

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 79020475
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 20.02.2023-05.12.2025
Belge Geçerlilik Tarihi / Document Validity Period : 5 Yıl/ 5 Years
Firma Unvanı ve Adresi /
Company Name and Address : PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
ŞERİFALİ MAH. MEVDUDİ SK. NO: 53 İÇ KAPI NO: 1
ÜMRANİYE/ İSTANBUL
Marka / Model / Brand / Model : SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-
145 - SV-146 - SV-147 - SV-148 - SV-149
Direktifi / Directive : 2016/425 REGULATION
Modül/Kategori / Module / Category : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Teknik Değerlendirme Rapor No/
Technical Evaluation Report No : MNA 79020475
Ürün Tipi / Product Type:
- EN ISO 13688:2013/A1:2021 Koruyucu giyecekler - Genel özellikler / Protective clothing - General requirements
- EN 13034:2005+A1:2009 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip PB 6-B) / Protective Clothing Against
Liquid Chemicals (Type PB 6-B)
- EN 14605:2005+A1:2009 Koruyucu Giyecekler - Sıvı Kimyasal Maddelere Karşı (Tip PB 3-B, Tip PB 4-B) /
Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)
- EN 14126:2003/AC:2004 Koruyucu Giyecekler - Patojen Organizmalara Karşı / Protective Clothing - Performance
Requirements And Tests Methods For Protective Clothing Against Infective Agents
- EN 1149-5: 2018 Koruyucu giysi - Elektrostatik özellikler / Protective clothing - Electrostatic properties
Ürünün Malzeme Bilgisi / Product Material Information: SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 -
SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ SUVICOM
SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model products are
manufactured using coated fabric.
Revizyon nedeni/ Reason for revision: Kapsam genişletilmiştir./ The scope has been expanded.

Volkan AKIN
20.02.2023
Karar Verici / Approver



Okan AKEL
20.02.2023
Şirket Müdürü / General manager



ATTACHMENTS (79020475)

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-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type PB 3-B, Type PB 4-B, 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
Flex Cracking Resistance	1
Seam Strength	2
Permeation by Liquids	NaOH: 2
Wet Bacterial Penetration	1
Dry Microbial Penetration	1
Phi-X174 Bacteriophage	3
Half Decay Time (t50, s)	2,95

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: <ul style="list-style-type: none">- EN ISO 13688:2013/A1:2021 Protective clothing - General requirements- EN 13034:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 6-B)- EN 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)- EN 14126:2003/AC:2004 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents- EN 1149-5: 2018 Protective clothing - Electrostatic properties
MODEL: SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149
PRODUCT SIZE: S, M, L, XL, 2XL, 3XL, 4XL

ATTACHMENTS (79020475)**PICTOGRAM AND PERFORMANCE LEVELS:**

EN ISO 13688:2013/A1:2021
EN 14605:2005+A1:2009
EN 14126:2003/AC:2004
EN 13034:2005+A1:2009
EN 1149-5:2018



NB 2841



"Flammable material. Keep away from fire."
"Do not re-use"

Type PB 3-B, Type PB 4-B, 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

SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148
- SV-149

DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 79020475

Report Date : 20.02.2023

Application No : 79020475

1. COMPANY INFORMATION:

PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
ŞERİFALİ MAH. MEVDUDİ SK. NO: 53 İÇ KAPI NO: 1 ÜMRANİYE/ İSTANBUL
Tel: +905333221100

2. PPE INFORMATION:

Disposable non-sterile gown.

3. PPE TYPE IDENTIFICATION

EN ISO 13688:2013/A1:2021 Protective clothing - General requirements
EN 13034:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 6-B)
EN 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)
EN 14126:2003/AC:2004 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149

5. PPE DIMENSIONS:

SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model coverall 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/A1:2021

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
pH value EN ISO 3071	6,73	3,5 – 9,5	PASS
Marking	Appropriate	-	PASS

