

# LATEX FREE DECLARATION OF CONFORMITY

## TO WHOM IT MAY CONCERN

We **PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.** hereby confirm that the products below are not made with latex.

**MANUFACTURER:** **PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.**  
YUKARI DUDULLU MAH. BAYRAK CAD. NO: 30 / 130 ÜMRANIYE  
34775 İSTANBUL / TURKEY

**DESCRIPTION:** DISPOSABLE GOWN

**SPECIFICATION:** STERILE AND NON-STERILE

**ITEM NUMBERS:** SV-140 – SV-141 – SV-142 – SV-143 – SV-144 – SV-145 – SV-146 –  
SV-147 – SV-148 – SV-149

**TRADE MARK:**



Issue Date: 06.04.2021

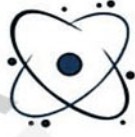
[www.podimamedikal.com](http://www.podimamedikal.com)

[info@podimamedikal.com](mailto:info@podimamedikal.com)



Sign - Stamp

**PODiMA MEDİKAL  
VE TEKSTİL SAN. TİC. LTD. ŞTİ.**  
Yukarı Dudullu Mah. Bayrak Cad. No: 30 D: 130  
Ümraniye / İSTANBUL Tic. Sic. No: 889545 - 0  
Sarıgazi V.D.: 730 037 5548



**mna**  
LABORATUVARLARI

Notified Body Number: 2841

# AB Tip İnceleme Sertifikası EU Type-Examination Certificate

**Belge No / Certificate No** : 63-20-08-R01  
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /  
Certification Date / Certificate Validity Date** : 05.04.2021-05.12.2025  
**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.  
Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130  
Ümraniye 34775 İstanbul / Türkiye

**Ürün Adı /Modeller / Product Name / Models** : 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  
**Modülü/Kategori / Module / Category** : B MODÜLÜ/ KATEGORİ III  
MODULE B / CATEGORY III  
**Test Rapor No/ları / Test Report No** : MNA M-2020-00451

**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 14605+A1 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 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-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:** Firma unvanı ve model adı revize edilmiştir./ Company name and model name has been revised.

**Volkan AKIN**

05.04.2021

**Karar Verici / Approver**

**Okan AKEL**

05.04.2021

**Şirket Müdürü / General manager**



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](http://www.mnalab.com)

**ATTACHMENTS (63-20-08-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-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 <sub>2</sub> SO <sub>4</sub> : 3 |
| Resistance To Penetration By Liquid | NaOH: 3, H <sub>2</sub> SO <sub>4</sub> : 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   |

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

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](http://www.mnalab.com)

**PICTOGRAM AND PERFORMANCE LEVELS:**

EN ISO 13688

EN 14605+ A1 (Type 3-B, 4-B)

EN 14126

EN 13034+A1 (Type 6-B)



NB 2841

"Flammable material. Keep away from fire."

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

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

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](http://www.mnalab.com)

Report No : 63-20-08-R01

Report Date : 05.04.2021

Application No : 63-20-08

**1. COMPANY INFORMATION:**

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

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

Tel: +905333221100

**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 14605+A1 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)

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

**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

| TEST     | RESULT | PERFORMANCE LEVEL | EVALUATION |
|----------|--------|-------------------|------------|
| pH value | 6,73   | 3,5 – 9,5         | PASS       |

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

| TEST                                 | RESULT   | PERFORMANCE LEVEL    | EVALUATION |
|--------------------------------------|--|----------------------|------------|
| Abrasion resistance                  | >10 cycles<br>>10 cycles<br>>10 cycles<br>>10 cycles | 1 (>10 cycle)        | PASS       |
| Tear resistance                      | 38,14  | 2 (>20N)             | PASS       |
| Tensile strength                     | 41,99  | 1 (>30N)             | PASS       |
| Puncture resistance                  | 6,20   | 1 (>5N)              | PASS       |
| Repellency to liquids                | H2SO4: 98,4<br>NaOH: 98,6                            | 3 (>90N)<br>3 (>90N) | PASS       |
| Resistance to penetration by liquids | H2SO4: 0,9   | 3 (<1%)              | PASS       |

|   |                              |                                       |      |
|---|------------------------------|---------------------------------------|------|
|   | NaOH: 0,7                    | 3 (<1%)                               |      |
| Seam Strength   | 65,94                        | 2 (>50N)                              | PASS |
| Resistance to penetration by jet of liquid (jet test) | 0 cm <sup>2</sup>            | 3 times the maximum calibration stain | PASS |
| Flex cracking resistance                              | >500 cycles                  | 1(>500 cycle)                         | PASS |
| Permeation  | No leakage (%40 NaOH 30 min) | 2 (>30 min)                           | PASS |

