



MEDICAL QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.

Yunus Emre Mah. 12.Yildirim Sok. No 17 Yildirim-Bursa/Turkey

by review of SA2-5076 numbered report for the scope

**Manufacture And Sales Of Disposable Surgical Sterile Gowns,
Drapes And Custom Packs, Non-Sterile Medical Textile Products**

to certify that a management system in accordance with
standard's clauses is established and being implemented

DIN EN ISO 13485:2016

Certificate No :MDMS 0520 006861

Original Certification Date : 22.04.2020

Issue / Revised Date : 13.04.2022

Expiry Date : 21.04.2023

Certification Period : 3 years (3rd year)



Universal GmbH

The authenticity of this certificate can be confirmed online or by e-mail to the Head Office via:

UNIVERSAL GmbH • Wilfried Diekmann Str., 20b, 44536 Lünen Germany • T : +49 (0) 231 9931 9960 • info@uni-cert.de • www.uni-cert.de



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Deutsche
Akkreditierungsstelle
D-ZM-16058-01-00

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Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Production Quality Assurance No. 09 0816 QS/NB

The quality system of manufacturer

Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.

Yunus Emre Mah. 12.Yıldırım Sok. No 17 Yıldırım –BURSA, Turkey

has been certified as meeting the requirements of

Directive 93/42/EEC
on medical devices, Annex V

for the following product category(ies):

Sterile Disposable Surgical Gowns and Drapes and Drape Sets

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with securing and maintaining sterile conditions. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

Valid from: 2020-06-23
Valid until: 2022-11-24
First Issued: 2009-11-26
Revision: f



Date: 2020-06-23

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Zeyni Medikal Tekstill Ins. San. Ve Tic. Ltd. Sti

Yunus Emre Mah. 12. Yildirim Sok. N° 17 Yildirim -BURSA, Turkey

Product(s):

Name: Drape sets

Trade name(s): -

Model(s): See table below

Class: Is

GMDN: 47783

Drape set types	Code number
General surgery drape set	101-001-S
Laparoscopy drape set	201-001-S
Minor surgery drape set	102-001-S
Dressing surgery drape set	103-001-S
Spinal surgery drape set	301-001-S
Craniotomy surgery drape set	401-001-S
Shunt surgery drape set	401-002-S
Valve Replacement surgery drape set	501-001-S
Cardiovascular Thoracic drape set	202-001-S
Anjyo drape set	601-001-S
By-pass drape set	602-001-S
Ophthalmic drape set 1	701-001-S
Ophthalmic drape set 2	701-002-S
Caesarean drape set	801-001-S
O.P.U surgery drape set	802-001-S
Delivery drape set	802-002-S
Dental drape set	803-001-S
Biopsie drape set	804-001-S
Cystoscopy drape set	901-001-S

GENERAL DIRECTOR:

Baki Canar
07.06.22

STAMP & SIGNATURE

ZEYNI MEDİKA
TEKS.İNŞ. SAN VE TİC. LTD. ŞTİ.
Yunusemre Mh. 12. Yildirim Sk. No: 17 Yildirim -BURSA
Yildirim V.D.: 998 141 1400 Ticaret Sic. No: 272000
Mersis No: 09981411400000000000

Zeyni Medikal Tekstill Ins. San. Ve Tic. Ltd. Sti

Yunus Emre Mah. 12. Yildirim Sok. N° 17 Yildirim -BURSA, Turkey

Drape set types	Code number
Percutaneous drape set	901-002-S
T.U.R drape set	901-003-S
Ear-nose-throat drape set	902-001-S
Vertebra surgery drape set	903-001-S
Arthroscopy drape set	904-001-S
Extremity drape set	904-002-S
Hip surgery drape set	904-003-S
Rhinoplasty set	905-001-S
Vertebra set	906-001-S
I.V.F Drape set	907-001-S
E.T set	907-002-S
Abdominal drape set	908-001-S
Hand surgery set	904-004-S
Chemotherapy drape set	909-001-S

Product(s):

Name: GOWNS

Trade name(s): -

Model(s): See table below

Class: Is

GMDN: 35778

Gown Types	Code number
Standard Surgery Gowns	100-001-S
Protected Surgery Gowns	200-001-S

GENERAL DIRECTOR:

Baki Canavar

07.06.22

STAMP & SIGNATURE

ZEYNI MEDİKAL
TEKS.İNŞ. SAN.VE TİC.LTD.ŞTİ.
Yunus Emre Mah. 12. Yildirim Sok. No: 17 Yildirim/BURSA
Yildirim V.K. 999041 Yasa: 102917
Tic. Sic. No: 268114400000000000

**ZEYNI
MEDICAL**

For medical devices, regulated in accordance with EC Directive 93/42/EEC

EC Declaration of Conformity

11042020-UB

Manufacturer : ZEYNI MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. İST.

Address : Yunus Emre Mah. 12. Yildirim Sok. No: 17 Yildirim-Bursa / TURKEY

Trade name : Zeyni Medical

Product Name : STERILE AND DISPOSABLE SURGICAL SUPPORTS, COVERS AND COVER SETS

STERILE AND DISPOSABLE SURGICAL LINERS, DRAWER AND LID SETS

(The list of products is given in appendix-1.)

Classification : Class 1-Sterile (with sterile function)

Conformity assessment according to Annex VII and the annexes of the applied directives
(Medical Device Directive 93/42/EEC; Class 1-as sterile device)

Applied harmonized standards: ISO 11135:2014, ISO 14644-3 2019, 13795 1 2019 ISO 14971
2012, 150 15223-1:2016, ISO 10993-7:2008, ISO 14937 2009

Notified body: ITC (Institute for testing and Certification, a s) Trida T Bati 299,76421 Zlin-Loky/
Czech Republic

Notified body number: CE 1023

EC certificate: 090816QS/NB

Validity of the CE certificate: 24.11.2022

GENERAL DIRECTOR:

Baki Cinar

07.06.22

STAMP & SIGNATURE

ZEYNI MEDİKAL
TEKS.İNŞ. SAN.VE TİC.LTD.ŞTİ.
Yunus Emre Mah. 12. Yildirim Sok. No: 17 Yildirim/BURSA
Yildirim V.D.: 998 144 1400 (Tic Sic No: 107917)
Mersis No: 9981400000000000000

ZEYNI
MEDICAL

Zeyni Medikal Tekstil İnş San. and Tic. Ltd. Şti hereby declares that the above mentioned products are in compliance with all applicable provisions of Directive 93/42/EEC. The product is safe under foreseeable and reasonably foreseeable conditions of storage and use.

The company has put in place measures to ensure that all products of the type mentioned above are safe and meet the essential requirements of Directive 93/42/EEC

The company has put in place a systematic procedure to review experience gained with the devices in the post-production phase and to apply appropriate means for any necessary corrective action and keeps this systematic procedure up to date. The company undertakes to report to the competent authority any malfunction or alteration in the properties, performance or inadequacy of the product's instructions for use that could lead to the death of the patient or serious damage to the patient's health, as well as the or medical reasons that led to the systematic recall of the product by the manufacturer.

If the device is modified without the consent of the undersigned, this statement becomes invalid with respect to the modified product.

Regulated in accordance with EC Directive 93/42/EEC concerning medical devices

EC DECLARATION OF CONFORMITY

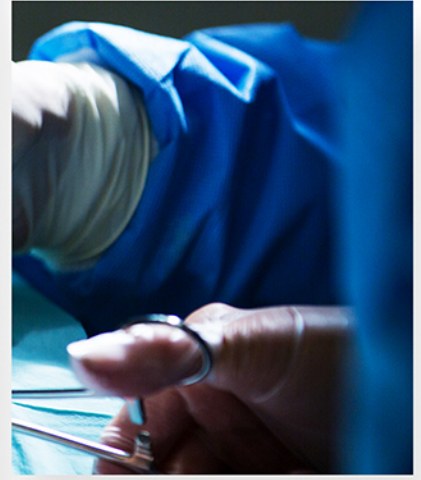
11042020-UB

GENERAL DIRECTOR:

Baki Canavar
07.06.22

STAMP & SIGNATURE

ZEYNI MEDİKAL
TEKS.İNŞ. SAN.VE TİC.LTD.ŞTİ.
Yunusemre Mh. 12. Yıldırım Sk. No: 12 Yıldırım/BURSA
Yıldırım V.D.: 999 441 400 Ticaret No: 102317
Mersis No: 0999041140000001



***“HYGIENE FOR HEALTH,
DISPOSABLE STERILE PRODUCTS FOR HYGIENE”***

Company's Presentation

Our company was established in Bursa. Our product range includes sterile and non-sterile products especially surgical gowns, surgical drape and other products to be applicable in clinical application. Our customers include hospitals, clinics, pharmacies, retailers and reputable industrial companies.

Our products are sterilized as controlled in our owner site with EO unit. As a manufacturer and exporter of medical devices Zeyni Medical operates in accordance with the following regulations and standards:

- The European Medical Device Directive 93/42/EEC (2007/47/EC)
- The Quality Management Standards ISO 9001 and
- The Medical Management Standards ISO 13485

Zeyni Medical Ltd holds a Quality System Certificates and CE certificates. Besides Turkey, Zeyni Medical products are also available in Europe, South America, Middle East and Africa area.

We are committed to be at the forefront of technological innovation in the healthcare industry. As our valued customers, you can rest assured that you will be access to the very best & latest technology in the field of medical disposables.

Hakkımızda

Bursa'da kurulmuş olan firmamız, steril ve non-steril ürünler özellikle cerrahi önlükler, cerrahi örtüler ve klinik uygulamalarında kullanılan diğer ürünleri üretmektedir. Müşterilerimiz hastaneler, klinikler, eczaneler, perakendeciler ve endüstri firmalarıdır.

