

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 73020443
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 20.02.2023-04.01.2028
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-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-
195 - SV-196 - SV-197 - SV-198 - SV-199
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Teknik Değerlendirme Rapor No/
Technical Evaluation Report No : MNA 73020443
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-190- SV-191 - SV-192 - SV-193 - SV-194 -
SV-195 - SV-196 - SV-197 - SV-198 - SV-199 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ SUVICOM
SV-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199 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 (73020443)

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-190 - SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199

| PPE SPECIFICATION | PERFORMANCE LEVELS |
|-------------------------------------|---|
| Classification | Type PB 3-B, Type PB 4-B, Type PB 6-B |
| Abrasion Resistance | 3 |
| 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 | 6 |
| Seam Strength | 3 |
| Permeation by Liquids | NaOH: 2 Methotrexate: 6 Cyclophosphamide: 6 Fluorouracil: 6 Vincristine Sulfate: 6 Daunorubicin: 6 Doxorubicin: 6 |
| Wet Bacterial Penetration | 6 |
| Dry Microbial Penetration | 3 |
| Phi-X174 Bacteriophage | 6 |
| Half decay time t_{50} | 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-190 - SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199 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

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-190 - SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199

DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 73020443

Report Date : 20.02.2023

Application No : 73020443

1. COMPANY INFORMATION:

PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
Şerifali mah. Mevdudi sk. No: 53 iç kapı no: 1 Ümraniye/ 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-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199

5. PPE DIMENSIONS:

SUVICOM SV-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199 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/A1:2021

| TEST | RESULT | PERFORMANCE LEVEL | EVALUATION |
|--------------------------------|-------------|-------------------|------------|
| pH value EN ISO 3071 | 7,86 | 3,5 – 9,5 | PASS |
| Marking EN ISO 13688 Part 7 | 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 | >100 cycles >100 cycles >100 cycles >100 cycles | 3 (>100 cycle) | PASS |
| Tear resistance EN ISO 9073-4+ BS EN 14325 Part 4.7 | 31,33 N 34,41 N 33,58 N 34,74 N 36,46 N 60,66 N 62,10 N 61,44 N 61,25 N 61,52 N | 2 (>20N) | PASS |
| Tensile strength ISO 13934-1 | 41,84 N 43,02 N 40,39 N 42,55 N 40,87 N 81,07 N 85,03 N 84,08 N 80,24 N 84,04 N | 1 (>30N) | PASS |
| Puncture resistance EN 863+ BS EN 14325 Part 4.10 | 6,68 (Newton) 9,24 (Newton) 7,20 (Newton) 7,55 (Newton) | 1 (>5N) | PASS |
| Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13 | H2SO4: 99,9 NaOH: 99,8 | 3 (>90N) 3 (>90N) | PASS |
| Resistance to penetration by liquids EN ISO 6530+ BS EN 14325 Part 4.12,13 | H2SO4: 0,1 NaOH: 0,2 | 3 (<1%) 3 (<1%) | PASS |
| Seam Strength EN ISO 13935-2 | 109,28 N 115,03 N 110,11 N | 3 (>75N) | PASS |

| | | | |
|--|--|---|------|
| Resistance to penetration by jet of liquid (jet test) BS 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 | >50000 cycles | 6(>50000 cycle) | PASS |
| Permeation ISO 6529 | 30 min No leakage (%40 NaOH) 480 min No leakage (1 ppm Methotrexate Cas no: 59-05-2, Cyclophosphamide Cas no: 6055-19-2, Fluorouracil Cas no: 51-21-8, Vincristine Sulfate Cas no: 2068-78-2, Daunorubicin Hydrochloride Cas no: 2354150-6, Doxorubicin Hydrochloride Cas no: 25316-40-9) | 2 (>30 min) 6 (>480 min) 6 (>480 min) 6 (>480 min) 6 (>480 min) 6 (>480 min) 6 (>480 min) | 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) See the table below | 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 | 0,9 | 0,20 | 60 | 2.8x10 ⁸ | 2,4x10 ⁸ | < 1 | No penetration |
| Sample 2 | | | | 2.8x10 ⁸ | 2,8x10 ⁸ | < 1 | No penetration |
| Sample 3 | | | | 2.8x10 ⁸ | 2,6x10 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 |

| TEST | RESULT | PERFORMANCE LEVEL | EVALUATION |
|--|--------------|-------------------|------------|
| Resistance to penetration by biologically contaminant dust BS EN ISO 22612+ EN 14126 Part 4.1.4.4 | 0,72 log cfu | 3 (log cfu≤1) | PASS |

EN 1149-5:2018

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

9. DECISION PROPOSAL

Analysis and examinations SUVICOM SV-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199 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-2022-0986, 2023-0347-R1)
- User Instruction

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 : 14020470
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 20.02.2023-16.01.2024
Belge Geçerlilik Tarihi / Document Validity Period : 1 Yıl / 1 Year
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-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-
195 - SV-196 - SV-197 - SV-198 - SV-199
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : C2 MODÜLÜ/ KATEGORİ III
MODULE C2 / CATEGORY III
Teknik Değerlendirme Rapor No/
Technical Evaluation Report No : 14020470
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-190- SV-191 - SV-192 - SV-193 - SV-194 -
SV-195 - SV-196 - SV-197 - SV-198 - SV-199 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ SUVICOM
SV-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199 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



CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (14020470)

Report No : 14020470

Report Date : 20.02.2023

Application No : 14020470

1. COMPANY INFORMATION:

PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
ŞERİFALİ MAH. MEVDUDİ SK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE/ 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-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199

5. PPE DIMENSIONS:

SUVICOM SV-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199
model product has been found to be produced using S, M, L, XL, 2XL, 3XL, 4XL sized.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of coated fabric.

