YALITKAN PASPAS
KAUÇUK ÜRÜNLERİ A.Ş.

AMSTERDAM

VISITOR AND SURGICAL GOWN

- Made from SMS
- 35 - 40 gram / m^2
- Blue Color

Yıkanmaz | Kurutma makinasında kurutulmaz | Kuru temizleme yapılmaz | Ütülenmez | Çamaşır suyu kullanılmaz | 2 kez kullanılmaz Tek kullanımlıktır

CE
EN 13795

UNIVERSAL CERTIFICATION

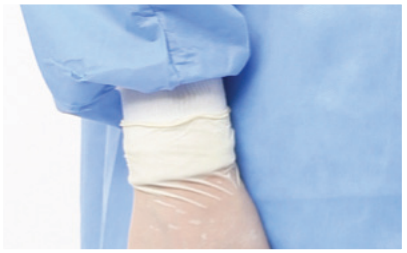
MADE IN TURKEY

sales.yalitkanpaspas.com.tr
www.yalitkanpaspas.com.tr

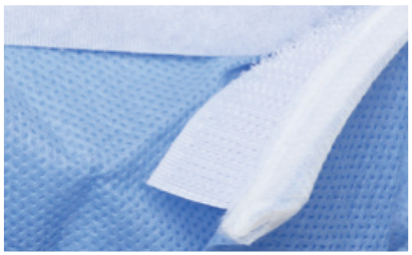
yalitkanpaspas.as
amsterdam_turkey

YALITKAN PASPAS
KAUÇUK ÜRÜNLERİ A.Ş.

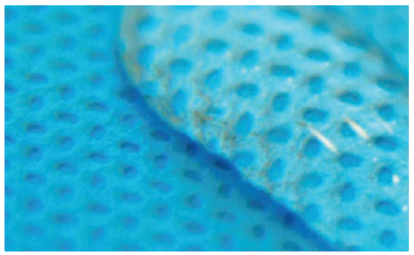
4 pcs ties give guarantees to keep more protective.



The Reinforced part in the arms are waterproof and gives extra protective.



Velcro on the back,keeping safe the neck part of gown that not open.



Thanks to latest technology, it provides good barrier and excellent air permeability. From 30gr/m2 up to 50gr/m2 gsm range.

General Features

Model: YLT003
Disposable surgical gown
35- 40 GSM
CE Certified
Approved by the European Approval Agency Universal
SMS Fabric

SİZE	S	M	L	XL	2XL	3XL
Length From HSP Omuz ucundan boy	105	110	115	120	126	134
Width - En	138	142	146	150	155	160
Total Sleeve Length Toplam kol boyu	54	56	58	60	62	64

YALITKAN PASPAS
KAUÇUK ÜRÜNLERİ A.Ş.

AMSTERDAM

PRODUCTION STAGES

- The product fabrics are cut on an automatic cutting machine and sewing processes are sewn on overlock and flat machines. 4 pcs ties are sewn from the product's own fabric and Ribana fabrics on the sleeve cuffs are sewn on round socks machines.
- If you desire we can sterile your orders in sterilization machine.

PACKAGE SİZE: 60x40x40 cm

1 BOX: 80 Pcs

1 PALLET: 1600 Pcs / 20 Boxes

1 TRUCK: 33 Pallets

AMSTERDAM PACKING

AMSTERDAM

DISPOSABLE SURGICAL GOWN

S	M	L	XL	XXL	3XL

SİZE	S	M	L	XL	2XL	3XL
Length From HSP Omuz ucundan boy	105	110	115	120	126	134
Width - En	138	142	146	150	155	160
Total Sleeve Length Toplam kol boyu	54	56	58	60	62	64

Cerrahi Önlük LOT Kodu Surgical Gown LOT Code

MODEL NO: YLT003

CE

EN 13795

- **Do not iron** – Ütülenmez
- **Do not dry in drayer.** – Kurutma makinasında kurutulmaz
- **Do not Bleach** – Çamaşır suyu kullanılmaz
- **Do Not Wash.** – Yıkanmaz
- **Do not dry clean** – Kuru temizleme yapılmaz
- **Do not use twice It is disposable** – 2.kez kullanılmaz Tek kullanımlıktır
- **Keep Awat From** Fire – Ateşten Uzak Tutunuz

MAN. DATE: 03/2021 EXP. DATE: 03/2026

YALITKAN PASPAS
KAUÇUK ÜRÜNLERİ A.Ş.
AMSTERDAM, YALITKAN PASPAS A.Ş. MARKASIDIR.

