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EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-T999

ADEM VE HAVALYA SAĞLIK DAN. HİZ. İNŞ. SAN. VE TİC. LTD. ŞTİ.

Cumhuriyet Mah. İçişitileme Cd. No:6-2 Şişli/İstanbul/TÜRKİYE

OBM Manufacturer: Ortadoğu Tekstil Sanayi ve Dış Tic. Ltd. Şti.

İttihabir Mah. Eski Edirne Asfaltı Cd. No: 996-998 B Sultangazi/İstanbul/Türkiye

It is certified that the manufacturer's technical file (Dated 01.11.2020) and the PPE product, described below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex I of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment

Brand Name: Adem & Havva Medical, Model: A13M-01

Protective coverall manufactured from white laminated polypropylene non-woven fabric with hood, inside overlock seams, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 7 nominal sizes.

The following harmonised standards have been applied:

EN ISO 13688:2013, (Essential requirements for protective clothing)

EN ISO 13982-1:2004/A1:2009, (Chemical protective clothing providing protection to the full body against airborne solid particulates) Type 5, limited wear life clothing.

EN 13054:2005+A1:2006, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type 6, limited wear life clothing.


EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type 5-B, 6-B.

Hereby the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with the below requirements:

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425** and Annex 9.
- Obtaining successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on Annex 7 (Module C2) or Annex 8 of the regulation

This certificate is initially issued on 16/12/2020 and will be valid for 5 years from the issue date.

CE
2163


Sait KACMAZ
UNIVERSAL CERTIFICATION
Director

Nispetiye Park Behin Keleşoğlu Sk.İz. Etilik Nispetiye Şişli Dışişleri Dairesi Başkanlığı - İSTANBUL - TÜRKİYE T: +90 212 440 80 80

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**EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.**
Euraspat Freelycity Bulvarı No:23 34223 Anadolu
İstanbul TÜRKİYE

**TEST REPORT
DENET RAPORU**

AB-5533-T
20043821
-04g
11-20

Customer name:	UNIVERSAL SERTİFİKASYON ve GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	NECİP FAZİL BULVARI KEYAP SİTESİ E2 ÜMRANIYE-İSTANBUL
Buyer name:	ADEM VE HAYVA SAĞLIK DAN. HİZ. İNŞ. SAN. VE TİC. LTD.ŞTİ.
Contract Person:	SUAT KAÇMAZ
Order No:	-
Article No:	AHM-01
Name and Identity of test item:	White surgical gown.
The date of receipt of test item:	20.11.2020
Re-audited/re-confirmation date:	-
Date of test:	20.11.2020-25.11.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	Not Specified
Number of pages of the report:	8
<p>The Turkish Accreditation Agency (TÜRKAK) is signatory to the multilateral agreement of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.</p> <p>EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number 14B-5533-T for ISO 17020:2017 as test laboratory.</p> <p>The test and/or measurement results, the uncertainties (if applicable with confidence probability and test methods are given on the following pages which are part of this report.</p>	
Date	Customer Representative
25.11.2020	YEŞİM SAHİN
	Head of Testing Laboratory
	Sevin A. PYZAK
	25.11.2020

This report shall not be reproduced other than in full except with the permission of the laboratory.
Testing reports without signature and seal are not valid.

Sayfa 1 / 8

Other Certificates



Disposable Protective Coverall



Disposable Coverall, 55 – 60 gsm

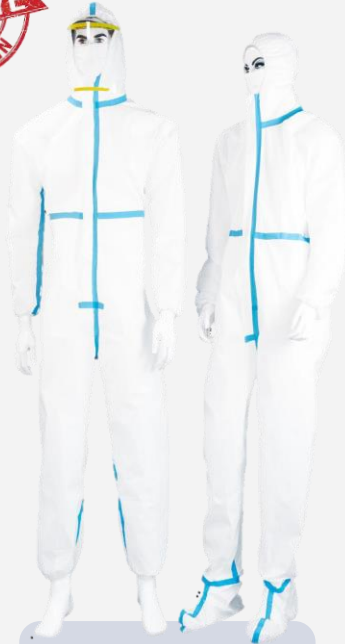
Material : Polypropylene Spunbond +
Polyethylene film Laminate

