

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 16-21-04
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 27.10.2021-27.10.2026
Belge Geçerlilik Tarihi / Document Validity Period : 5 Yıl/ 5 Years
**Firma Unvanı ve Adresi /
Company Name and Address** : İDEAL SAĞLIK DANIŞMANLIK EĞİTİM HİZMETLERİ İŞ
GÜVENLİĞİ MALZEMELERİ İÇ VE DIŞ TİC. SAN. LTD. ŞTİ.
İvedik OSB Mah.1470 Cad.No:34/1-2 Yenimahalle/ANKARA
Ürün Adı /Modeller / Product Name / Models : İSGAPEX 313
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 16-21-04
Ürün Tipi / Product Type:
- EN ISO 13688:2013 Koruyucu giyecekler - Genel özellikler / Protective clothing - General requirements
- EN 13034:2005+A1:2009 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip 6-B) / Protective Clothing Against
Liquid Chemicals (Type 6-B)
- EN ISO 13982-1: 2004+A1:2010 Katı Parçacıklara Karşı Koruyucu Giysi (Tip 5-B)/ Protective Clothing For Use
Against Solid Particulates (Type 5-B)
- EN 14126:2003 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
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Ürünün Malzeme Bilgisi / Product Material Information: İSGAPEX 313 model ürünleri kaplamalı kumaş kullanılarak
imal edilmiştir./ İSGAPEX 313 model products are manufactured using coated fabric.

Volkan AKIN
27.10.2021
Karar Verici / Approver



Okan AKEL
27.10.2021
Şirket Müdürü / General manager



ATTACHMENTS (16-21-04)

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 : İSGAPEX 313

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type 5-B, Type 6-B
Abrasion Resistance	1
Tear Resistance (Trapezoidal)	2
Tensile Strength	3
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	2
Wet Bacterial Penetration	6
Dry Microbial Penetration	3
Phi-X174 Bacteriophage	1
Half decay time (t50, s)	2,11

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: İDEAL SAĞLIK DANIŞMANLIK EĞİTİM HİZMETLERİ İŞ GÜVENLİĞİ MALZEMELERİ İÇ VE DIŞ TİC. SAN. LTD. ŞTİ.

PPE TYPE:

- EN ISO 13688:2013 Protective clothing - General requirements
- EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
- EN 13034:2005+A1:2009 Protective Clothing Against Liquid Chemicals (Type 6-B)
- EN ISO 13982-1: 2004+A1:2010 Protective Clothing For Use Against Solid Particulates (Type 5-B)
- EN 1149-5: 2018 Protective clothing - Electrostatic properties

MODEL: İSGAPEX 313

PRODUCT SIZE: S, M, L, XL, 2XL, 3XL

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 (16-21-04)

PICTOGRAM AND PERFORMANCE LEVELS:

EN ISO 13688:2013

EN 14126:2003

EN 13034:2005+A1:2009 (Type 6-B)

EN ISO 13982-1: 2004+A1:2010 (Type 5-B)

EN 1149-5: 2018

"Flammable material. Keep away from fire."

"Do not re-use"



NB 2841



Type 5-B, Type 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

İSGAPEX 313

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

Report No : 16-21-04

Report Date : 27.10.2021

Application No : 16-21-04

1. COMPANY INFORMATION:

İDEAL SAĞLIK DANIŞMANLIK EĞİTİM HİZMETLERİ İŞ GÜVENLİĞİ MALZEMELERİ İÇ VE DIŞ TİC. SAN. LTD. ŞTİ.
İvedik OSB Mah.1470 Cad.No:34/1-2 Yenimahalle/ANKARA
Tel : +90 312 395 52 52
E-mail: info@idealisg.com

2. PPE INFORMATION:

Disposable non-sterile coverall.