#### EN 14126:2003

| TEST   | RESULT                            | PERFORMANCE LEVEL | EVALUATION |
|--|-----------------------------------|-------------------|------------|
| Penetration by blood borne pathogens (Bacteriophage) | 0 (PFU/ml)<br>See the table below | 3 (3,5 kPa)       | PASS       |

| TEST                                    | RESULT  | PERFORMANCE LEVEL | EVALUATION |
|---|---|-------------------|------------|
| Resistance to wet bacterial penetration | Total penetration 0,19 %<br>See the table below | 1 (t≤15 min)      | PASS       |

| TEST                      | RESULT       | PERFORMANCE LEVEL | EVALUATION |
|---------------------------|--------------|-------------------|------------|
| Dry microbial penetration | 2,04 log cfu | 1 (2<log cfu≤3)   | 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, EN 13034:2005+A1:2009, EN 14605:2005+A1:2009, EN 14126:2003 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
- User Instruction

Reason for revision : Company name and model name has been revised.

CONTROLLER : VOLKAN AKIN

SING : 

DATE : 05.04.2021

Report No : 63-20-08-01-R01

Report Date : 05.04.2021

Application No : 63-20-08-01

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

2. PPE INFORMATION:

Disposable non-sterile gown.

3. PPE TYPE IDENTIFICATION

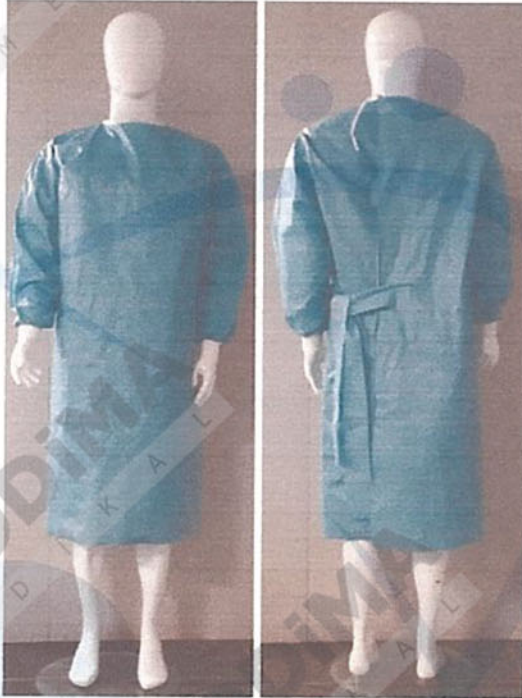
EN 13688 Protective clothing - General requirements

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

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

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

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 product has been found to be produced using S-M-L-XL-2XL-3XL-4XL size.



**CONFORMITY TO TYPE BASED ON INTERNAL  
PRODUCTON CONTROL PLUS SUPERVISED PRODUCT  
CHECK AT RANDOM INTERVALS  
(MODULE C2, ANNEX VII) (63-20-08-01-R01)**

**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 | 6,44   | 3,5 – 9,5         | PASS       |

**EN 13034**

| TEST                                 | RESULT                    | PERFORMANCE LEVEL | EVALUATION |
|--------------------------------------|---------------------------|-------------------|------------|
| Abrasion resistance                  | >10 cycles                | 1                 | PASS       |
| Tear resistance                      | 34,57 N                   | 2                 | PASS       |
| Tensile strength                     | 37,32 N                   | 1                 | PASS       |
| Puncture resistance                  | 5,87 N                    | 1                 | PASS       |
| Repellency to liquids                | H2SO4: 99,2<br>NaOH: 99,1 | 3<br>3            | PASS       |
| Resistance to penetration by liquids | H2SO4: 0,3<br>NaOH: 0,6   | 3<br>3            | PASS       |
| Seam strength                        | 50,78 N                   | 2                 | PASS       |

## EN 14605+A1

| TEST   | RESULT                       | PERFORMANCE LEVEL | EVALUATION |
|--|------------------------------|-------------------|------------|
| Resistance to penetration by jet liquid (jet test) | 0cm <sup>2</sup>             | -                 | PASS       |
| Permeation   | No leakage (%40 NaOH 30 min) | 2                 | PASS       |

## 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                    | %0,19              | 1                 | PASS       |
| Resistance to penetration by biologically contaminant dust | 2,02 (log cfu)     | 1                 | 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 13688, EN 13034+A1, EN 14605+ A1, EN 14126 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-2020-00629)
- User Instruction

Reason for revision : Company name and model name has been revised.