EN 13034:2005+A1:2009, EN 14605:2005+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	38,96 (Newton) 38,14 (Newton) 39,19 (Newton) 41,02 (Newton) 43,56 (Newton) 89,34 (Newton) 80,74 (Newton) 86,19 (Newton) 83,47 (Newton) 86,40 (Newton)	2 (>20N)	PASS
Tensile strength ISO 13934-1	85,17 (Newton) 96,32 (Newton) 95,14 (Newton) 94,28 (Newton) 96,82 (Newton) 43,04 (Newton) 42,19 (Newton) 45,17 (Newton) 48,22 (Newton) 41,99 (Newton)	1 (>30N)	PASS
Puncture resistance EN 863+ BS EN 14325 Part 4.10	6,20 (Newton) 6,98 (Newton) 6,33 (Newton)	1 (>5N)	PASS

	7,69 (Newton)		
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H2SO4: 98,4 NaOH: 98,6	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H2SO4: 0,9 NaOH: 0,7	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	65,94 (Newton) 77,77 (Newton) 78,81 (Newton) 67,09 (Newton) 91,15 (Newton) 88,06 (Newton)	2 (>50N)	PASS
Resistance to penetration by jet of liquid (jet test) EN ISO 17491-3	0 cm ²	3 times the maximum calibration stain	PASS
Flex cracking resistance EN ISO 7854+ BS EN 14325 Part 4.5	>500 cycles	1(>500 cycle)	PASS
Permeation ISO 6529	No leakage (%40 NaOH 30 min)	2 (>30 min)	PASS

EN 14126:2003/AC:2004

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage) BS ISO 16604+ TS EN 14126 Part 4.1.4.1	0 (PFU/ml)	3 (3,5 kPa)	PASS
TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	Total penetration 0,19 %	1 (t≤15 min)	PASS
TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Dry microbial penetration BS EN ISO 22612+ TS EN 14126 Part 4.1.4.4	2,04 log cfu	1 (2<log cfu≤3)	PASS

EN 1149-5: 2018

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Half decay time (t ₅₀ , s) TS EN 1149-3:2004 Method 2	2,95	T ₅₀ < 4 sn	PASS

9. DECISION PROPOSAL

Analysis and examinations SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model coded personal protective equipment; EN ISO 13688:2013/A1:2021, EN 13034:2005+A1:2009, EN 14605:2005+A1:2009, EN 14126:2003/AC:2004, EN 1149-5:2018 standards are evaluated. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports(M-2020-00451, 2023-0347-R1)
- User Instruction

Reason for revision : The scope has been expanded.

CONTROLLER : VOLKAN AKIN

SIGNATURE :

DATE : 20.02.2023



CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED
PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)

MODÜL C2 - ÜRETİMİN DÂHİLİ KONTROLÜ VE ÜRÜNÜN RASTGELE
ARALIKLARLA DENETİMLİ MUAYENESİNE DAYALI TİPE UYGUNLUK

Belge No / Certificate No : 54020442
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 20.02.2023-22.04.2023
Belge Geçerlilik Tarihi / Document Validity Period : 1 Yıl / 1 Years
Firma Unvanı ve Adresi /
Company Name and Address : PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
ŞERİFALİ MAH. MEVDUDİ SK. NO: 53 İÇ KAPI NO: 1
ÜMRANİYE/ İSTANBUL
Marka / Model / Brand / Model : SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-
145 - SV-146 - SV-147 - SV-148 - SV-149
Direktifi / Directive : 2016/425 REGULATION
Modül/Kategori / Module / Category : C2 MODÜLÜ/ KATEGORİ III
MODULE C2 / CATEGORY III
Teknik Değerlendirme Rapor No/
Technical Evaluation Report No : MNA 54020442
Ürün Tipi / Product Type:
- EN ISO 13688:2013/A1:2021 Koruyucu giyecekler - Genel özellikler / Protective clothing - General requirements
- EN 13034:2005+A1:2009 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip PB 6-B) / Protective Clothing Against
Liquid Chemicals (Type PB 6-B)
- EN 14605:2005+A1:2009 Koruyucu Giyecekler - Sıvı Kimyasal Maddelere Karşı (Tip PB 3-B, Tip PB 4-B) /
Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)
- EN 14126:2003/AC:2004 Koruyucu Giyecekler - Patojen Organizmalara Karşı / Protective Clothing - Performance
Requirements And Tests Methods For Protective Clothing Against Infective Agents
- EN 1149-5: 2018 Koruyucu giysi - Elektrostatik özellikler / Protective clothing - Electrostatic properties
Ürünün Malzeme Bilgisi / Product Material Information: SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 -
SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ SUVICOM
SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model products are
manufactured using coated fabric.
Revizyon nedeni/ Reason for revision: Kapsam genişletilmiştir./ The scope has been expanded.