EO sterilizasyonun kendi tesislerinde kurduğu sistemle kontrollü olarak gerçekleşmektedir. ZEYİNİ MEDİKAL, Medikal ürünler üreticisi ve ihracatçısı olarak aşağıdaki yasa ve standartlar doğrultusunda faaliyet göstermektedir.

- Avrupa tarafından yayınlanmış Medikal Cihaz Direktifi 93/42/EEC
- Kalite Yönetim Sistem Standardı ISO 9001 ve
- Medikal Kalite Yönetim Sistem Standardı ISO 13485

Zeyni Medikal, yukarıda adı geçen kalite yönetim sistem sertifikaları ve CE sertifikasına sahip bir firmadır.

RESISTANCE

Two and three layer materials, used for gowns and drapes production, are laminated with plastic film that works as a perfect barrier against body fluids and microorganism penetration.

LINTING

The surface is resistant to abrasion, material does not release any fibres.

ABSORBENCY

The drape surface is made from absorbent viscose with high capacity of absorbency
250 ml water/sqm.

ADHESIVE ZONES

Sides of drapes and apertures are lined with adhesive zones, which allow simple effective and safe fixation of the drape to patient body.

ACCESSORIES

Following elements may be integrated in the drape upon request:

- Incision drape
- Complements for tubes and cables fixation
- Equipment pouch
- Fluid collection bags, etc.

FOLDING AND PACKING

Special folding technique enables that drapes and integrated accessories are applied without any contact with sterile and non-sterile surfaces.

FUNCTIONAL PROPERTIES

- Each part is anatomically shaped
- Materials perfectly adhere to the surface
- All components are ranked into logic sets which include all that is necessary for a surgery preparation
- Always ready to use



USED MATERIALS / KULLANILAN MATERYALLER**1- TWO LAYER LAMINATE 54 gsm***İKİ KATLI NONWOVEN 54 gr/m²*

Two layer laminate, upper layer is made of absorbent viscose 28 g/sqm, bottom layer is bacterial barrier polyethylene foil 25µm.
Application:

- Drapes & Reinforcement Zones
- EquipmentCovers

İki kat lamisyonlu, üst katı emici medikal nonwoven 28gr/m², alt katı 25 mikron bakteri bariyerli polietilen.

**2- TWO LAYER SPUNBOND LAMINATE 54 gsm***İKİ KATLI NONWOVEN 54 gr/m²*

Non-woven material composed of two layers, upper layer is absorbent spunbond 30 g/sqm, bottom layer polyethylene foil 25µm.

Application:

- Drapes & Reinforcement Zones
- EquipmentCovers

İki kattan oluşmuş nonwoven materyal, üst katı emici medikal spunbond 30 gr/m², alt katı 25 mikron bakteri bariyerli polietilendir.

**3- THREE LAYER LAMINATE 70 gsm***ÜÇ KATLI NONWOVEN 70 gr/m²*

Three layer laminate, upper layer is made of absorbent viscose 28 g/sqm, middle layer is made of polyethylene foil 25µm and bottom layer is made of absorbent non-woven textile.

Application:

- Drapes & Reinforcement Zones

Üç kat laminasyonlu, üst katı emici medikal nonwoven 28 gr/m², orta katı 25 mikron bakteri bariyerli polietilen ve alt katı emici nonwoven materyal

**4- SMMS 50 gsm**

SMMS fabrics is composed of two layers of spunbonded fabrics and two layer of Meltblown fabrics. With good tensile strength, high filtration and remarkable softness. It prevent and isolate dust particle, alcohol, blood, bacteria and virus.

Application:

- Gowns&Drapes
- Sterilization Wraps

İki kat medikal nonwoven ve iki kat meltblown'dan oluşur. İyi çekme mukavemeti sayesinde yüksek filtrasyon ve dikkate değer bir yumuşaklık sağlar. Toz partikül, kan, alkol, bakteri ve virüslere karşı koruma ve izolasyon sağlar.



5- SPUNBOND 50 gsm

Spunbond material which doesn't show resistance to liquid is used in the production of non-sterile gowns and textiles.

Spunbond, sıvı direnci olmayan, non-steril tekstil ürünleri ve önlük imalatı yapılan bir materyaldir.

**6- POLYETHYLENE FOIL 60µm (PE 60 micron)**

A turquoise very drapeable, micro embossed PE coex film, Impermeable to fluids, non toxic, very high strength.

Application:

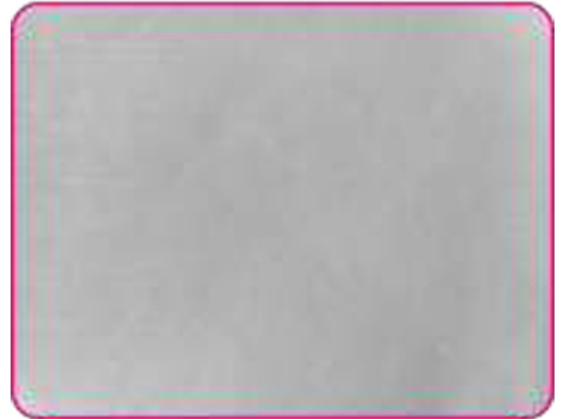
- Back Table Cover&Mayo Stand Cover
- EquipmentCovers

Turkuaz renginde, geçirimsiz, toksik olmayan, yüksek dirençli bir üründür.

**7- TOWEL 63 gsm
HAVLU 63gr/m²**

It has high absorbency and lint free. It is using for drying the hands of surgeons before operation.

Yüksek emici ve hava bırakmama özelliklerine sahip olup, ameliyat öncesi doktorların el kurulaması işleminde kullanılır.

**8- STERILIZATION WRAP 60 gsm
STERİLİZASYON BOHÇASI 60 gr/m²**

It is used for covering and keeping of drape packs during the sterilization process, and it supplies Hygienic security and tight packing.

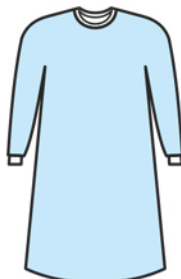
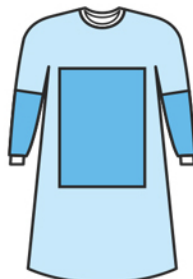
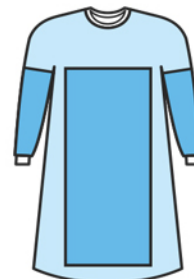
Örtü setlerini sterizasyon prosesi süresince korumayı sağlar, ayrıca hijyen ve sıkı bir paketlenme sağlar.



STERILE PRODUCTS	STERİL ÜRÜNLER	PAGE SAYFA
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**UNICERT**
ISO 13485:2016**UNICERT**
ISO 9001:2015**CE**1023***"Hygiene for health, Disposable Sterile Products for hygiene"*****SURGICAL GOWN CLASSIC**

- Made from non-woven textile hydrophobic material SMMS that protects against fluid penetration
- Gowns are fixed with four ties system
- Sleeves are finished with knitted elastic cuffs
- Surgical gowns are a tie-round type which enables to keep the sterility of surgeons back side
- There are three types of surgical gown classic; standard, reinforced, full reinforced
- Reinforced and full reinforced types have front side and sleeves with impermeable material that assures perfect protection of surgeon during major surgeries
- Fulfil requirements of EN 13795 standard

6**STANDARD****REINFORCED****FULL REINFORCED**

Surgical Gown Cerrahi Önlük



UNICERT
ISO 13485:2016



UNICERT
ISO 9001:2015

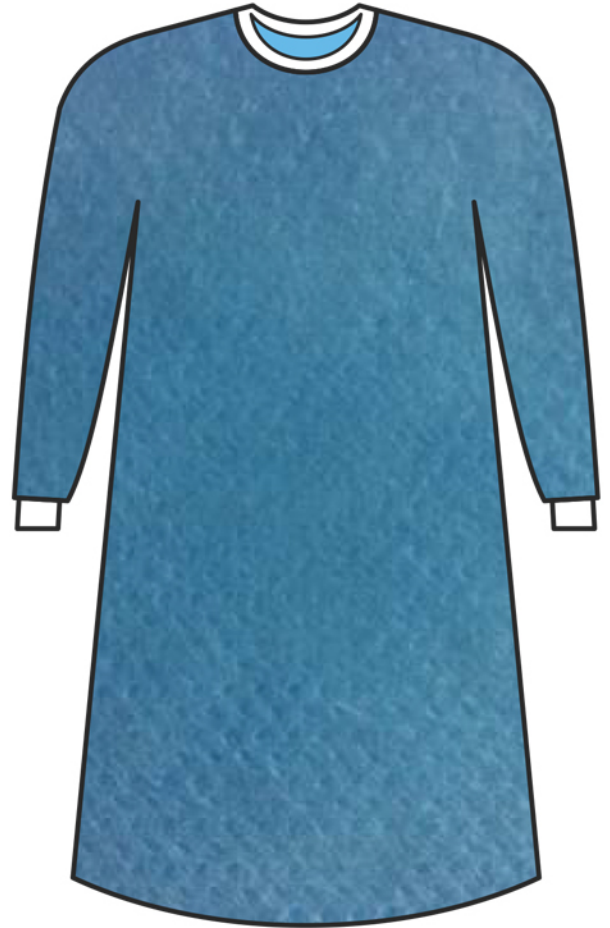


CE₁₀₂₃

"Hygiene for health, Disposable Sterile Products for hygiene"

SURGICAL GOWN COMFORT

- Made from non-woven textile triplex repellent material against fluid penetration
- Gowns are fixed with four ties system
- Sleeves are finished with knitted elastic cuffs
- Surgical gowns are a tie-round type, which enables to keep the sterility of surgeons back side
- Fully reinforced
- Fulfil requirements of EN 13795 standard