Sizes : M – L – XL – XXL

Colors : White

Type : Level 5 - 6

Disposable Protective Coverall



AHM-T02

Disposable Coverall, 55 – 60 gsm

Material : Polypropylene Spunbond +
Polyethylene film Laminate + Blue Stripe

Sizes : M – L – XL – XXL

Colors : White

Type : Level 3 – 4 - 5 - 6

Technical & Physical Specifications

PRODUCT	: Hotmelt Laminate	Document	Rev.	Of 11 February 2020
Total Grammage	:60 gsm	Composition: Carded thermobonded polyester based		
Nonwoven Weight	: 33 gsm	Product Code : THP 201-60 (2 Layers)		
Pe / Cast Weight	: 25 gsm	Film: Antistatic Multilayer cast embossed polyolefine based		
Hotmelt Weight	: 2 gsm			
Weight Tolerance	: +/- 2	Type Of Lamination: Hotmelt		
Widht Tolerance	: +/- 5			
Color	: White	Color Ref.	: 002	

Physical Properties	Test Method	Unit	EN ISO 13795	TDL Values (Test Result)
Resistance To Liquid Penetration	EN ISO 20811	Cm/H ₂ O	≥100	214,6
Bursting Strength Dry	EN ISO 13938-1	kPa	≥40	118
Bursting Strength Wet	EN ISO 13938-1	kPa	≥40	110
Tensile Strength - Dry	EN ISO 29073-3	N	≥20	MD:48.05 CD: 42,12
Resistance To Microbial Penetration-Dry	EN ISO 22612	CFU	≤300	14
Resistance To Microbial Penetration-Wet	EN ISO 22610	BI	6,0	6,0
Cleanliness-Particular matter	EN ISO 9073-10	IPM	≤3,5	3,3
Linting	EN ISO 9073-10	Log(10)	≤4,0	3,4

Cytotoxicity	Non-cytotoxic as per ISO 10993-5:2009 tests for in vitro cytotoxicity.
Skin Sensitisation	Non-sensitizer as per ISO 10993-10 tests for skin sensitization.
Skin Irritating	Non-irritant as per ISO 10993-10 tests for irritation.

*Due to the nature of polyolefins, recrystallization occurs which may change the physical values.
 *The above figures are an estimate of expected mean values measured after EO sterilization.
 *The tests have been performed according to EN ISO standards.
 *These figures must only be used as guideline as they are an estimate.



Disposable Surgical Gowns



SS Surgical Gown

Material : SS 30 – 40 Gsm
(Spunbound + Spunbound)

Sizes : M – L – XL – XXL

Colors : Blue – White

Type : Level 1 – Level 2



Disposable Surgical Gowns



AHM-G02

SMS Surgical Gown

Material : SMS 40 Gsm
(Spunbound + Meltblown + Spunbound)
Sizes : M – L – XL – XXL
Colors : Blue – White
Type : Level 3



Disposable Surgical Gowns



AHM-G03

SMS Surgical & Isolation Gown

Material : SMS 40 gsm + PE Breathable 18 gsm Laminated Film.

Sizes : M – L – XL – XXL

Colors : Blue – White

Type : Level 4



Disposable Surgical Gowns



AHM-G04

SMS Surgical & Isolation Gown

Material : SMS 40 gsm + PE Breathable 18 gsm

Laminated Film + Blue Stripe

Sizes : M – L – XL – XXL

Colors : White

Type : Level 4

Technical & Physical Specifications

Parameter (parametre)	Method (yöntem)	Value (değer)
Colour (renk)	/	medical blue/ medikal mavi
Tensile Strength (kopma, mukavemeti)	BS EN ISO 13934-2:2014	Warp (çözü) 154,4 N Weft (atki) 102,3 N
Water Penetration (su geçirmezlik)	DIN EN ISO 811:2018	685 cm/H2O
Air Permeability (hava geçirgenlik)	ISO 9237:1995	0,67 mm/s
Tearing Strength (yırılma dayanımı)	ISO 13937-1:2000	Warp (çözü) 24,1 N Weft (atki) 6,4 N
Thickness (kalınlık)	/	0,500 mm
Width (genişlik)	/	1500 mm
Surface (yüzey)	/	%100 PES Nonwoven
Surface Weight (yüzey ağırlık)	/	38-40 gr/m2
PE layer (PE katmanı)	/	18-21 gr/m2
Adhesive (tutkal cinsi)	/	PSA (pressure sensitive adhesive)
Total Weight (toplam ağırlık)	/	58-62 gr/m2