Volkan AKIN
20.02.2023

Karar Verici / Approver



Okan AKEL
20.02.2023

Şirket Müdürü / General manager



d.



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

Report No : 54020442

Report Date : 20.02.2023

Application No : 54020442

1. COMPANY INFORMATION:

PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
ŞERİFALİ MAH. MEVDUDİ SK. NO: 53 İÇ KAPI NO: 1 ÜMRANİYE/ İSTANBUL

2. PPE INFORMATION:

Disposable non-sterile gown.

3. PPE TYPE IDENTIFICATION

EN ISO 13688:2013/A1:2021 Protective clothing - General requirements

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 6-B)

EN 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)

EN 14126:2003/AC:2004 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

EN 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149

5. PPE DIMENSIONS:

SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model gown 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 EVALUATION AND MARKING:

EN ISO 13688:2013/A1:2021

TEST	RESULT	PERFORMAN CE LEVEL	EVALUATION
pH value TS EN ISO 3071	6,95	3,5 – 9,5	PASS
Banned Azodyes EN ISO 14362-1	<5	Max. 30 ppm	PASS
Marking	Appropriate	-	PASS

EN 13034:2005+A1:2009, EN 14605:2005+A1:2009

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance EN 13034:2005+A1:2009 / 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	34,11(Newton) 30,72(Newton) 28,37(Newton) 25,57(Newton) 21,98(Newton) 47,73(Newton) 39,38(Newton) 38,71(Newton) 51,50(Newton) 43,42(Newton)	2 (>20N)	PASS
Tensile strength ISO 13934-1	30,13(Newton) 33,89(Newton) 33,69(Newton)	1 (>30N)	PASS

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (54020442)**

	38,18(Newton) 47,06(Newton) 56,29(Newton) 54,51(Newton) 45,01(Newton) 32,73(Newton) 48,54(Newton)		
Puncture resistance EN 863+ BS EN 14325 Part 4.10	5,74(Newton) 6,90(Newton) 7,88(Newton) 6,64(Newton)	1 (>5N)	PASS
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H2SO4: 99,1 NaOH: 99,1	3 (>90%) 3 (>90%)	PASS
Resistance to penetration by liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H2SO4: 0,6 NaOH: 0,8	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	50,95(Newton) 50,16(Newton) 53,70(Newton)	2 (>50N)	PASS
Resistance to penetration by jet of liquid (jet test) EN ISO 17491-3	0 cm ²	3 times the maximum calibration stain	PASS
Flex cracking resistance EN ISO 7854+ BS EN 14325 Part 4.5	>500 cycles	1(>500 cycle)	PASS
Permeation ISO 6529	No leakage (%40 NaOH 30 min)	2 (>30 min)	PASS

EN 14126:2003/AC:2004

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage) BS ISO 16604+ TS EN 14126 Part 4.1.4.1	0 (PFU/ml) See the table below	3 (3,5 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	2,5x10 ⁸	2,4x10 ⁸	< 1	No penetration
Sample 2				2,5x10 ⁸	2,2x10 ⁸	< 1	No penetration
Sample 3				2,5x10 ⁸	2,4x10 ⁸	< 1	No penetration

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	Total penetration 0,24 %	1 (t≤15 min)	PASS

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Dry microbial penetration BS EN ISO 22612+ TS EN 14126 Part 4.1.4.4	2,02 log cfu	1 (2<log cfu≤3)	PASS

EN 1149-5: 2018

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Half decay time (t ₅₀ , s) TS EN 1149-3:2004 Method 2	2,95	T ₅₀ < 4 sn	PASS

9. DECISION

Analysis and examinations SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model coded personal protective equipment; EN ISO 13688:2013/A1:2021, EN 13034:2005+A1:2009, EN 14605:2005+A1:2009, EN 14126:2003/AC:2004, EN1149-5:2018 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(M-2022-0371,2023-347-R1)
- User Instruction

Reason for Revision: The scope has been expanded.

CONTROLLER : VOLKAN AKIN

SIGNATURE :

DATE : 20.02.2023