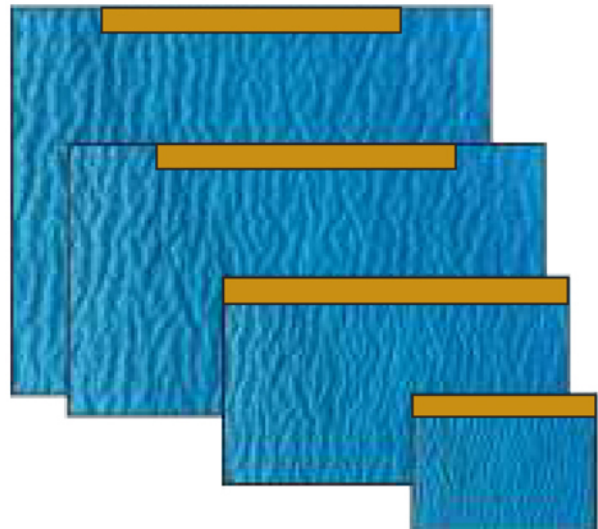
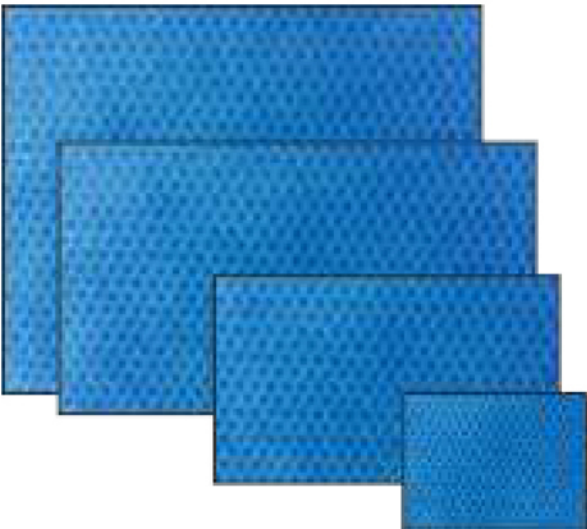


Plain Drapes

Material	Size (cm)
sms	50x50
	50x70
	75x75
	75x90
	150x180
	200x240
bilaminate	50x50
	50x70
	75x75
	75x90
	150x180
	200x240
trilaminate	50x50
	50x70
	75x75
	75x90
	150x180
	200x240

Surgical Drapes with Adhesive Tape

Material	Size (cm)
sms	50x50
	50x70
	75x75
	75x90
	150x180
	200x240
bilaminate	50x50
	50x70
	75x75
	75x90
	150x180
	200x240
trilaminate	50x50
	50x70
	75x75
	75x90
	150x180
	200x240

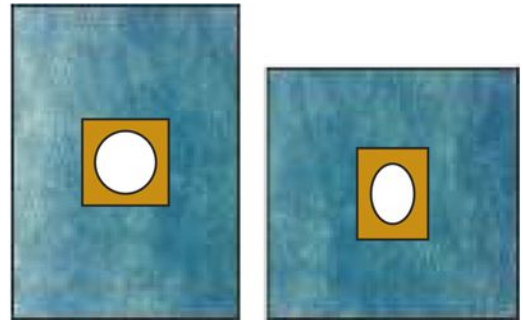
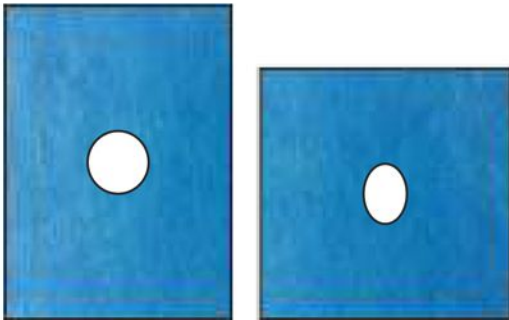


STERILE SURGICAL DRAPES / STERİL CERRAHİ ÖRTÜLER
Fenestrated Drapes

Material	Size (cm)	
bilaminate	50x70	7
	50x70	10
	75x90	7
	75x90	10
	75x110	10
	100x150	6x8
	50x50	6x8
	50x70	6x8
	160x200	12
trilaminate	50x70	7
	50x70	10
	75x90	7
	75x90	10
	75x110	10
	100x150	6x8
	50x50	6x8
	50x70	6x8

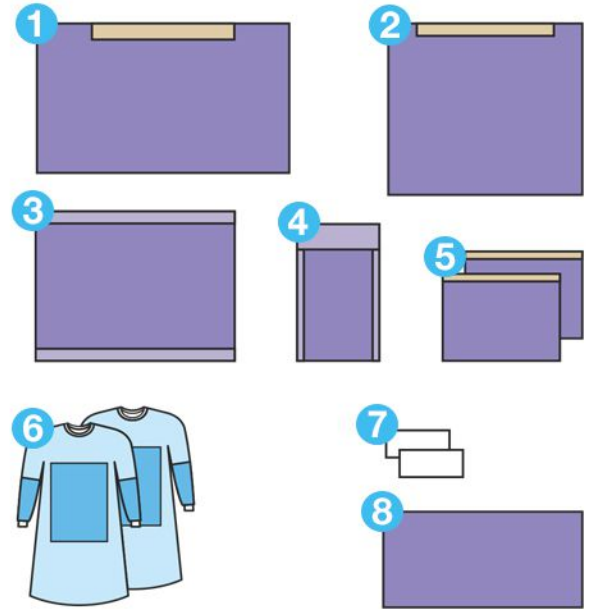
Fenestrated Drapes with Adhesive Tape

Material	Size (cm)	
bilaminate	50x70	7
	50x70	10
	75x90	7
	75x90	10
	75x110	10
	90x110	7
	120x150	10
	45x75	7
	240x280	10
trilaminate	50x70	7
	50x70	10
	75x90	7
	75x90	10
	75x110	10
	90x110	7
	120x150	10
	45x75	7

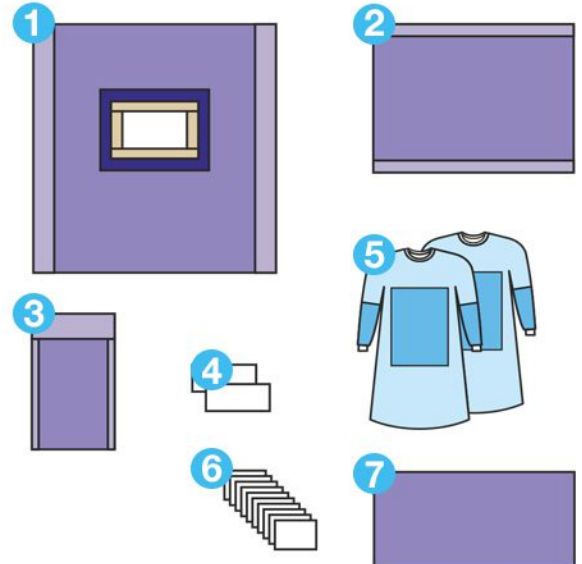


**UNICERT**
ISO 13485:2016**UNICERT**
ISO 9001:2015**CE**1023**"Hygiene for health, Disposable Sterile Products for hygiene"****GENERAL SURGERY PACK / GENEL CERRAHİ ÖRTÜ SETİ**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Anesthesia Drape / Anestezi Örtüsü	150x240	1 Pc.
2. Foot Drape with Adhesive Tape / Yapışkan Bantlı Ayak Örtüsü	150x180	1 Pc.
3. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
4. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
5. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	75x100	2 Pc.
6. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		2 Pc.
7. Medical Towel / Medikal Havlu	40x40	2 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

**LAPAROSCOPY PACK / LAPAROSKOPİ SETİ** **10**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Laparoscopy Drape / Laparoskopi Örtüsü	200x300	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
3. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Reinforced Surgical Gown / Korumalı Önlük		2 Pc.
6. Sponge / Spanç	7.5x7.5	10 Pc.
7. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.



General Surgery Sets Genel Cerrahi Seti



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ISO 13485:2016



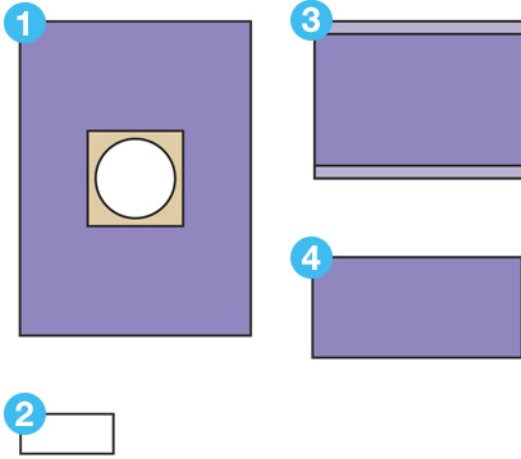
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CE 1023

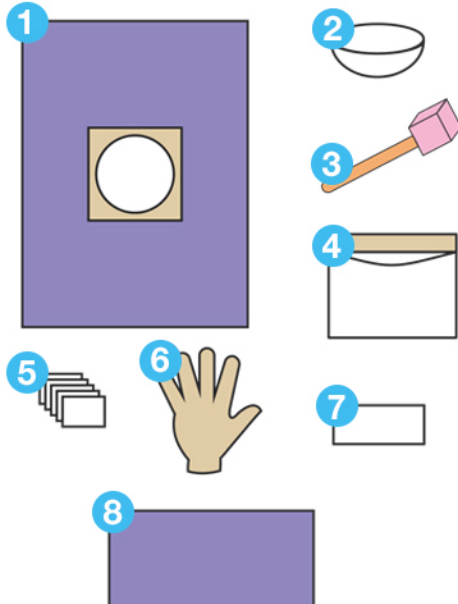
"Hygiene for health, Disposable Sterile Products for hygiene"

MINOR SURGERY PACK / MİNÖR CERRAHİ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Minor Surgery Drape / Minör Cerrahi Örtüsü	75x75	1 Pc.
2. Medical Towel / Medikal Havlu	40x40	1 Pc.
3. Back Table Cover / Alet Masa Örtüsü	40x50	1 Pc.
4. Sterilization Wrap / Sterilizasyon Bohçası	50x50	1 Pc.

