GESPRIN

MATERIAL SANITARIO

BATA LAMINADA IMPERMEABLE 55g

Polígono Espíritu Santo
Parcela 12
Oviedo - 33010

TLF:608 134 210
648 654 347
info@gesprin.es

www.gesprin.es

BATA QUÍRURGICA LAMINADA 55G

7040LAM

CARACTERÍSTICAS

- ✓ Material no tejido Spunbond 40 gr / m^2 + capa de poliuretano de 15 gr / m^2
- ✓ Costura Overlock
- ✓ Antialérgico y permeable al aire.
- ✓ No contiene látex ni fibra de vidrio
- ✓ Adecuado para la esterilización
- ✓ Un solo uso
- ✓ Mangas largas, cuello cerrado, espalda abierta con cinturón elástico tejido en los brazos.

APLICACIONES

CE

- ✓ Uso clínico
- ✓ Fabricante electrónica
- ✓ Laboratorio
- ✓ Ambientes controlados

REFERENCIA	DESCRIPCIÓN	PRESENTACIÓN
7040LAM	Bata quirúrgica laminada 55g	Individual 80 pcs/pack

DIRECTIVAS

Reglamento 93/42 / CEE sobre dispositivos médicos (clase I)

725/2017 Reglamento de equipos de protección personal (Clase III)

NORMATIVA

EN 14126 Requisitos de rendimiento y métodos de prueba para ropa protectora contra agentes infecciosos

EN 13795-1 Ropa y paños quirúrgicos. Requisitos y métodos. Parte 1: Paños y paños quirúrgicos.

EN 15223-1 Productos sanitarios - Símbolos que se utilizarán con las etiquetas de productos sanitarios, etiquetado e información que se suministrará - Parte 1: Requisitos generales

EN ISO 14791 Dispositivos médicos: aplicación de la gestión de riesgos a los dispositivos médicos

EN ISO 10993-1 Evaluación biológica de dispositivos médicos - Parte 1: Evaluación y pruebas

