

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 37012835
**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-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-
155 - SV-156 - SV-157 - SV-158 - SV-159
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 37012835
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 14126:2003/AC:2004 Koruyucu Giyecekler - Patojen Organizmalara Karşı / *Protective Clothing - Performance
Requirements And Tests Methods For Protective Clothing Against Infective Agents*
- 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 1149-5: 2018 Koruyucu giysi - Elektrostatik özellikler / *Protective clothing - Electrostatic properties*
Ürünün Malzeme Bilgisi / Product Material Information: SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 -
SV-155 - SV-156 - SV-157 - SV-158 - SV-159 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir. / *SUVICOM
SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159 model products are
manufactured using coated fabric.*
Revizyon nedeni/ Reason for revision: Kapsam genişletilmiştir. / *The scope has been expanded.*

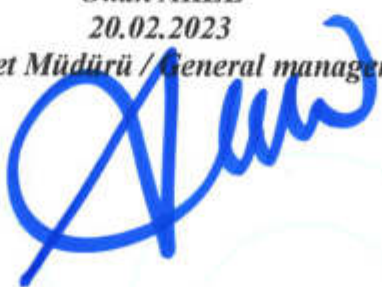
Volkan AKIN
20.02.2023

Karar Verici / Approver



Okan AKEL
20.02.2023

Şirket Müdürü / General manager



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

ATTACHMENTS (37012835)

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-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type PB 6-B, PB 3-B, PB 4-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
Permeation	NaOH: 2
Seam Strength	1
Wet Bacterial Penetration	1
Dry Microbial Penetration	1
Phi-X174 Bacteriophage	3
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 14126:2003/AC:2004 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 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)- EN 1149-5: 2018 Protective clothing- Electrostatic properties
MODEL: SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159
PRODUCT SIZE: S, M, L, XL, 2XL, 3XL, 4XL

ATTACHMENTS (37012835)

PICTOGRAM AND PERFORMANCE LEVELS:

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



NB 2841

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

Type PB 6-B, PB 3-B, PB 4-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-150 - SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159

DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 37012835

Report Date : 20.02.2023

Application No : 37012835

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 boot-cover.

3. PPE TYPE IDENTIFICATION

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

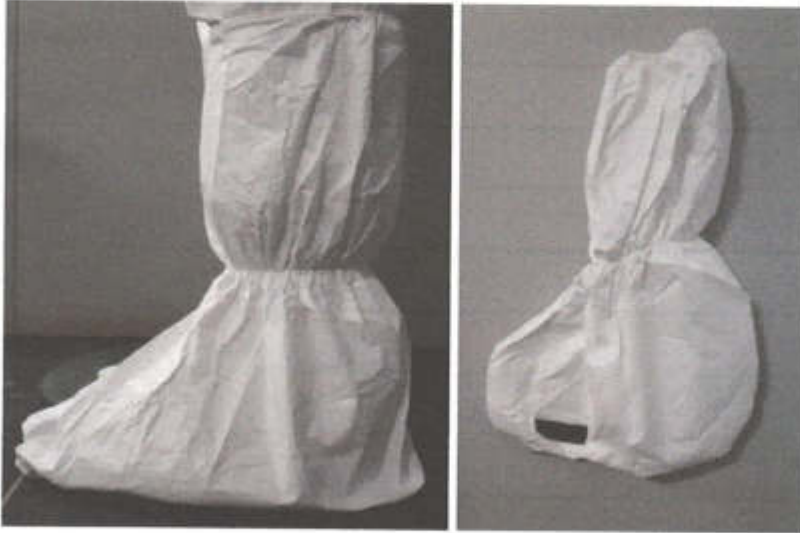
EN 13034:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 6-B)

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

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

EN 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159

5. PPE DIMENSIONS:

SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159 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	6,95	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	10 (Cycle) 10 (Cycle) 10 (Cycle) 10 (Cycle)	1 (>10 cycle)	PASS
Tear resistance EN ISO 9073-4+ BS EN 14325 Part 4.7	39,96 (Newton) 37,14 (Newton) 38,29 (Newton) 39,12 (Newton) 39,96 (Newton) 86,34 (Newton) 82,17 (Newton) 88,25 (Newton) 86,03 (Newton) 84,21 (Newton)	2 (>20N)	PASS
Tensile strength ISO 13934-1	95,17 (Newton) 86,32 (Newton) 85,14 (Newton) 84,28 (Newton) 86,82 (Newton) 48,04 (Newton) 46,19 (Newton) 41,17 (Newton) 40,22 (Newton) 40,31 (Newton)	1 (>30N)	PASS