UNIVERSAL CERTIFICATION

MADE IN TURKEY

GÜVENLİK TALİMATI
Bütün koruyucu giyisiler, kullanmadan önce, yırtık, delik, sökük, kir gibi olumsuzluk yaratabilecek defo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli ise kesinlikle giyilmemelidir.

DİKKAT !
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

SAFETY INSTRUCTION
All protective clothing should be checked before use against defects and faults which may cause negativity such as torns, holes, rips and dirts. If it is defected and dirty, it should definitely not be wom.

ATTENTION!
Playing with a bag is dangerous and can cause suffocation. Please keep away from children and infants.

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utillsation contre les défauts et les imperfections pouvant causer des négations teis que les déchiquetages, les trous, les déchirures et les saletés. Si elle est défectueuse et sale, elle ne devrait certainement pas être portéa.

ATTENTION!
Jouer avec un sac est dangereux et peut provoquer une étouffement. Gardez-vous à l'écart des enfants et des nourrissons.

SICHERUNGSANWEISUNG
Sämtliche Schutzanzüge sind vor Einsatz gegen Risse, Löcher, Laufmaschen und Probleme hervorrufende sonstige Störungen zu kontrollieren. Gestörte und kontaminierte Anzüge nicht verwenden.

ACHTUNG!
Das Spielen mit dem Beutel ist gefähriich und kann zum Ersticken führen. Bitte halten Sie den Beutel von Kindern und Kleinkindern fern.

INSTRUCCIONES DE SEGURIDAD
Toda la ropa de protección debe controlar antes de su uso contra defectos y fallas como las rasgados ,los agujeros, las rasgónes y las suciedades. No deben usarse si tengan defectos y sucias.

ATENCIÓN!
Es peligroso jugar con las bolsas puede causar asfixia. Por favor, mantenga alejado de los niños y bebés.

ISTRUZIONI DI SICUREZZA
Tutti gli indumenti protettivi devono essere controllati prima dell'utilizzo nei confronti di difetti e guasti che possono causare negatività, quali difetti, fori, strappi e sporcizia. Se è defattato e sporco, non dovrebbe essere indossato.

ATTENZIONE!
Giocare con i sacchetti è pericoloso e può causare soffocamento. Si prega di tenere lontano da bambini e neonati.

INSTRIÇÕES DE SEGURANÇA
Todas as roupas de proteção devern ser verificadas contra defeitos antes do uso, como furos e sujeiras. Se é defeito e sujo, definitivamente não deve ser usado.

ATENÇÃO!
Jogar com cobertura é perigoso e pode causar afogamento. Mantenha-se afastado de crianças e bebês.

VEILIGHEIDSVOORSCHRIFT
Alle beschermingskledingen moeten vooraf aantrekken gecontrolleerd worden tegen gebrekken en defecten zoals scheuren, gaten, open gesprongen stukken en vuil. Als deze gebrekkig of vuil is, moet beslist niet gebruikt worden.

ATTENTIE !
Het is gewaarlijk om met het zakje te speies, het kan stikken veroorzaken. A.u.b. uit het zicht van kinderen en babys houden.

BEZPEČNOSTNÍ POKYNY
Veškeré ochranné oděvy musí být před jejich použtím zkontrolovány, zda neobsahují negativní vady nebo poškození, nejsou prasklé, děravé, roztrhané, rozpárané nebo špinavé. Poškozené odévy by v žádním případě použity být neměly.

UPOZORNĚNÍ !
Hrát si se sáčkem je nebezpečné, může dojít k udušení. Prosím uchovejte mimo dosah dětí.

ПРАВИЛА БЕЗОПАСНОСТИ
Всю защитную одежду перед применееием необходимо проверять на наличие дыр, распоротых швов, загрязнений, а также неисправностей и повреждений, способных негативно сказаться на зффективности защиты. Ни в коем случае нельзя надевать поврежденную и загрязненную защитную одежду.

ВНИМАНИЕ !
Нельзя играть с пакетом, возможен риск удушения. Пожалуйста, храните в местах, недоступных для младенцев и детей.

SIKKERHEDSINSTRUKTIONER
Før brug bør alt beskyttelsestøj kontrolleres for revner, huller, rippede syninger, snavs som kan skabe negative virkninger samt for fejl og mangler. Defekte og beskidte overtræksdrager bør ikke benyttes.

ADVARSEL!
Det er farligt at lege med poserne, det kan forårsage kvæining. Opbevares veniigst væk fra børn og spædbørn.

SÄKERHETSFÖRESKRIFTER
Före användning bör alla skyddskläder kontrolleras för sprickor, hål, slitning i sömmar, smuts och fel som kan orsaka negativa effekter.
Defekta och smutsiga overaller bör inte användas.

VARNING!
Att leka med ompackningen kan innebära fara och kan orsaka kvävning. Håll vänligen bort ifrån barn och spädbarn.

TURVAOHJEET
Kaikki suojavaatteet tulee tarkastaa aina ennen käyttöä mahdollisten repeämien, reikien, painaumien, lian ym. haittojen varalta. Mahdollisten virheiden ja epäkuntoisuuden varalta tulee aina tehdä tarkistus. Virheellistä tai likaista tuotetta ei missään nimessä tule käyttää.

HUOMIO!
Pussin kanssa leikkiminen on vaarallista. Se voi aiheuttaa tuketumiskuoleman. Pitäkää poissa lasten ja vauvojen uluttuvilta.

NSTRUKCJA BEZPIECZEŃSTWA
Wszystkie ubrania ochronne przed używaniem muszą być sprawdzane, czy nie są podarte, przedziurawione, rozprute, brudne albo nie posiadają nnych nie pożądanych wad Odzieży brudnych i z wadami absolutnie nie należy zakladać.

UWAGA!
Zabawa z torebką jest niebezpieczna, może spowodować uduszenie. Przechowywać z dala od dzieci i niemowląt.

BEZPEČNOSTNÉ POKYNY
Všetky ochranné odevy musia byť pred ich použtím skontrolované, či neobsahujú negatívne vady alebo poškodenia, nie sú prasknuté, deravé, roztrhané, rozpárané alebo špinavé. Poškodené odevy by v zadnom prípade použité byť nemali.

UPOZERNENIE!
Hrať sa so sáčkom je nebezpečné, môže dôjsť k uduseniu. Prosím uchovajte mimo dosahu deti.

INSTRUCŢIUNI DE SIGURANŢĂ
Totalitatea îmbrăcămintei ptotectoare, înainte de utilizare trebuie controlate în vederea depistări posibilelor imperfecţiuni şi defecte cum ar fi rupturi, găuri, destrămări, mizeriei. Nu trebuieîmbrăcate sub nici o formă dacă prezintă imperfecţiuni şi urme de mizerie.

ATENŢIE!
Joaca cu punga esta periculoasă, poate provoca asfixiere, Vă rugăm să păstraţi în locuri inaccesibile copiilor şi bebeluşilor.

BIZTONSÁGI ELŐÍRÁSOK
Használat előtt minden védőruhán meg kell viszgálni azt, hogy van-e rajta szakadás, lyuk, varrási hiba, szennyeződés vagy bármi olyan dolog ami problémát okozhatna.

VIGYÁZAT!
A zacskóval játszani veszélyes, mert fulladást okozhat. Kérjük, tartsák távol a gtermekektől és a csecsemőktől!

VARNOSTNA NAVODILA
Pred uporabo varnostnih oblačil, jih vedno preverite, da niso raztrgana, preluknjana, odtrgana ali umazana, saj bi to negativno vplivalo na zaščito. Varnostnega oblačila ne smete uporabljati, če je umazano all poškodovano.

OPOZORILO!
Vreča ni igrača za dojenčke in otroke in lahko povzroči zadušitev, zato jo shranjujte stran od ortok.

ΟΔΗΓΙΑ ΑΣΦΑΛΕΙΑΣ
Ολα τα προστατευτικά ρούχα πριν από τη χρήση πρέπει να ελεγχτούν αν έχουν κανένα ελάπωμα όπως σκίσιμο, τρύπα, ξήλωμα, λέρωμα κλπ. που είναι ενδεχόμενα να δημιουργήσουν καμία αρνητική κατάσταση. Τα λερώμενα και ελαπωματικά ρούχα δεν πρέπει να φορεθούν.

ΠΡΟΣΟΧΗ!
Είναι επικίνδυνο το παίξιμο με σακούλα, μπορεί να προκαλέσει πνιγμό. Παρακαλώ διατηρήστε μακριά από τα παιδιά και μωρά

تــوجيهات الامـان
يجبـمر اقبة كافة الملابس الو اقية ضد العيوبـاواخطاء التي يمكن ان تسبب تاثيرات سلبية مثل القص , وشب , والمزق او التوسخ قبل استعمالها .
يمنع ارتداء الملابسالواقية اذا كانتخاطنة او متوسخة .

انتبة!
التلاّلعبـمعالكيس خطرة يمكن ان شبب الاخشاق . يرجى حفظالمنتوج بغيداعن الاطغفال الاطغلالر ضمة

ÖNLÜK NASIL ÇIKARTILIR

A) Omuz kısımlarından tutulur. B) Kontamine dışyüz içe doğru çevrilir.
C) Yuvarlanarak katlanır. D) Çıkarıldığında sadecetemiz taraf görünmelidir.

SAKLAMA / SON KULLANIM:

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 25 ˚C'de muhafaza edilmesi tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 5 yıl içinde kullanılmalıdır.

İMHA ve GERİ DÖNÜSÜM:

Bulaşma olmamış ürünler genel çöp olarak işlem görülebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmeli ve milli düzenlemelere uygun olarak tehlikeli atık olarak bertaraf edilmelidir.

USAGE INSTRUCTION

A) It is held from sholders. B) Contaminated outer face is turned inwards. C) Foldby rolling.
D) Whenremoved, only the clean sideshould appear.

STORAGE END USE:

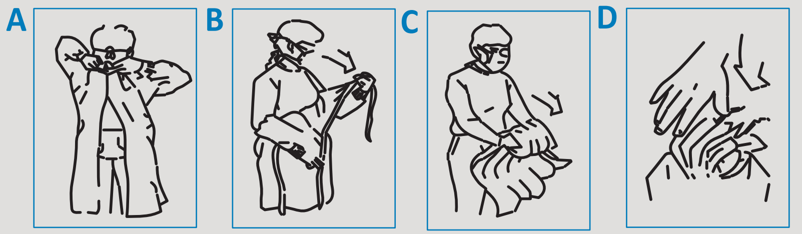
It is recomended to be stored in a cardboard or cardboardbox, awayfrom sunlight, at 15 25 ˚C. If stored under suitable conditions, it should be used for 5 year safter the production date.

DISPOSAL AND RECYLING:

Non contaminatde products can be treated asgeneral waste or recyled. Contaminated products should be treated as hazardouswaste and disposed of as hazardous waste in accordance with national regulations.

Ürün giyinme ve ürün çıkarma talimatı görseldeki gibidir.

The instructions for dressing the product and removing the product are as in the picture.



MANUFACTURER

YALITKAN PASPAS
KAUÇUK ÜRÜNLERİ A.Ş.
AMSTERDAM, YALITKAN PASPAS A.Ş. MARKASIDIR.

Oruçreis Mah. Tekstilkent Cad. GD1 Blok No:148 Esenler 34325 İstanbul / Türkiye
+90 850 304 37 07
www.yalitkanpaspas.com.tr

UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD-358

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Commission directive 2007/47/EEC amending Medical Devices Directive dated 05 September 2007,

the products manufactured by

YALITKAN PASPAS KAUÇUK ÜRÜNLERİ A.Ş.

at the following address

Oruçreis Mah. Tekstil Kent Cad. Gdı Blok No:148 Esenler 34325 ISTANBUL / TURKEY

EN 13795-1:2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns

Brand Name: AMSTERDAM
Model: YLT003
(Standard Performance) are tested according to the following initial type tests by the manufacturer

For the assessment of conformity, the following documents were also reviewed:
Laboratory test results for Microbial Penetration (wet/dry), Bioburden,
Bursting and Tensile Strengths (wet/dry)

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the surgical gowns manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; performance level and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 09/03/2021 and valid until 08/03/2022 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

ISTANBUL –09/03/2021

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Chairman of the Board

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

EU DECLARATION OF CONFORMITY

MANUFACTURER

YALITKAN PASPAS KAUÇUK ÜRÜNLERİ A.Ş.

Oruçreis Mah. Tekstilkent Cad. Tekstilkent Gd1 Blok No:148 Esenler-İstanbul/TURKEY

PRODUCT DESCRIPTION

Brand Name: AMSTERDAM, Model:YLT003

Surgical Gowns with standard performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as Medical Device(Class I)

We declare on our sole responsibility that the product abo ve is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely n accordance with the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- European Regulation (EU) 2017/745 and 93/42/EEC Medical Devices Directive establishing technical requirements for medical devices, in effective wording
- Technical standard EN 13795-1:2019 Surgical clothing and drapes – Requirements and test methods – Part I: Surgical drapes and gowns
- Other relevant harmonized legislation and standards
- Fort he assessment of conformity, the following documents were also applied to:
- Results of laboratory tests for Microbial Penetrations, Microbial Cleanliness (Bioburden), Bursting and Tensile Strengths by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.

MARKING, LABELLING

Annex I, &13 of the Medical Devices Directive (93/42/EEC) or Annex I, &23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the surgical gown is supplied. The information supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2013

MEASURES TO ENSURE CONFORMITY

We declare that we have taken all necessary measures to ensure the conformity of products placed on the market with technical documentaion and basic requirements fort his type of product.

YALITKAN PASPAS
KAUÇUK ÜRÜNLERİ A.Ş.
Oruç Reis Mah. Tekstilkent Cad. Tekstilkent Gd1
No:10 AE Daire No: 220 Esenler / İSTANBUL
Atışalanı V.D.: 9330926051 - Sicil No: 223853-5
Mersis No: 0933092605100001

Engin Özavcı
General Manager

09/03/2021

CE

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

Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

AB-0583-T
21007476-ing
03-21

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	Yukarı Dudullu Mahallesi, KEYAP E2 No:84, 34775 Dudullu Organize Sanayi Bölgesi/Ümraniye/İstanbul
Buyer name:	YALITKAN PASPAS KAUÇUK ÜRÜNLERİ AŞ
Contact Person:	SUAT KAÇMAZ
Order No:	-
Article No:	-
Name and identity of test item:	Blue gown
The date of receipt of test item:	25.02.2021
Re-submitted/re-confirmation date:	-
Date of test:	25.02.2021-04.03.2021
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

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.
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.

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
TESTED BY EKOTEKS TEST EDİLMİŞTİR	04.03.2021	Servin ÜRAL SEVEN	Sevim A. RAZAK 04.03.2021

Gen.f136-2/03

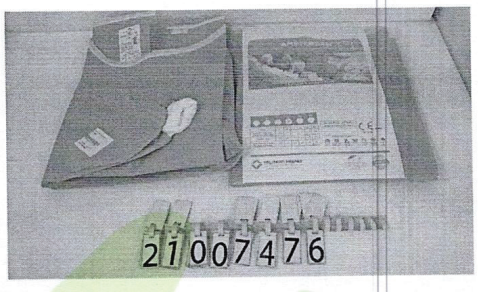
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
21007476-ing
03-21

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	

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 %. The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. Tests marked (*) in this report are not included in the accreditation schedule



Gen.f136-2/03

AB-0583-T
21007476-ing
03-21

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/100cm²)	129 cfu/100 cm²	≤300 cfu/100 cm²

***cfu= Colony forming unit.**

Gen.f136-2/03

EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.

AB-0583-T
21007476-ing
03-21

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):	$5x10^3$ kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X_1	95	R_{CUM1}	0.09
X_2	96	R_{CUM2}	0.18
X_3	102	R_{CUM3}	0,28
X_4	126	R_{CUM4}	0,40
X_5	156	R_{CUM5}	0,55
Z	458		
T	1033		

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	4.47	≥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.*

Gen.f136-2/03

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	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	0

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

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

Gen.f136-2/03

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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	62.3 N	≥ 20N (Dry)
Length	102.9 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	62.8 N	≥ 20N (Wet)
Length	99.0 N	≥ 20N (Wet)

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 ;	162.6 kPa	≥ 40 kPa (Dry)
Height at Burst*	17.5 mm	

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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 ;	148.5 kPa	≥ 40 kPa (Wet)
Height at Burst*	16.1 mm	

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