OPCIONES

TALLAS

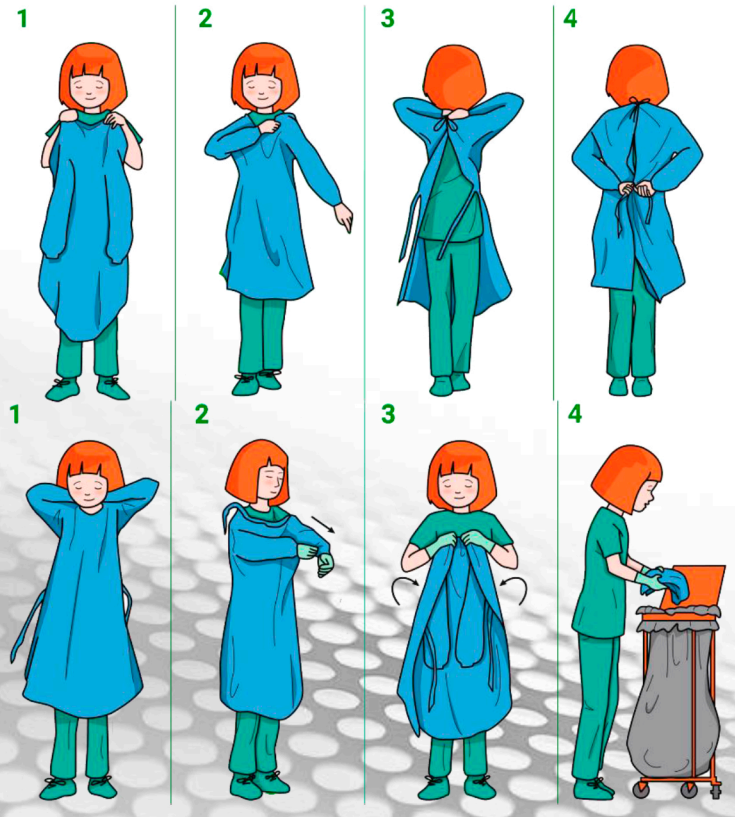
S-M-L-XL-XXL

COLOR AZUL / VERDE

INSTRUCCIONES DE USO

- Realizar un lavado de manos quirúrgico.
- Colocarse la bata y guantes alejado de la mesa de instrumental, teniendo precaución de no mojar la mesa al coger la bata.
- Realizar un buen secado de manos sin friccionar antes de ponerse la bata.
- Tocar solo el interior de la bata antes de ponérsela, evitando contaminar la parte delantera.
- Evitar tocar el envoltorio de los guantes o los mismos guantes hasta después de colocarse la bata.
- Mantener las manos cubiertas por las mangas de la bata antes de ponerse los guantes para evitar su contaminación.

Colocación y retirada de batas



CE EC DECLARATION OF CONFORMITY

We **APEX Teknik Tekstil ve Sağlık Ürünleri San. Tic. Ltd. Şti.**

Herewith declare that the following described product meets the provisions of the following directives. All supporting documentation is retained under the permises of the manufacturer.

PRODUCTS

55G LAMINATED REINFORCED SURGICAL GOWN

STANDARDS

93/42/ECC MEDICAL DEVICES REGULATION (CLASS I ANEX VII)
2016/425 PERSONAL PROTECTIVE EQUIPMENT REGULATION

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns
EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements
EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices
EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
EN ISO 9001:2000 Quality Management System – Requirements
EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
TS EN 14126/AC Protective clothing – Performance requirements and test methods for protective clothing against infective agents.
TS EN 13688 Protective clothing – General requirements
TS EN 13034+A1 Protective clothing against liquid chemicals – Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (type 6 and type PB (6) equipment).
TS EN ISO 13982-1/A1 Protective clothing for use against solid particulates – part 1: performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates(type 5 clothing)

CONTACT INFORMATIONS

APEX Teknik Tekstil ve Sağlık Ürünleri San. Tic. Ltd. Şti.
Hacı Sabancı Organize Sanayi Bölgesi Ordu Caddesi No: 23 Yüreğir / Adana
+90 322 394 44 70 (Pbx)
+90 322 394 44 73
info@amet.com.tr

Apex TEKNİK TEKSTİL VE SAĞLIK ÜRÜNLERİ SANAYİ TİCARET LİMİTED ŞİRKETİ
Hacı Sabancı Organize Sanayi Bölgesi
Ordu Cad. No: 23 Sarıçam / ADANA
Tel: 0322 394 44 70 (Pbx) Fax: 0322 394 44 73
Yüreğir V.D. 519 014 8335

Date: 23/04/20

CERTIFICATE OF QUALITY
ÜRÜN ANALİZ SERTİFİKASI

Product : Lamination

Customer / Müşteri Adı :

Order Productioın Date/ Üretim Tarihi :

Product Type / Ürün Tipi : SPUNBOND BLUE NONWOVEN FABRIC ROLL

Product Description / Ürün Tanımı : Spunbond, Polyethylene Film

Material / Materyal : 35 gr/m2 Blue SB, 18 gr/m2 Blue PE FILM, 2 gr/m2 ADHESIVE

Application on Fabric / Aplikasyon : Normal

Fabric Colour / Renk : Blue / Mavi

Weight / Gramaj : 55 gr

Width / Kumaş Eni : 160

Packing / Paketleme : PE Bag with label, core diameter :

PROPERTIES		TEST METHOD	UNIT	TOLERANS FOR AVARAGE RESULTS (+/-)	TEST VALUE
WEIGHT / GRAMAJ		ISO 9073-1	g/sq.m	%10	55
TENSILE STRENGTH / KOPMA MUKAVEMETİ	**MD**	ISO 9073-3	N / 5 cm	%10	64,0
	CD				34,0
ELONGATION / KOPMA UZAMASI	**MD**	ISO9073-3	%	%10	67,0
	CD				65,0