CONTROLLER : VOLKAN AKIN

SIGN : 

DATE : 05.04.2021

# LATEX FREE DECLARATION OF CONFORMITY

## TO WHOM IT MAY CONCERN

We **PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.** hereby confirm that the products below are not made with latex.

**MANUFACTURER:**

**PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.**  
YUKARI DUDULLU MAH. BAYRAK CAD. NO: 30 / 130 ÜMRANIYE  
34775 İSTANBUL / TURKEY

**DESCRIPTION:**

**DISPOSABLE GOWN**

**SPECIFICATION:**

**STERILE AND NON-STERILE**

**ITEM NUMBERS:**

**SV-180 – SV-181 – SV-182 – SV-183 – SV-184 – SV-185 – SV-186 –  
SV-187 – SV-188 – SV-189**

**TRADE MARK:**

  
**SUVICOM**

*Issue Date: 06.04.2021*

[www.podimamedikal.com](http://www.podimamedikal.com)

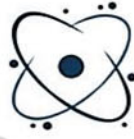
[info@podimamedikal.com](mailto:info@podimamedikal.com)



*Sign - Stamp*

**PODiMA MEDİKAL  
VE TEKSTİL SAN. TİC. LTD. ŞTİ.**  
Yukarı Dudullu Mah. Bayrak Cad. No: 30 D: 130  
Ümraniye / İSTANBUL Tic. Sic. No: 889545 - 0  
Sarıgazi V.D.: 730 037 5548





**mna**  
LABORATUVARLARI

Notified Body Number: 2841

# AB Tip İnceleme Sertifikası EU Type-Examination Certificate

**Belge No / Certificate No** : 63-20-13-R01  
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /  
Certification Date / Certificate Validity Date** : 05.04.2021-08.01.2026  
**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.  
Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130  
Ümraniye 34775 İstanbul / Türkiye

**Ürün Adı /Modeller / Product Name / Models** : SUVICOM SV-180- SV-181 - SV-182 - SV-183 - SV-184 -  
SV-185 - SV-186 - SV-187 - SV-188 - SV-189  
**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 M-2020-00670  
**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) / *Protective Clothing Against Liquid Chemicals (Type PB 6)*

**Ürünün Malzeme Bilgisi / Product Material Information:** SUVICOM SV-180- SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ *SUVICOM SV-180- SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189 model products are manufactured using coated fabric.*

**Revizyon nedeni/ Reason for revision:** Firma unvanı ve model adı revize edilmiştir./ *Company name and model name has been revised.*

**Volkan AKIN**

05.04.2021

**Karar Verici / Approver**

**Okan AKEL**

05.04.2021

**Şirket Müdürü / General manager**



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](http://www.mnalab.com)




**ATTACHMENTS (63-20-13-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-180- SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189

| PPE SPECIFICATION                   | PERFORMANCE LEVELS                          |
|-------------------------------------|---|
| Classification                      | Type PB 6                                   |
| Abrasion Resistance                 | 1   |
| Tear Resistance (Trapezoidal)       | 2   |
| Tensile Strength                    | 1   |
| Puncture Resistance                 | 1   |
| Liquid Repellency                   | NaOH: 3, H <sub>2</sub> SO <sub>4</sub> : 3 |
| Resistance To Penetration By Liquid | NaOH: 3, H <sub>2</sub> SO <sub>4</sub> : 3 |
| Seam Strength                       | 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  |  |
|--|--|
| <b>MANUFACTURER:</b> PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.   |  |
| <b>PPE TYPE:</b> <ul style="list-style-type: none"><li>- EN ISO 13688 Protective clothing - General requirements</li><li>- EN 13034+ A1 Protective Clothing Against Liquid Chemicals (Type PB 6)</li></ul> |  |
| <b>MODEL:</b> SUVICOM SV-180- SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189   |  |
| <b>PRODUCT SIZE:</b> S, M, L, XL, 2XL, 3XL, 4XL  |  |
| <b>PICTOGRAM AND PERFORMANCE LEVELS:</b><br>EN ISO 13688<br>EN 13034+A1 (Type PB 6)  |  |
|   |   |
| NB 2841  |  |
| "Flammable material. Keep away from fire."<br>"Do not re-use"  | Type PB 6  |