3. PPE TYPE IDENTIFICATION

EN ISO 13688:2013 Protective clothing - General requirements
EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN 13034:2005+A1:2009 Protective Clothing Against Liquid Chemicals (Type 6-B)
EN ISO 13982-1: 2004+A1:2010 Protective Clothing For Use Against Solid Particulates (Type 5-B)
EN 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



İSGAPEX 313

5. PPE DIMENSIONS:

İSGAPEX 313 model product has been found to be produced using S-M-L-XL-2XL-3XL 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	6,42	3,5 – 9,5	PASS

EN 13034:2005+A1:2009, EN ISO 13982-1: 2004+A1:2010

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles >10 cycles >10 cycles >10 cycles	1 (>10 cycle)	PASS
Tear resistance	57,77 (Newton) 48,37 (Newton) 51,61 (Newton) 55,41 (Newton) 50,12 (Newton) 41,35 (Newton) 46,27 (Newton) 39,59 (Newton) 47,11 (Newton) 41,60 (Newton)	2 (>20N)	PASS
Tensile strength	125,08 (Newton) 126,03 (Newton) 127,97 (Newton) 131,90 (Newton) 120,20 (Newton)	3 (>100N)	PASS

	121,49 (Newton) 114,20 (Newton) 124,49 (Newton) 136,83 (Newton) 130,61 (Newton)		
Puncture resistance	9,48 (Newton) 10,82 (Newton) 8,00 (Newton) 9,07 (Newton)	1 (>5N)	PASS
Repellency to liquids	H2SO4: 99,2 NaOH: 99,3	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids	H2SO4: 0,7 NaOH: 0,3	3 (<1%) 3 (<1%)	PASS
Seam Strength	97,42 (Newton) 137,37 (Newton) 137,50 (Newton) 71,28 (Newton) 99,52 (Newton) 107,32 (Newton)	2 (>50N)	PASS
Resistance to penetration by spray liquid (spray test)	0 cm ²	3 times the maximum calibration stain	PASS
Flex cracking resistance	>50000 cycles	6(>50000 cycle)	PASS
Total inward leakage	Ljmn, 82/90:12,00 Ls,8/10:8,2 See the table below	Ljmn≤30 - Ls≤15	PASS

		% Total Inward Leakage										Average
		Subject 1 Sample 1	Subject 1 Sample 2	Subject 2 Sample 1	Subject 2 Sample 2	Subject 3 Sample 1	Subject 3 Sample 2	Subject 4 Sample 1	Subject 4 Sample 2	Subject 5 Sample 1	Subject 5 Sample 2	
Standing still	Knee	7,8	6,8	5,6	4,3	9,6	5,6	2,7	2,7	1,4	1,2	4,8
	Waist	12,3	12,5	9,4	9,2	5,1	9,6	5,4	5,5	2,7	5,8	7,7
	Chest	10,7	12,4	8,2	11,3	5,1	12,0	4,1	2,7	8,8	8,5	8,4
Walking	Knee	9,7	6,9	6,9	4,2	-2,6	6,9	8,0	5,3	5,0	14,1	6,5
	Waist	8,3	8,4	5,3	5,4	1,3	4,1	9,7	5,3	4,9	9,6	6,2
	Chest	13,8	11,1	9,6	11,5	8,9	2,8	9,9	2,6	7,4	8,0	8,6
Squatting	Knee	9,7	10,9	6,7	7,4	8,9	7,9	9,0	7,7	2,6	6,9	7,8
	Waist	12,5	9,0	10,4	6,0	5,6	7,7	8,3	9,7	5,0	6,9	8,1
	Chest	12,2	9,8	10,7	8,3	5,5	5,3	11,3	5,6	8,5	12,3	9,0
	Average	10,8	9,8	8,1	7,5	5,2	6,9	7,6	5,2	5,1	8,2	7,4



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MNA LABORATUVARLARI

TECHNICAL EVALUATION REPORT (16-21-04)

EN 14126:2003

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage)	0 (PFU/ml) See the table below	1 (0 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	0,21	60	2,9x10 ⁸	2,8x10 ⁸	< 1	No penetration
Sample 2				2,9x10 ⁸	2,7x10 ⁸	< 1	No penetration
Sample 3				2,9x10 ⁸	2,8x10 ⁸	< 1	No penetration

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration	Total penetration 0 %	6 (t> 75 min)	PASS

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Dry microbial penetration	0,12 log cfu	3 (log cfu≤1)	PASS

EN 1149-5: 2018

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Half decay time (t ₅₀ , s)	2,11	T ₅₀ < 4 sn	PASS

9. DECISION PROPOSAL

Analysis and examinations İSGAPEX 313 model coded personal protective equipment; EN ISO 13688:2013, EN 13034:2005+A1:2009, EN ISO 13982-1: 2004+A1:2010, EN 14126:2003, 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 (MNA M-2021-01482, BUTEKOM 2021-1958)
- User Instruction

CONTROLLER : VOLKAN AKIN

SING :

DATE : 27.10.2021