MD : Machine Direction
CD : Cross Direction

Date	Quality Control Officer	Quality Control Manager

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

20022805-ing
07-20

TEST REPORT
DENEY RAPORU

Customer name:	APEX TEKNİK TEKSTİL VE SAĞLIK ÜRÜNLERİ SAN. TİC. LTD. ŞTİ.
Address:	HACI SABANCI ORGANİZE SANAYİ BÖLGESİ ORDU CAD. NO:23 SARIÇAM/ADANA
Buyer name:	-
Contact Person:	KADİR ATİK
Order No:	-
Article No:	PE LAMINATED SURGICAL GOWN
Name and identity of test item:	Blue surgical gown
The date of receipt of test item:	06.07.2020
Re-submitted/re-confirmation date:	-
Date of test:	06.07.2020-13.07.2020
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:	7

Gen.f136-2/03

TESTED BY Seal EKOTEKS TEST EDİLMİŞTİR

Date	***Customer Representative***	***Head of Testing Laboratory***
13.07.2020	Servin YÜKSEVEN	Sevim A. RAZAK

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Testing reports without signature and seal are not valid.

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REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry- Bacterial Penetration	P	
PHYSICAL PROPERTIES TESTS		
Tensile Stregth / **Dry**	P	
Tensile Stregth / **Wet**	P	
Bursting Strength / **Dry**	P	
Bursting Strength / **Wet**	P	
Water Permeability	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties Critical Sample Group limit values (Table 1)

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified.If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. Tests marked (*) in this report are not included in the accreditation schedule.

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TEST RESULTS

Surgical clothing and drapes - Requirements and test methods – Part 1: Surgical drapes and gowns EN 13795-1 :2019

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN ISO 11737-1:2018 /TS EN ISO 11737-1 :2018 (*)

The sample is put in extraciton liquid after shaking well after shaking well (250 rpm,5 min), inoculated on the suitable agar.The plates are incubated for 3 days at 30 ± 1 ° C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively.
Total microoragnisms counts are calculated.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	249 cfu/100 cm^2	≤300 cfu/100 cm^2

***cfu= Colony forming unit.**

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07-20

TEST RESULTS

WET-BACTERIAL PENETRATION

Test Method: BS EN 22610: 2006 (Surgical drapes, garments and fresh air clothes used as medical devices for patients, hospital staff and equipment - Test method for determination of resistance to wet bacterial permeability) (*)

A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are placed on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force (3N ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X_1	0	R_{CUM1}	0
X_2	0	R_{CUM2}	0
X_3	0	R_{CUM3}	0
X_4	12	R_{CUM4}	0,03
X_5	24	R_{CUM5}	0,09
Z	327		
T	363		

X1 ..... X5: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: $X_1 + X_2 + X_3 + X_4 + X_5 + Z$

$R_{CUM1} = X1/T$
$R_{CUM2} = (X2 + X1)/T$
$R_{CUM3} = (X3 + X2 + X1)/T$
$R_{CUM4} = (X4 + X3 + X2 + X1)/T$
$R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T$

BARRIER INDEX (I_B)		
	Result	**Expected value (*)**
I_B	5,8	≥2,8

$I_B = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$

** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.*

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07-20

TEST RESULTS

Test Method: ISO 22612: 2005 (Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration)

Samples and containers are sterilized. Agar plates are placed in each container. Samples are placed aseptically in the apparatus. The covers are closed. After making a pot in the sample with the piston, the pistons are removed and 0.5 g ± 0.1 g are added to five samples from the powder contaminated with bacteria and the six to the non-contaminated powder. Then all openings are closed with a plastic bag. The device is operated to give 20,800 vibrations per minute. The test time is 30 minutes. After the test is over, all agar plates are incubated at 35 ° C for 24 hours.