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-180- SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189

DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 63-20-13-R01

Report Date : 05.04.2021

Application No : 63-20-13-R01

**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)

**4. PPE PICTURES**



SUVICOM SV-180- SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189

**5. PPE DIMENSIONS:**

SUVICOM SV-180- SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189 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

| TEST            | RESULT | PERFORMANCE LEVEL | EVALUATION |
|-----------------|--------|-------------------|------------|
| pH value        | 6,99   | 3,5 – 9,5         | PASS       |
| Bannaed Azodyes | <5     | Max. 30 ppm       | PASS       |

### EN 13034:2005+A1:2009

| TEST                  | RESULT   | PERFORMANCE LEVEL    | EVALUATION |
|-----------------------|--|----------------------|------------|
| Abrasion resistance   | >10 cycles<br>>10 cycles<br>>10 cycles<br>>10 cycles | 1 (>10 cycle)        | PASS       |
| Tear resistance       | 39,66  | 2 (>20N)             | PASS       |
| Tensile strength      | 34,21  | 1 (>30N)             | PASS       |
| Puncture resistance   | 6,24   | 1 (>5N)              | PASS       |
| Repellency to liquids | H2SO4: 98,4<br>NaOH: 99,1                            | 3 (>90N)<br>3 (>90N) | PASS       |





MNA LABORATUVARLARI SAN. TIC. LTD. ŞTI.

## MNA LABORATUVARLARI

### TECHNICAL EVALUATION REPORT (63-20-13-R01)

|                                      |                         |                    |      |
|--------------------------------------|-------------------------|--------------------|------|
| Resistance to penetration by liquids | H2SO4: 0,4<br>NaOH: 0,7 | 3 (<1%)<br>3 (<1%) | PASS |
| Seam Strength                        | 64,59                   | 2 (>50N)           | PASS |

#### 9. DECISION PROPOSAL

Analysis and examinations SUVICOM SV-180 - SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189 model coded personal protective equipment; EN ISO 13688:2013, EN 13034:2005+A1:2009 standards are evaluated. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

Reason for revision: Company name and model name has been revised.

#### 10. ATTACHMENTS

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

CONTROLLER : VOLKAN AKIN

SING :

DATE : 05.04.2021

Notified Body Number: 2841

Report No : 63-20-13-R01-01

Report Date : 16.04.2021

Application No : 63-20-13-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

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)

4. PPE PICTURES



SUVICOM SV-180- SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189

5. PPE DIMENSIONS:

SUVICOM SV-180- SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189 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.

**CONFORMITY TO TYPE BASED ON INTERNAL  
PRODUCTON CONTROL PLUS SUPERVISED PRODUCT  
CHECK AT RANDOM INTERVALS  
(MODULE C2, ANNEX VII) (63-20-13-R01-01)**

**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 | 7,08   | 3,5 – 9,5         | PASS       |

**EN 13034**

| TEST                                 | RESULT                    | PERFORMANCE LEVEL | EVALUATION |
|--------------------------------------|---------------------------|-------------------|------------|
| Abrasion resistance                  | >10 cycles                | 1                 | PASS       |
| Tear resistance                      | 33,76 N                   | 2                 | PASS       |
| Tensile strength                     | 32,39 N                   | 1                 | PASS       |
| Puncture resistance                  | 5,67 N                    | 1                 | PASS       |
| Repellency to liquids                | H2SO4: 99,0<br>NaOH: 99,1 | 3<br>3            | PASS       |
| Resistance to penetration by liquids | H2SO4: 0,6<br>NaOH: 0,4   | 3<br>3            | PASS       |
| Seam strength                        | 53,97 N                   | 2                 | PASS       |

CONFORMITY TO TYPE BASED ON INTERNAL  
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT  
CHECK AT RANDOM INTERVALS  
(MODULE C2, ANNEX VII) (63-20-13-R01-01)

**9. DECISION**

Analysis and examinations SUVICOM SV-180 - SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 - SV-187 - SV-188 - SV-189 model coded personal protective equipment; EN 13688, EN 13034+A1 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-2021-00038)
- User Instruction

CONTROLLER : VOLKAN AKIN

SING : 

DATE : 16.04.2021