Puncture resistance EN 863+ BS EN 14325 Part 4.10	6,89 (Newton) 5,47 (Newton) 5,46 (Newton) 5,19 (Newton)	1 (>5N)	PASS
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H2SO4: 98,8 NaOH: 99,0	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H2SO4: 0,9 NaOH: 0,8	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	48,48 51,07 43,09	1 (>30N)	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)	2 (>30 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)	3 (3,5 kPa)	PASS

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration ISO 22610:2018 + EN 14126 Part 4.1.4.2	Total penetration 0,24 %	1 (t≤15 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	2,07 log cfu	1 (2<log cfu≤3)	PASS

9. DECISION PROPOSAL

Analysis and examinations SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159 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. 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-2020-00450, M-2023-045, 2023-0376)
- 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 : 16020497
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 21.02.2023-09.05.2023
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.
Şerifali Mah. Mevdudi Sk. No: 53 İç Kapı No: 1
Ümraniye/ İSTANBUL
Marka /Model / Brand / Model : SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-
155 - SV-156 - SV-157 - SV-158 - SV-159
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 : MNA 16020497
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 14126:2003/AC:2004 Koruyucu Giyecekler - Patojen Organizmalara Karşı / *Protective Clothing - Performance Requirements And Tests Methods For Protective Clothing Against Infective Agents*
- 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 1149-5: 2018 Koruyucu giysi - Elektrostatik özellikler / *Protective clothing - Electrostatic properties*
Ürünün Malzeme Bilgisi / Product Material Information: SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir. / *SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159 model products are manufactured using coated fabric.*
Revizyon nedeni/ Reason for revision: Kapsam genişletilmiştir. / *The scope has been expanded.*

Volkan AKIN
21.02.2023
Karar Verici / Approver



Okan AKEL
21.02.2023
Şirket Müdürü / General Manager



**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (16020497)**

Report No : 16020497
Report Date : 21.02.2023
Application No : 16020497

1. COMPANY INFORMATION:

PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
Şerifali Mah. Mevdudi Sk. No: 53 İç Kapı No: 1 Ümraniye/ İstanbul

2. PPE INFORMATION:

Disposable non-sterile boot-cover.

3. PPE TYPE IDENTIFICATION

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

EN 14126:2003/AC:2004 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 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)

EN 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159

5. PPE DIMENSIONS:

SUVICOM SV-150- SV-151 - SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159 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.

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (16020497)**

- 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	6,89	3,5 – 9,5	PASS
Marking EN ISO 13688:2013/A1:2021 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	>10 cycles >10 cycles >10 cycles >10 cycles	1 (>10 cycle)	PASS
Tear resistance EN ISO 9073-4+ BS EN 14325 Part 4.7	31,97(Newton) 40,60(Newton) 31,64(Newton) 38,89(Newton) 32,94(Newton) 50,00(Newton) 47,24(Newton) 43,14(Newton) 53,83(Newton) 50,01(Newton)	2 (>20 N)	PASS
Tensile strength ISO 13934-1	78,15(Newton) 77,52(Newton) 79,25(Newton) 84,48(Newton) 85,10(Newton) 39,55(Newton) 54,51(Newton) 52,16(Newton) 58,08(Newton) 51,95(Newton)	1 (>30 N)	PASS
Puncture resistance EN 863+ BS EN 14325 Part 4.10	7,92(Newton) 6,89(Newton) 9,32(Newton) 7,42(Newton)	1 (>5 N)	PASS
Repellency to liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H2SO4: 99,8 NaOH: 99,8	3 (>90%) 3 (>90%)	PASS
Resistance to penetration by liquids EN ISO 6530+ BS EN 14325 Part 4.12,13	H2SO4: 0,2 NaOH: 0,2	3 (<1%) 3 (<1%)	PASS
Seam Strength EN ISO 13935-2	48,48 51,07 43,09	1 (>30N)	PASS

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (16020497)**

Notified Body Number: 2841

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)	2 (>30 min)	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	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	1,1	0,20	60	2.7x10 ⁸	2,3x10 ⁸	< 1	No penetration
Sample 2				2.7x10 ⁸	2,5x10 ⁸	< 1	No penetration
Sample 3				2.7x10 ⁸	2,3x10 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 0,23 %	1 (t≤15 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	2,08 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	2,95	T ₅₀ < 4 sn	PASS

9. DECISION

Analysis and examinations SUVICOM SV-150- SV-151- SV-152 - SV-153 - SV-154 - SV-155 - SV-156 - SV-157 - SV-158 - SV-159 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.



Notified Body Number: 2841

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (16020497)**

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Report (MNA M-2022-0369, M-2023-045, 2023-0376)
- User Instruction

Reason for Revision : The scope has been expanded.

CONTROLLER : VOLKAN AKIN

SIGNATURE :

DATE : 21.02.2023