Sample amount:	6 pieces 20x20 cm^2
Mikroorganism:	*Bacillus subtilis ATCC 9372*
Bacterial concentration (cfu/ml):	$1x10^8$
Incubation conditions:	35°C / 24 hours

RESULTS	
Number of Populationg Bacteria (cfu)	
1	4
2	2
3	2
4	0
5	1
6 (Control)	0
Total	9
Logarithm	0,95

EVALUATION	
Result	**Class (*)**
≤ 1	3

** EN 14126: 2003 Protective Clothing - Performance Properties and Test Methods of Protective Clothing Against Infectious Agents are evaluated according to Table-4.*

Sınıf	**Penetrasyon (log kob)**
3	*≤ 1*
2	1 < log kob ≤ 2
1	2 < log kob ≤ 3

** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.*

RESULT	
Result (cfu/g)	**Expected Value**
9 cfu/g	≤300 cfu/g

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07-20

TEST RESULTS

TENSILE STRENGTH; EN 29073-3:1996 (*)

Instron 5969 (Load: 5 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. Without wetting samples.
The average results are given for width and length direction of four samples
Performed in the conditioned room (20±2°C-65%±4).

Dry ;

	RESULT	REQUIREMENT
Width	134.2 N	≥ 20N (Dry)
Length	62.7 N	≥ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996 (*)

Instron 5969 (Load: 5 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. With wetting samples.
The average results are given for width and length direction of four samples
Performed in the conditioned room (20±2°C-65%±4).

Wet ;

	RESULT	REQUIREMENT
Width	135.2 N	≥ 20N (Wet)
Length	68.3 N	≥ 20N (Wet)

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BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Dry ;	192.5 kPa	≥ 40 kPa (Dry)
Height at Burst*	11.6 mm	

20022805-ing
07-20

TEST RESULTS

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Wet ;	193.8 kPa	≥ 40 kPa (Wet)
Height at Burst*	11.6 mm	

WATER PERMEABILITY; ISO 811:2018

Hydrostatic Head Tester, Textest marka FX 3000-IV model
Temperature of water 20°C. Pressure increase ratio 10 mbar/dk.
Performed in the conditioned room (20±2°C-65%±4)

	RESULT	REQUIREMENT
Sample 1	317.2 cmSS	≥ 20 cmSS
Sample 2	326.4 cmSS	
Sample 3	328.4 cmSS	
Sample 4	318.2 cmSS	
Sample 5	326.4 cmSS	
Average	323.3 cmSS	

Gen.f136-2/03

CERTIFICATE
of Registration

This is to Certify that the

Medical Devices – Quality Management System

of

APEX TEKNİK TEKSTİL VE SAĞLIK ÜRÜNLERİ SAN. TİC. LTD. ŞTİ.

MERKEZ ADRESİ: ACIDERE OSB MAH. ORDU CD. NO:23 SARIÇAM / ADANA / TÜRKİYE

ŞUBE ADRESİ: ORUC REİS MAH. BARBAROS CAD. GİYİMKENT SİTESİ 16. SOK.NO:102-104 ESENLER / İSTANBUL / TÜRKİYE

has been independently assessed and is compliant with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

PRODUCTION AND SALES OF SINGLE USE MEDICAL CONSUMABLES (MASK, CAPS, SHOE COVER, SLEEVE COVER, COVERALL, GOWN, SHEET, DRAPE AND SURGICAL SETS)

TEK KULLANIMLIK SAĞLIK ÜRÜNLERİ (MASKE, BONE, KEP, GALOŞ, KOLLUK, TULUM, ÖNLÜK, ÖRTÜ VE AMELİYAT SETLERİ) ÜRETİMİ VE SATIŞI

:: Certificate No :: TR51529H

Date of initial registration	**07 February 2020**
Date of this Certificate	**07 February 2020**
Surveillance audit on or before	**06 February 2021**
Recertification Due / Certificate expiry	**06 February 2023**

This Certificate is property of Staunchly Management & System Services Ltd. and remains valid subject to satisfactory surveillance audits.

Director

STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.
Suite 48, 88-90 Hatton Garden, London, EC1N 8PN.