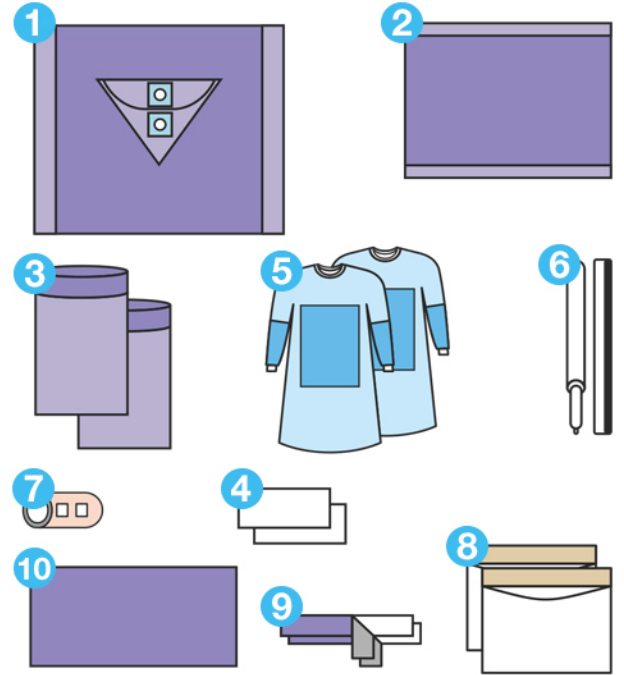
11 DRESSING PACK / PANSUMAN SETİ



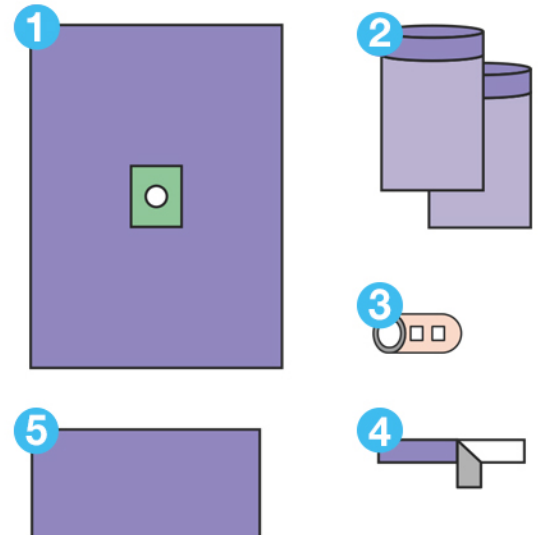
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Fenestrated Drape with Adhesive Tape/Yapışkan Bantlı Delikli Örtü	60x60	1 Pc.
2. 250 cc Solution Cup / Solüsyon Kabi		1 Pc.
3. Betadine Sponge / Boyama Sünger		1 Pc.
4. Universal Bag / Universal Torba	30x35	1 Pc.
5. Sponge / Spanç	7.5x7.5	5 Pc.
6. Gloves / Eldiven		1 Pair
7. Medical Towel / Medikal Havlu	40x40	1 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

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Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Arthroscopy Drape with LCP / Poşlu Artroskopi Örtüsü	200x300	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
3. Leggings / Bacak Kılıfı	40x75	2 Pc.
4. Medical Towel / Medikal HavluXL	40x40	2 Pc.
5. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		2 Pc.
6. Skin Marker & Ruler / Cilt Kalemi ve Cetveli		1 Pc.
7. Elastic Bandage / Elastik Bandaj	15x150	1 Pc.
8. Universal Bag / Universal Torba	30x35	2 Pc.
9. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x30	2 Pc.
10. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

**ARTHROSCOPY PACK WITHOUT POUCH / POŞSUZ ARTROSKOPİ SETİ****12**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Arthroscopy Drape / Artroskopi Örtüsü	200x310	1 Pc.
2. Leggings / Bacak Kılıfı	40x75	2 Pc.
3. Elastic Bandage / Elastik Bandaj	15x150	1 Pc.
4. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x50	1 Pc.
5. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.



Orthopedic Packs Ortopedi Setleri



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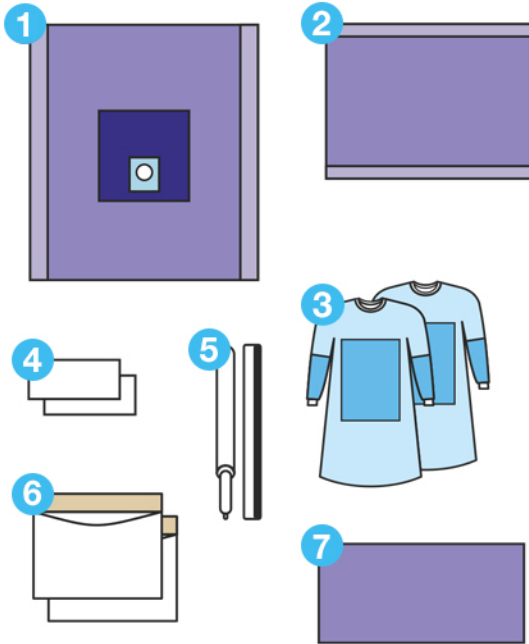
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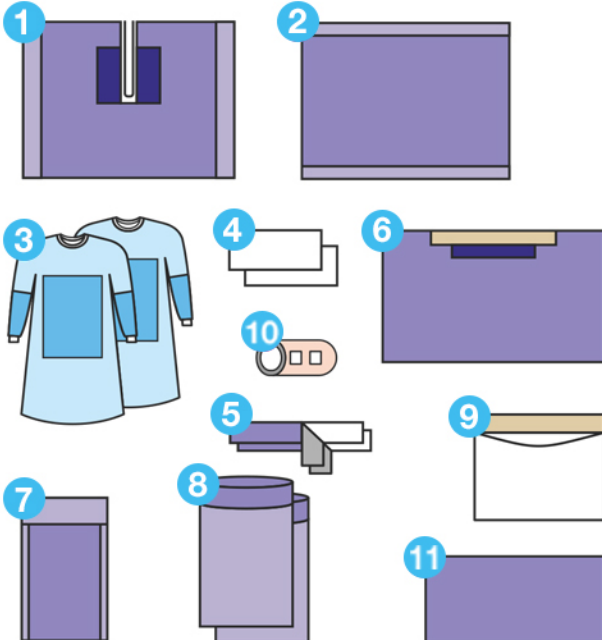
"Hygiene for health, Disposable Sterile Products for hygiene"

EXTREMITY PACK / EKSTREMİTE ÖRTÜ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Extremity Knee Drape / Ekstremitte Diz Örtüsü	200x310	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü XL	150x200	1 Pc.
3. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Skin Marker & Ruler / Cilt Kalemi ve Cetveli		1 Pc.
6. Universal Bag / Universal Torba	30x35	2 Pc.
7. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

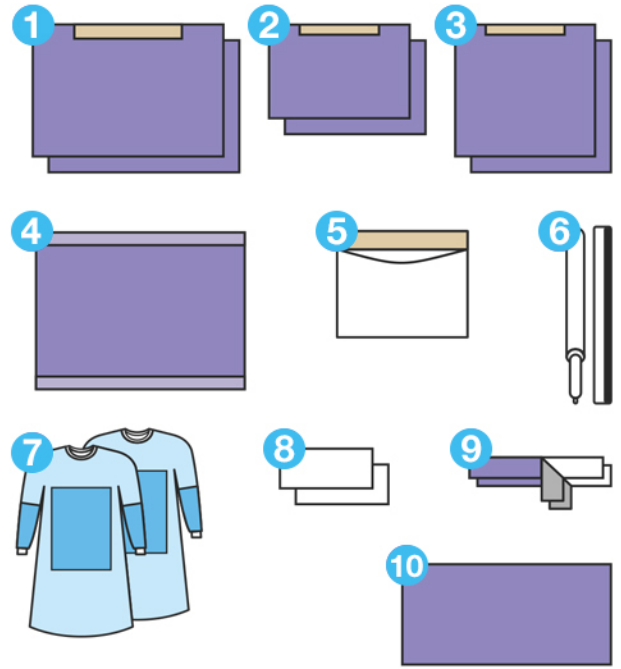
13 HIP PACK / KALÇA ÖRTÜ SETİ



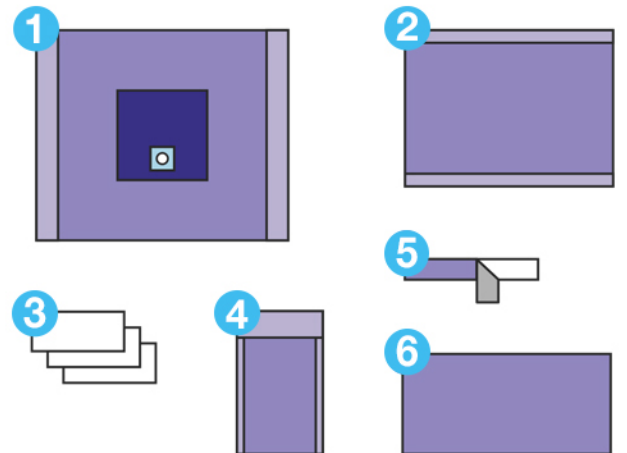
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Drape with U Aperture / U Yankılı Örtü	200x240	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü XL	150x200	1 Pc.
3. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x50	2 Pc.
6. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	150x240	1 Pc.
7. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
8. Leggings / Bacak Kılıfı	40x75	8 Pc.
9. Universal Bag / Universal Torba	30x35	2 Pc.
10. Elastic Bandage / Elastik Bandaj	10x150	1 Pc.
11. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

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Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	150x240	2 Pc.
2. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	50x120	2 Pc.
3. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	100x120	2 Pc.
4. Back Table Cover / Alet Masa Örtüsü	150x200	2 Pc.
5. Universal Bag / Universal Torba	30x35	1 Pc.
6. Skin Marker & Ruler / Cilt Kalemi ve Cetveli XL		1 Pc.
7. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		2 Pc.
8. Medical Towel / Medikal Havlu	40x40	2 Pc.
9. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x50	2 Pc.
10. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

**HAND/FOOT DRAPE PACK / EL-AYAK CERRAHİ ÖRTÜ SETİ****14**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Hand/Foot Drape / El-Ayak Örtüsü	200x300	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
3. Medical Towel / Medikal Havlu	40x40	3 Pc.
4. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
5. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x50	1 Pc.
6. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.