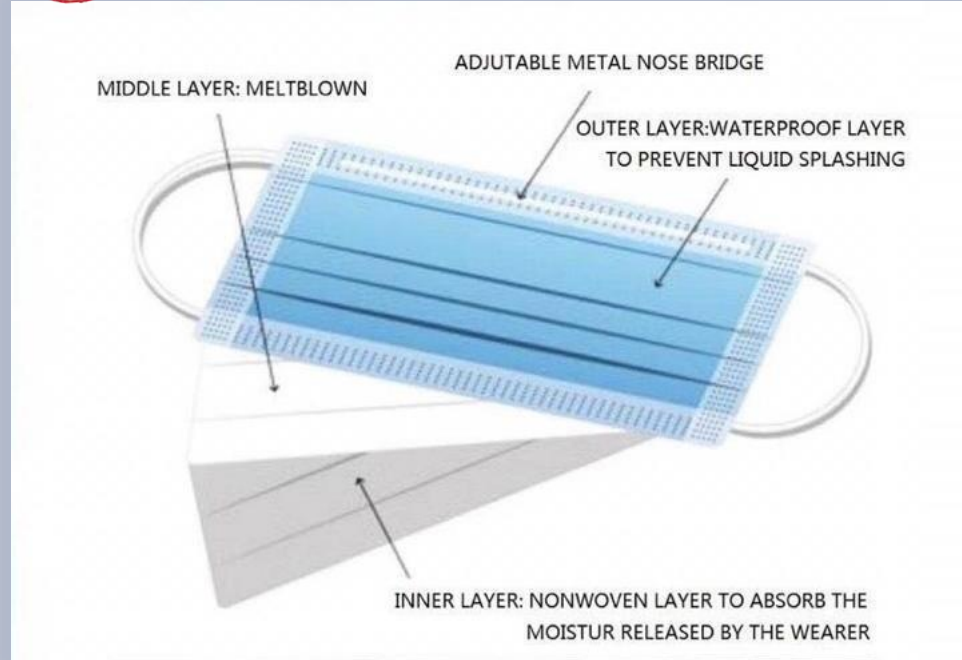
TECHNICAL DATA SHEET

Product : SMS Nonwoven
Product Matrix : 100% Polypropylene (PP)
Type : M01

Physical Properties	Specification	LSL	USL	Unit	Test Standard
Basis Weight	40	38	42	gr/m ²	WSP 130.1 (05)
Tensile Strength MD	135	115	162	N/50mm	WSP 110.4 (05)
Tensile Strength CD	60	51	72		
Elongation MD	-	60	120	%	
Elongation CD	-	60	120		
Air Permeability	660	560	760	l/m2/s (@ 200 Pa)	WSP 70.1 (05)
Color	Blue				
Treatment	N/A				

Revision Date: 20.05.2020
Revision Number: 01

3 Ply Mask (with Meltblown)



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OVERSHOE



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* **High quality:** Made of PE material, which is very durable and waterproof.

* Protects and keeps your shoes and boots safe from dirt, dust, liquid, or other contaminants.

* **Common Uses:** Strong and reliable material is suitable for indoor/outdoor and everyday/industrial use. Light Duty Cleaning, Paintwork, Warehousing, Domestic DIY, Gardening, Food Processing, General Maintenance, Manufacturing.

* **One size fits all:** Shoe Covers have a snug elastic top which provides flexibility to fit most of US Men's and US Women's footwear adult sizes.

* Total 1000 pieces / package.

HEAD COVER



- * Non-Woven, 100 % Spun-bonded Polypropylene Fabric.
- * Soft, Light-Weight And Breathable For User Comfort.
- * Ideal For- Food Service, Hospital, Laboratories, Manufacturing, etc.
- * Latex-free elastic headband provides snug fit while working.
- * 21" Diameter provides full coverage.
- * Total 1000 pieces / package.

Adem Havva



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