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (14020470)**

Notified Body Number: 2841

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 | PERFORMANCE LEVEL | EVALUATION |
|--------------------------------|-------------|-------------------|------------|
| pH value EN ISO 3071 | 7,34 | 3,5 – 9,5 | PASS |
| Banned Azo Dyes | < 5 mg/kg | < 30 mg/kg | PASS |
| Marking EN ISO 13688 Part 7 | Appropriate | - | PASS |

EN 13034:2005+A1:2009

| TEST | RESULT | PERFORMANCE LEVEL | EVALUATION |
|--|---|-------------------|------------|
| Abrasion resistance BS EN 14325 Part 4.4 | >100 cycles >100 cycles >100 cycles >100 cycles | 3 (>100 cycle) | PASS |
| Tear resistance EN ISO 9073-4+ BS EN 14325 Part 4.7 | 35,45 N 30,36 N 31,25 N 31,39 N 32,24 N 71,28 N 77,13 N 71,58 N 70,17 N 77,10 N | 2 (>20N) | PASS |
| Tensile strength ISO 13934-1 | 41,68 N 45,18 N 41,68 N 38,90 N 41,31 N 102,46 N 100,62 N 104,21 N 95,68 N 97,41 N | 1 (>30N) | PASS |
| Puncture resistance EN 863+ BS EN 14325 Part 4.10 | 8,39 N 8,27 N 8,13 N | 1 (>5N) | PASS |

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (14020470)**

| | | | |
|--|----------------------------------|----------------------|------|
| | 8,1 N | | |
| Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13 | H2SO4: 99,8 NaOH: 99,9 | 3 (>90%) 3 (>90%) | PASS |
| Resistance to penetration by liquids EN ISO 6530+ BS EN 14325 Part 4.12,13 | H2SO4: 0,2 NaOH: 0,1 | 3 (<1%) 3 (<1%) | PASS |
| Seam Strength EN ISO 13935-2 | 111,69 N 112,12 N 135,75 N | 3 (>75N) | PASS |

EN 14605: 2005+A1:2009

| TEST | RESULT | PERFORMANCE LEVEL | EVALUATION |
|--|--|---|------------|
| Resistance to penetration by jet of liquid (jet test) BS EN ISO 17491-3 | 0 cm ² | 3 times the maximum calibration stain | PASS |
| Permeation ISO 6529 | No leakage (%40 NaOH 30 min) 480 min No leakage (1 ppm Methotrexate Cas no: 59-05-2, Cyclophosphamide Cas no: 6055-19-2, Fluorouracil Cas no: 51-21-8, Vincristine Sulfate Cas no: 2068-78-2, Daunorubicin Hydrochloride Cas no: 2354150-6, Doxorubicin Hydrochloride Cas no: 25316-40-9) | 2 (>30 min) 6 (>480 min) 6 (>480 min) 6 (>480 min) 6 (>480 min) 6 (>480 min) 6 (>480 min) | PASS |
| Flex cracking resistance EN ISO 7854+ BS EN 14325 Part 4.5 | 50000 cycles | 6 | PASS |

EN 14126:2003/AC:2004

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

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (14020470)**

Notified Body Number: 2841

| | | | | | | | |
|----------|--|--|--|-------------------|-------------------|-----|----------------|
| Sample 2 | | | | 2.8×10^8 | 2.7×10^8 | < 1 | No penetration |
| Sample 3 | | | | 2.8×10^8 | 2.5×10^8 | < 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 |

| TEST | RESULT | PERFORMANCE LEVEL | EVALUATION |
|---|--------------|-------------------|------------|
| Resistance to penetration by biologically contaminant dust BS EN ISO 22612+ EN 14126 Part 4.1.4.4 | 0,60 log cfu | 3 (log cfu < 1) | PASS |

EN 1149-5:2018

| TEST | RESULT | PERFORMANCE LEVEL | EVALUATION |
|--|--------|-------------------|------------|
| Half decay time (t_{50} , s) TS EN 1149-3:2004 | 2,95 | $T_{50} < 4$ sn | PASS |

9. DECISION

Analysis and examinations SUVICOM SV-190- SV-191 - SV-192 - SV-193 - SV-194 - SV-195 - SV-196 - SV-197 - SV-198 - SV-199 model coded personal protective equipment; EN ISO 13688:2013/A1:2021, EN 13034:2005+A1:2009, EN 14126:2003/AC:2004, EN 14605: 2005+A1:2009, EN 1149-5:2018 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-2023-010, 2023-0347-R1)
- User Instruction

CONTROLLER : VOLKAN AKIN

SIGNATURE :

DATE : 20.02.2023