Cardiovascular Packs Kardiyovasküler Örtü Setleri



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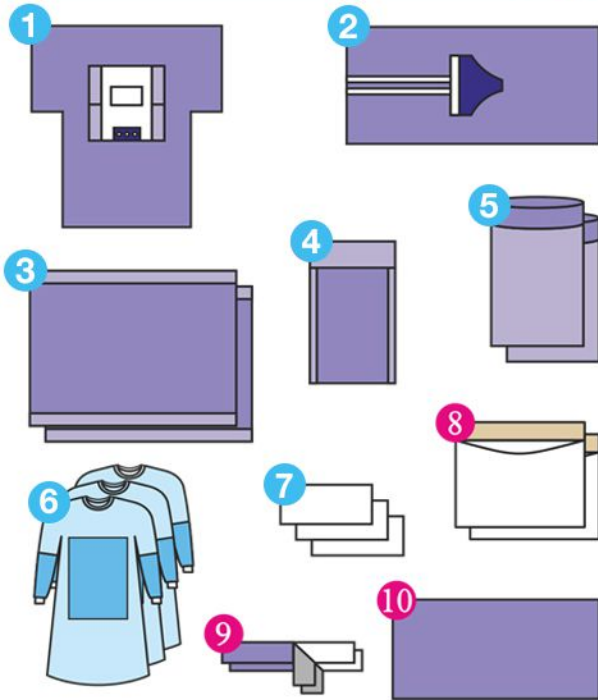
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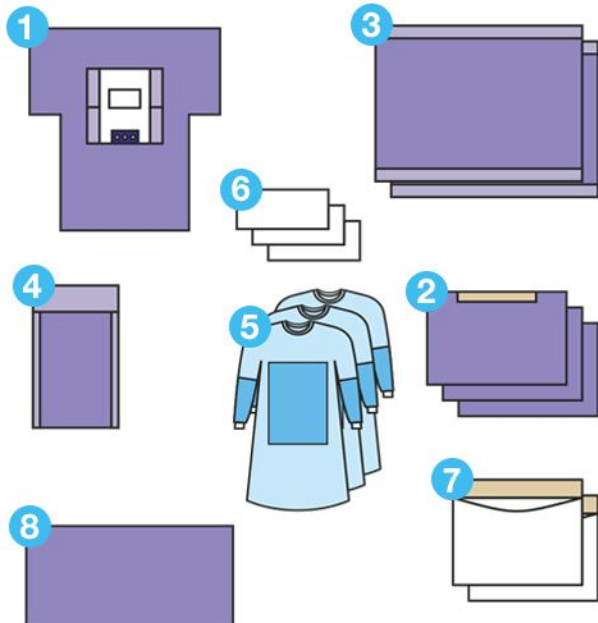
"Hygiene for health, Disposable Sterile Products for hygiene"

BY PASS DRAPE PACK / BY PASS ÖRTÜ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Bypass Drape / Bypass Örtüsü	240x340	1 Pc.
2. Perineum Drape with U Aperture / U Yarıklı Perine Örtüsü	150x240	1 Pc.
3. Back Table Cover / Alet Masa Örtüsü	150x200	2 Pc.
4. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
5. Leggings / Ayak Kılıfı XXL		Pair.
6. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		3 Pc.
7. Medical Towel / Medikal Havlu	40x40	3 Pc.
8. Universal Bag / Universal Torba	30x35	2 Pc.
9. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x50	2 Pc.
10. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

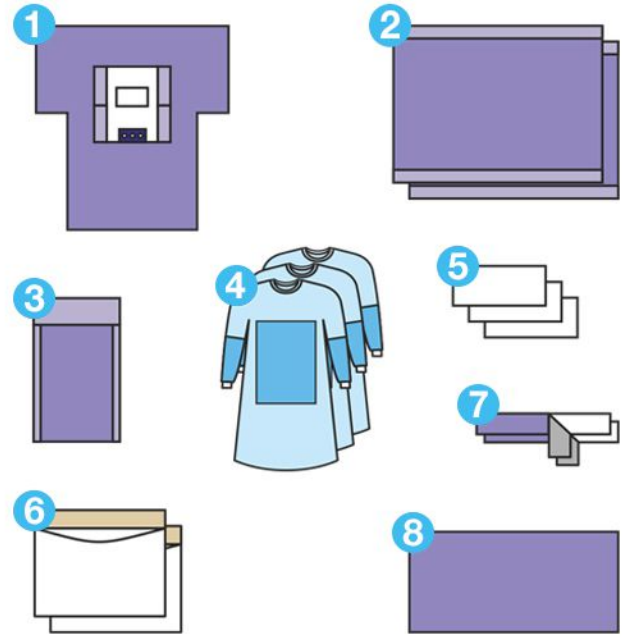
15 CARDIOVASCULAR PACK / KARDİOVASKÜLER ÖRTÜ SETİ



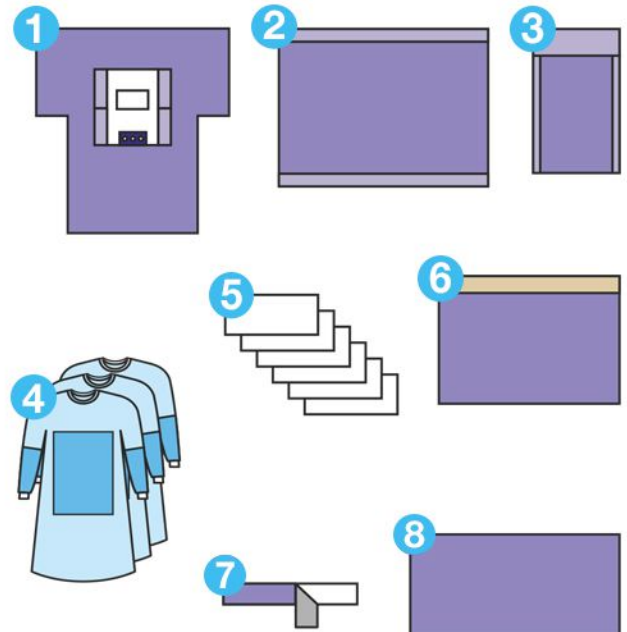
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. C.V.C Drape / K.V.C Örtüsü	200x300	1 Pc.
2. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	75x90	3 Pc.
3. Back Table Cover / Alet Masa Örtüsü	150x200	2 Pc.
4. Mayo Stand Cover / Mayo Masa Örtüsü XXL	78x145	1 Pc.
5. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		3 Pc.
6. Medical Towel / Medikal Havlu	40x40	3 Pc.
7. Universal Bag / Universal Torba	30x35	2 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

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Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Valve Replacement Drape / Kapak Örtüsü	240x340	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	150x200	2 Pc.
3. Mayo Stand Cover / Mayo Masa Örtüsü XXL	78x145	1 Pc.
4. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		3 Pc.
5. Medical Towel / Medikal Havlu	40x40	3 Pc.
6. Universal Bag / Universal Torba	35x35	2 Pc.
7. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x50	2 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

**THORACIC PACK / TORAKS ÖRTÜ SETİ 16**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Thoracic Drape / Toraks Örtüsü	250x340	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
3. Mayo Stand Cover / Mayo Masa Örtüsü XXL	78x145	1 Pc.
4. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		3 Pc.
5. Medical Towel / Medikal Havlu	40x40	6 Pc.
6. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	100x120	1 Pc.
7. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x50	1 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.