This Certificate is the property of Staunchly Management & System Services Private Limited and shall be returned immediately when demanded

CENTROCOT
Innovation experience

CE
Notified Body n. 0624

© Centro Tessile Cotoniero e Abbigliamento S.p.A.
I - Piazza S.Anna, 2 - 21052 Busto Arsizio (VA)
tel. +39 0331 696711 - fax +39 0331 680056

EU TYPE-EXAMINATION CERTIFICATE

No **CE 1284200831 -00 - 00**

According to "Regulation (EU) 2016/425 of the European Parliament and of the Council" of 9th March 2016 on Personal Protective Equipment and repealing Council Directive 89/686/EEC

Centro Tessile Cotoniero e Abbigliamento S.p.A.
P.zza Sant'Anna, 2 - 21052 Busto Arsizio (VA) - Italia

EEC Notified Body N° 0624

- in view of the firm's application submitted on: 26th November 2020;
- in view of the positive results of the Technical File verification submitted by the manufacturer together with the above mentioned request;
- in view of the manufacturer's declaration stated in the Technical File attached to the above mentioned request
- having verified that technical specification of design and manufacture is in compliance with basic requirements specified in annex II of Regulation (EU) 2016/425 and that technical manufacturing documentation is in compliance with above mentioned specifications;
- in view of the positive test results carried out on the basic model representative of production according to paragraph 4 of annex V of Regulation (EU) 2016/425;

Issues to:

APEX TEKNIK TEXSTIL VE SAGLIK URUNLERI SAN.VE TIC.LTD.STI
ACIDERE OSB MAH. ORDU CAD. No. 102 ESENLER ISTAMBUL TURKEY

the EU Type-Examination Certificate concerning the following PPE model:

Protective GOWN against infective agents

code 7040

Category: **III** (third)

The model of Personal Protective Equipment is subject to conformity to type assessment according to Section 19 c) of Regulation (EU) 2016/425 (Module C2 or D)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
PRD N° 163B LAB N° 0033
LAT N° 226
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

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tel. +39 0331 696711 - fax +39 0331 680056

Basic type description

Art. 7040

Gown with long sleeve, knitted cuff, simple seam, back fastening system by laces.
Fabric three-layer: 100% polypropylene, + polyethylene film, 52 g/m2, color medical green.
Knitted cuffs: 100% polyester

Variations description

No variations

Sizes

From S to XXXL

Standards

EN ISO 13688:2013	Protective clothing - general requirements
EN 14126:2003 +AC:2004	Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

Performance levels

EN 14126	**Type PB 6-B**	Limited protective performance against light spray, liquid aerosol or low pressure, low volume splashes - Partial body protection
	Class 6	Resistance to penetration by contaminated liquids under hydrostatic pressure.
	Class 6	Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.
	Class 3	Resistance to penetration by contaminated liquid aerosols.
	Class 3	Resistance to penetration by contaminated solid particles

Use

Clothing to be worn to protect against infective agents. Other uses than those listed above are excluded.

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tel. +39 0331 696711 - fax +39 0331 680056

Tests

The test results are included in the report: 20RA13283, 20RA13292, 20RA13295, 20RA13390

Marking

The following information are listed on the label inside the garment:

- CE marking
- Company name
- Article code
- Standards
- Standardized pictograms
- Maintenance symbols
- Fabric composition
- PPE category

Validity

- This certificate has 5-year validity from issue date. On expiration date the Manufacturer will be responsible to require the renewal.
- Any change on model and materials object of this Certificate shall be notified and then approved by Centrocot.

This certificate must be filed by the manufacturer and must be shown, if requested, to the Body that performs controls or to the surveillance authority

Busto Arsizio,

Issue date:
03rd December 2020

Expiry date:
03rd December 2025

CENTRO TESSILE COTONIERO e ABBIGLIAMENTO S.p.A. NOTIFIED BODY 0624

General Manager
Dr. Grazia Cerini

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
PRD N° 163B LAB N° 0033
LAT N° 226
Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC