency to liquids	H2SO4: 98,4 NaOH: 99,1	3 3	PASS
Resistance to penetration by liquids	H2SO4: 0,8 NaOH: 0,7	3 3	PASS
Seam Strength	99,02 N	3	PASS

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (63-20-02-R01-01)**

EN 14126

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage)	3,5 kPa 0 (PFU/ml)	3	PASS
Resistance to wet bacterial penetration	%0,16	1	PASS
Resistance to penetration by biologically contaminant dust	2,02 (log cfu)	1	PASS

9. DECISION

Analysis and examinations SUVICOM SV-20 model coded personal protective equipment; EN 13688, EN 14126, EN 13034 Experiments and Marking standards are evaluated. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- User Instruction

CONTROLLER :ERHAN ÜSTÜNEL**SING :****DATE : 20.04.2021**