Obstetrics & Gynecology Surgery Packs

Kadın Doğum & Jinekoloji Setleri



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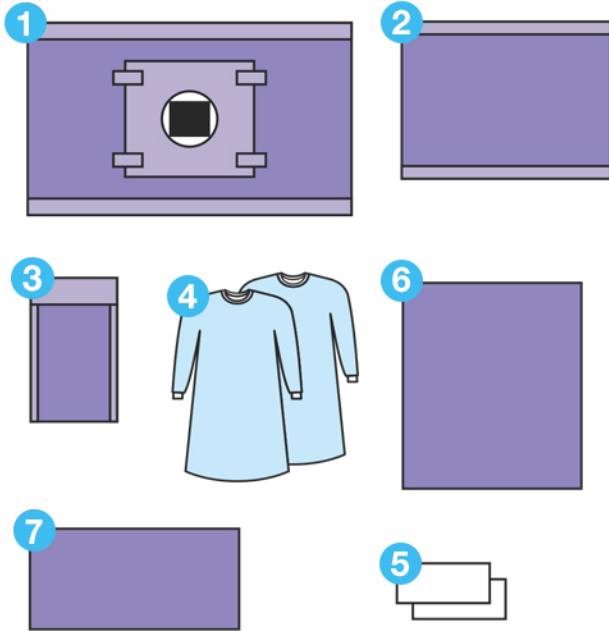
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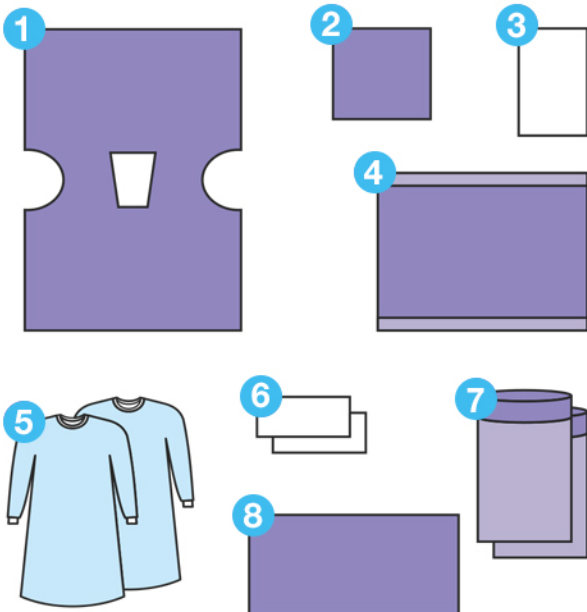
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CAESAREAN SECTION PACK / SEZERYAN ÖRTÜ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Section Drape L.T.T / Sezeryan Örtüsü L.T.T	200x300	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
3. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
4. Standard Surgical Gown XL / Standart Cerrahi Önlük XL		2 Pc.
5. Medical Towel / Medikal Havlu	40x40	2 Pc.
6. Baby Drape / Bebek Örtüsü	75x75	1 Pc.
7. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

17 O.P.U DRAPE PACK / O.P.U ÖRTÜ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. O.P.U Drape with hollow / Delikli O.P.U Örtüsü	130x150	1 Pc.
2. Plain Drape / Düz Örtü	75x100	1 Pc.
3. Transparent Drape / Şeffaf Örtü	60x60	1 Pc.
4. Back Table Cover / Alet Masa Örtüsü	100x150	1 Pc.
5. Standard Surgical Gown XL / Standart Cerrahi Önlük XL		2 Pc.
6. Medical Towel / Medikal Havlu	40x40	2 Pc.
7. Leg Cover / Bacak Kılıfı	50x110	2 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

Obstetrics & Gynecology Surgery Packs Kadın Doğum & Jinekoloji Setleri



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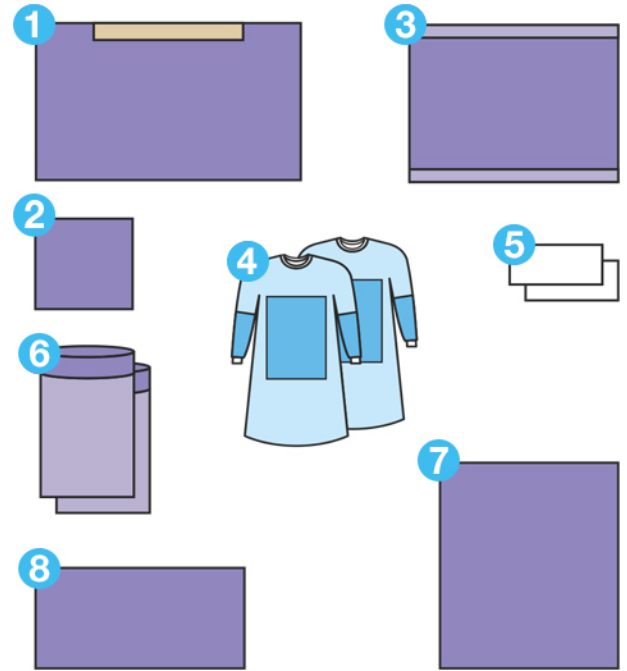


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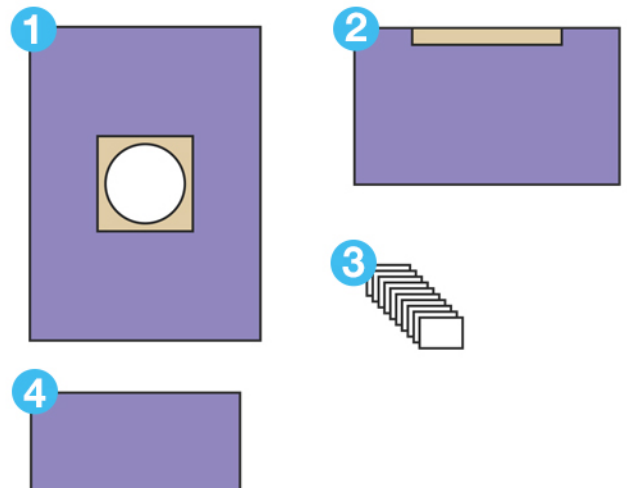
DELIVERY DRAPE PACK / DOĞUM ÖRTÜ SETİ

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Abdominal Drape / Abdominal Örtü	75x150	1 Pc.
2. Plain Drape / Düz Örtü	75x100	1 Pc.
3. Back Table Cover / Alet Masa Örtüsü	100x150	1 Pc.
4. Reinforced Surgical Gown XL / Korumalı Cerrahi Önlük XL		2 Pc.
5. Medical Towel / Medikal Havlu	40x40	2 Pc.
6. Leg Cover / Bacak Kılıfı	50x110	2 Pc.
7. Baby Drape / Bebek Örtüsü	75x75	1 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.



E.T DRAPE PACK / E.T ÖRTÜ SETİ **18**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Perforated Drape With Adhesive Tape / Delikli Yapışkan Bantlı Örtü	80x80	1 Pc.
2. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	50x90	1 Pc.
3. Sponge / Spanç	7,5x7,5	10 Pc.
4. Sterilization Wrap / Sterilizasyon Bohçası	75x75	1 Pc.



Urology Drape Packs Üroloji Örtü Setleri



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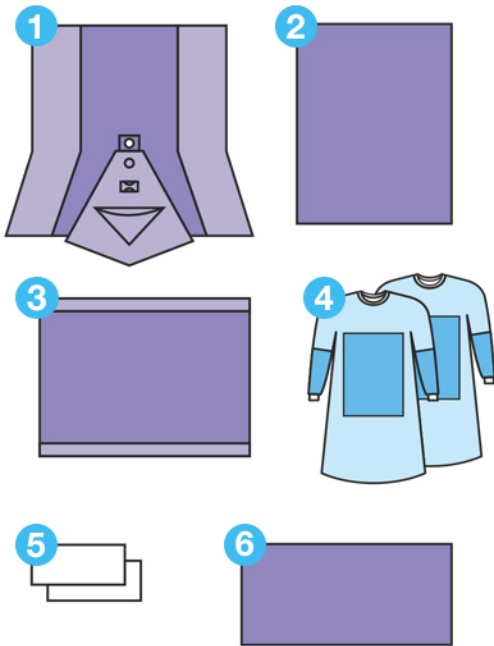
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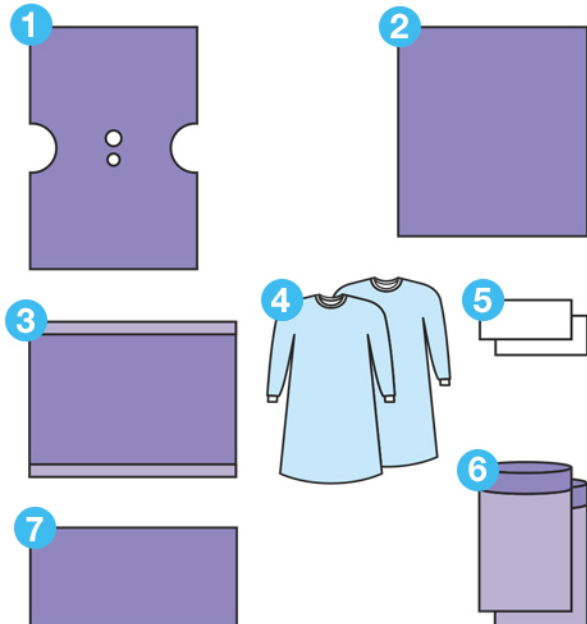
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T.U.R DRAPE PACK / T.U.R ÖRTÜ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. TUR Drape / TUR Örtüsü	180x200	1 Pc.
2. Plain Drape / Düz Örtü	100x120	1 Pc.
3. Back Table Cover / Alet Masa Örtüsü	100x150	1 Pc.
4. Reinforced Surgical Gown XL / Korumalı Cerrahi Önlük XL		2 Pc.
5. Medical Towel / Medikal Havlu	40x40	2 Pc.
6. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

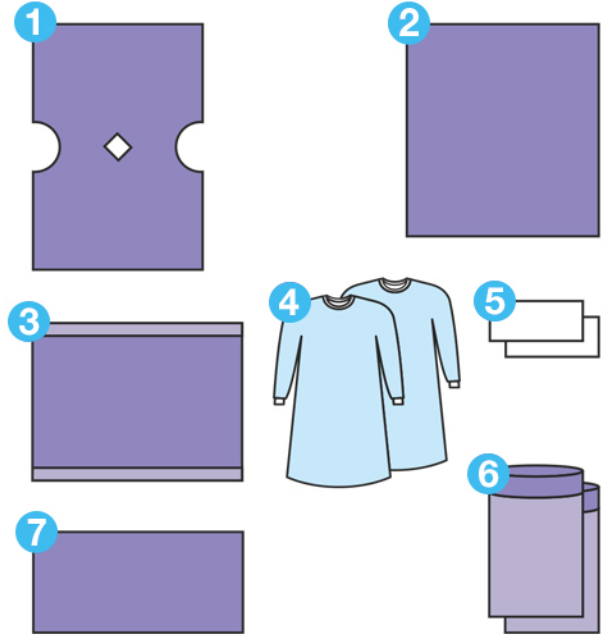
19 UROLOGY DRAPE PACK / ÜROLOJİ ÖRTÜ SETİ



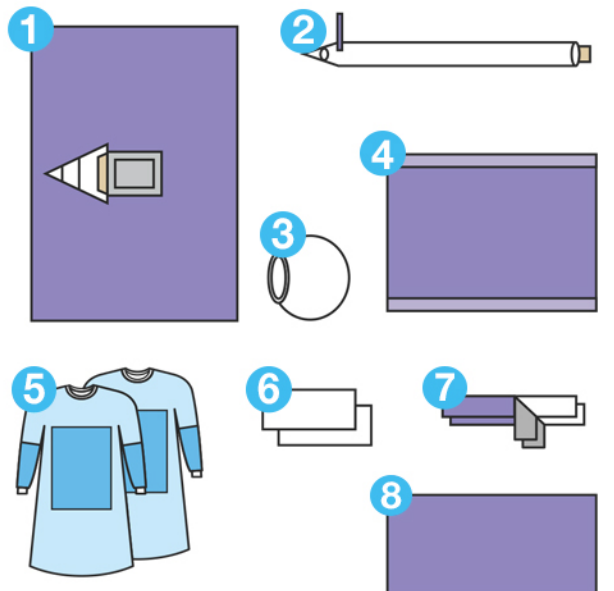
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Urology Drape / Üroloji Örtüsü	100x150	1 Pc.
2. Plain Drape / Düz Örtü	100x120	1 Pc.
3. Back Table Cover Standart / Alet Masa Örtüsü	150x200	1 Pc.
4. Surgical Gown XL / Standart Cerrahi Önlük XL		2 Pc.
5. Medical Towel / Medikal Havlu	40x40	2 Pc.
6. Leg Cover / Bacak Kılıfı	60x115	2 Pc.
7. Sterilization Wrap / Sterilizasyon Bohçası	75x75	1 Pc.

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Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Cystoscopy Drape / Sistoskopi Örtüsü	75x150	1 Pc.
2. Plain Drape / Düz Örtü	100x120	1 Pc.
3. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
4. Standart Surgical Gown XL / Standart Cerrahi Önlük XL		2 Pc.
5. Medical Towel / Medikal Havlu	40x40	2 Pc.
6. Leg Cover / Bacak Kılıfı	60x115	2 Pc.
7. Sterilization Wrap / Sterilizasyon Bohçası	75x75	1 Pc.

**PERCUTANEOUS DRAPE PACK / PERKÜTAN ÖRTÜ SETİ** **20**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Percutaneous Drape / Perkütan Örtüsü	150x300	1 Pc.
2. Camera Cover / Kamera Kılıfı		1 Pc.
3. Scopy Cover / C Skopi Kılıfı		1 Pc.
4. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
5. Reinforced Surgical Gown XL / Korumalı Cerrahi Önlük XL		2 Pc.
6. Medical Towel / Medikal Havlu	40x40	2 Pc.
7. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x30	2 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.



Cardiology Packs Kardiyoloji Örtü Setleri



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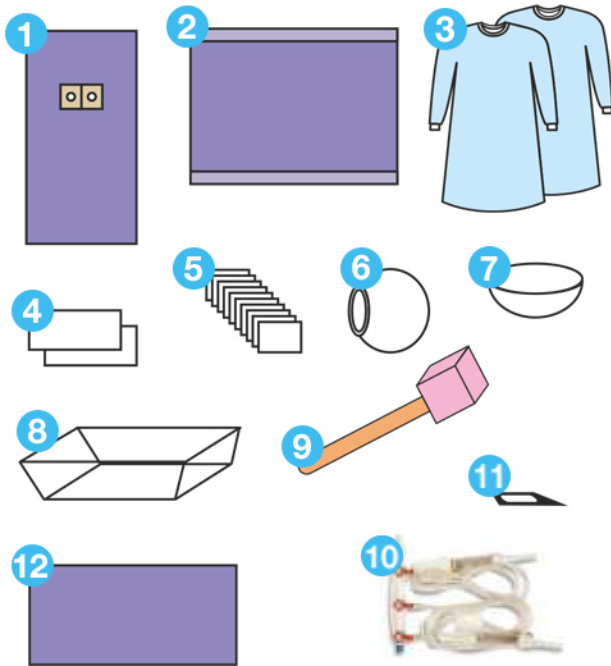
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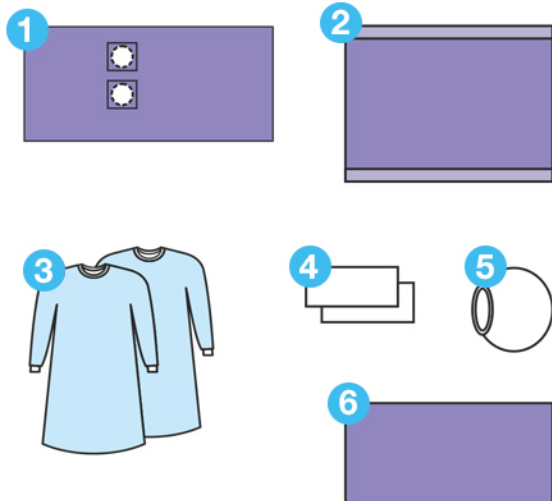
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ANGIOGRAPHY PACK / ANJİOGRAFİ ÖRTÜ SETİ -I-



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Angiography Drape / Anjio Örtüsü	180x300	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü XL	100x150	1 Pc.
3. Standard Surgical Gown / Standart Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Sponge / Spanç	7.5x7.5	10 Pc.
6. Fluoroscopy Cover 86cm / Fluoroscopi Kılıfı 86cm		1 Pc.
7. Solution Bowl 200cc / Solüsyon Kabı 200cc		2 Pc.
8. Tray / Tepsi		1 Pc.
9. Betadine Sponge / Boyama Sünger		1 Pc.
10. Opaque Set / Opak Set		1 Pc.
11. Scalpel Tip No:11/ Bistüri Ucu No:11		1 Pc.
12. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

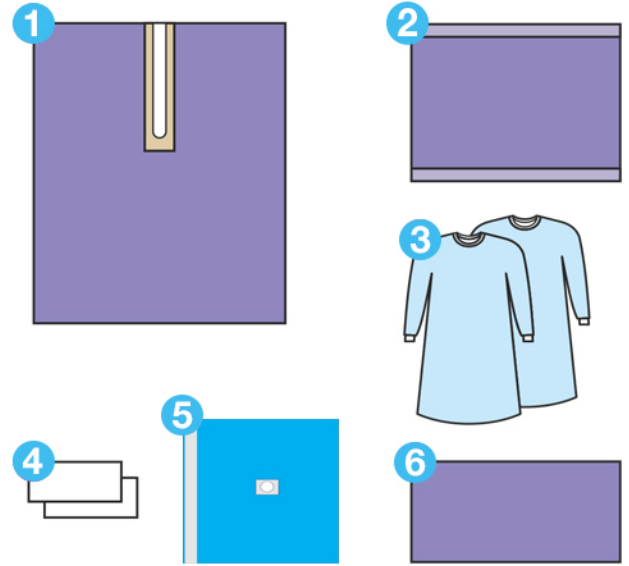
21 ANGIOGRAPHY PACK / ANJİOGRAFİ ÖRTÜ SETİ -II-



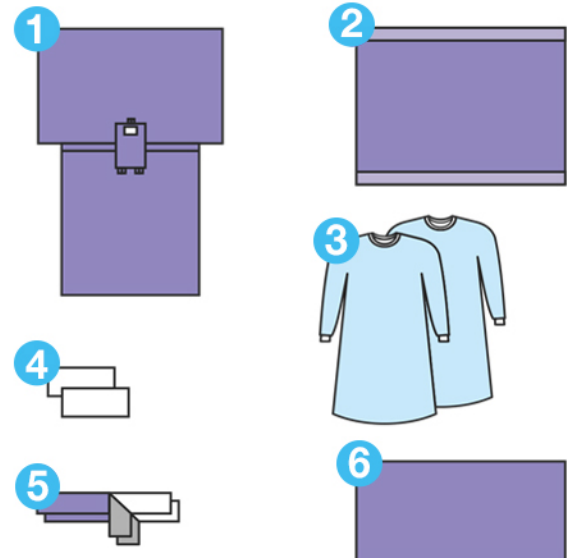
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Angiography Drape / Anjio Örtüsü	150x300	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü XL	100x150	1 Pc.
3. Standard Surgical Gown / Standart Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Fluoroscopy Cover 86cm / Fluoroscopi Kılıfı 86cm		1 Pc.
6. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

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Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Splint E.N.T U Drape / K.B.B U Örtüsü	150x250	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü Standard	100x150	1 Pc.
3. Surgical Gown / Standart Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Fenestrated Drape with Adhesive Tape / Bantlı Delikli Örtü	100x100	1 Pc.
6. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

**THYROID PACK / TROİD ÖRTÜ SETİ****22**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Thyroid Drape / Troid Örtüsü	240x320	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	100x150	1 Pc.
3. Standard Surgical Gown / Standart Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x30	2 Pc.
6. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.



Neurosurgery Packs Beyin Cerrahi Örtü Setleri



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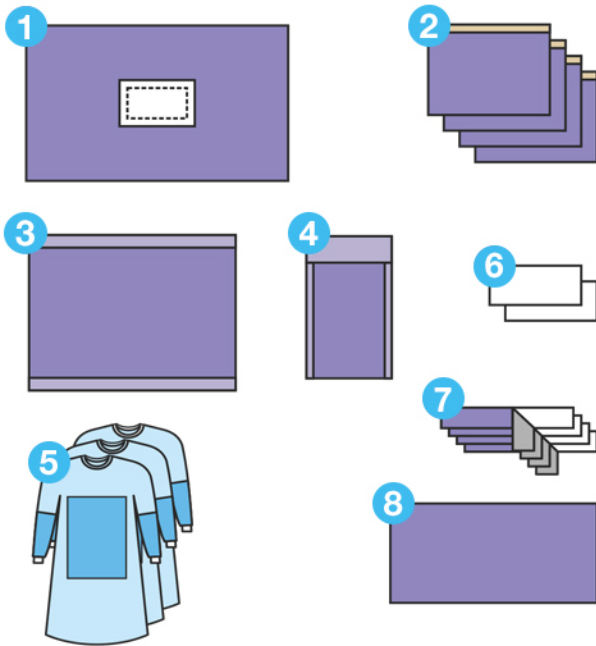
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ISO 9001:2015



CE 1023

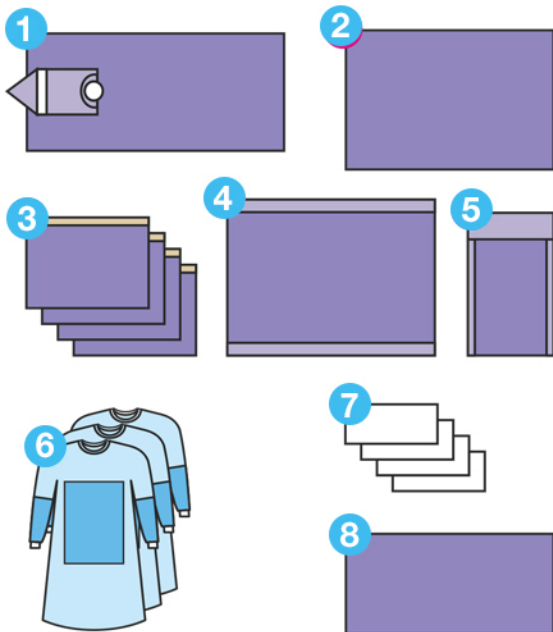
"Hygiene for health, Disposable Sterile Products for hygiene"

SPINAL (LAMINECTOMY) PACK / SPİNAL (LAMİNEKTOMİ) ÖRTÜ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Spinal Vertebra Drape / Spinal Vertebra Örtüsü	160x300	1 Pc.
2. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	100x120	4 Pc.
3. Back Table Cover / Alet Masa Örtüsü	100x150	1 Pc.
4. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
5. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		3 Pc.
6. Medical Towel / Medikal Havlu	40x40	4 Pc.
7. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x30	4 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

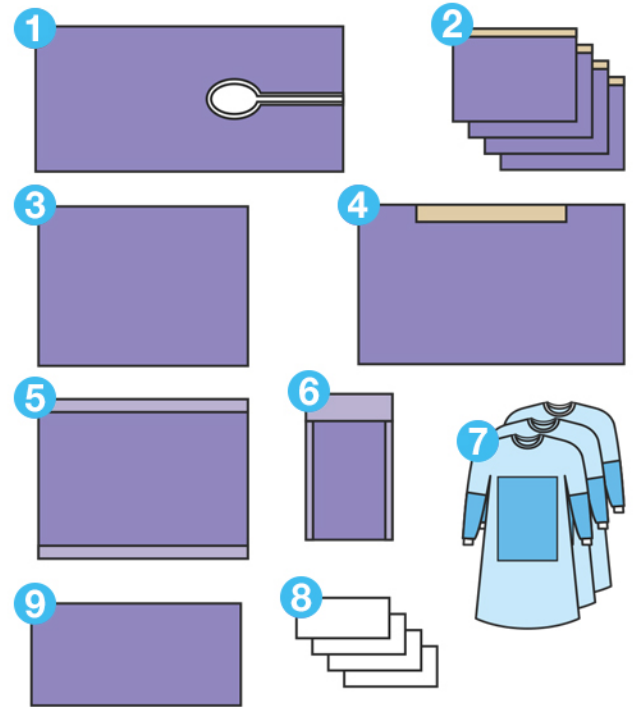
23 CRANIOTOMY PACK / KRANIOTOMİ ÖRTÜ SETİ



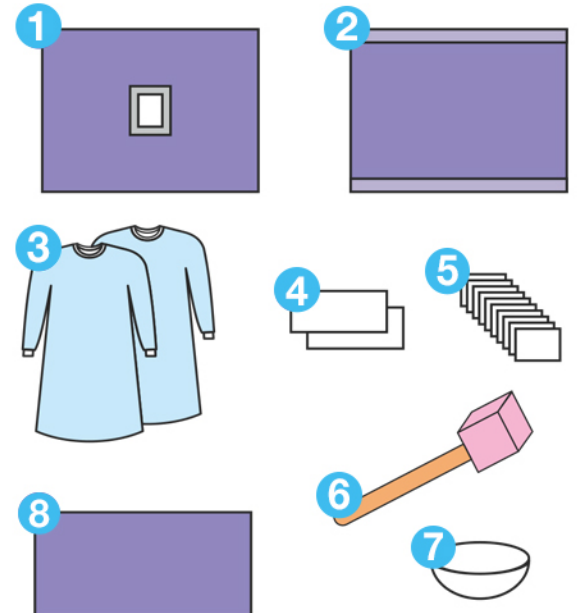
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Craniotomy Drape / Kraniotomi Örtüsü	220x350	1 Pc.
2. Plain Drape / Düz Örtü	150x250	1 Pc.
3. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	100x100	4 Pc.
4. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
5. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
6. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		3 Pc.
7. Medical Towel / Medikal Havlu	40x40	4 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

**UNICERT**
ISO 13485:2016**UNICERT**
ISO 9001:2015**CE**1023**"Hygiene for health, Disposable Sterile Products for hygiene"****SHUNT PACK / SHUNT ÖRTÜ SETİ**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Shunt Drape / Shunt Örtüsü 100x120	150x300	1 Pc.
2. Drape with Adhesive Tape / Yapışkan Bantlı Örtü		4 Pc.
3. Plain Drape / Düz Örtü	150x180	1 Pc.
4. Anesthesia Drape / Anestezi Örtüsü	150x240	1 Pc.
5. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
6. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
7. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		3 Pc.
8. Medical Towel / Medikal Havlu	40x40	4 Pc.
9. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

**BIOPSY PACK / BİYOPSİ ÖRTÜ SETİ** **24**

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Biopsy Drape / Biyopsi Örtüsü	120x150	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	100x150	1 Pc.
3. Standard Surgical Gown / Standart Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Sponge / Spanç	7.5x7.5	10 Pc.
6. Betadine Sponge / Boyama Sünger		1 Pc.
7. Solution Bowl 500cc / Solüsyon Kabı 500cc		1 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.



Oftalmology & Dentistry Packs Göz & İmplant Örtü Setleri



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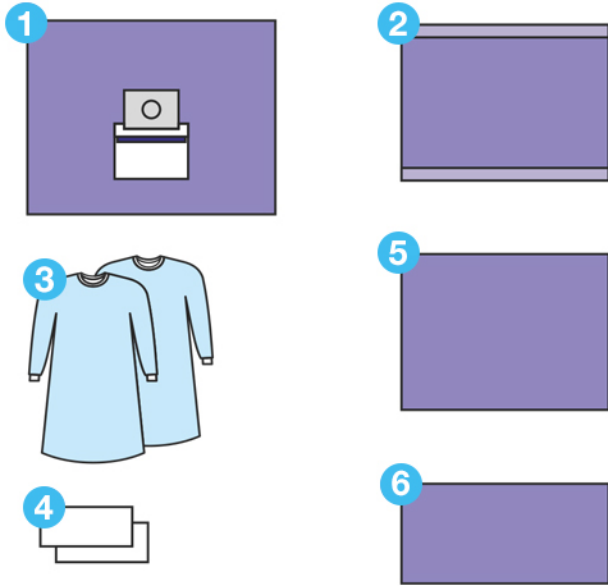
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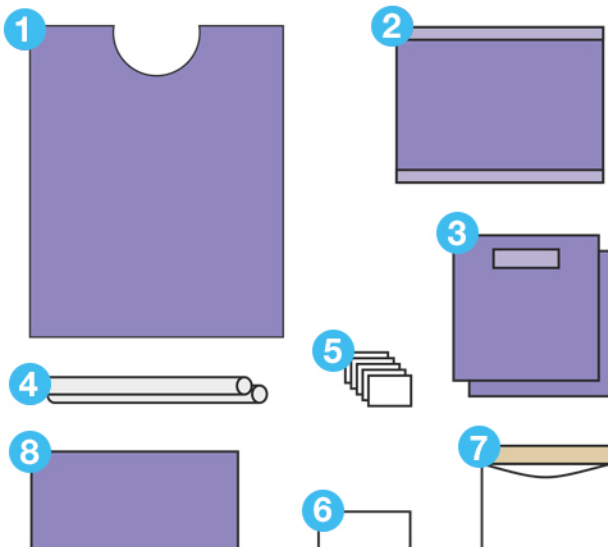
"Hygiene for health, Disposable Sterile Products for hygiene"

OPHTHALMIC DRAPE PACK / GÖZ ÖRTÜ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Ophthalmic Drape with Pouch / Poşlu Göz Örtüsü	100x130	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	100x150	1 Pc.
3. Standard Surgical Gown / Standart Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Plain Drape / Düz Örtü	150x170	1 Pc.
6. Sterilization Wrap / Sterilizasyon Bohçası	75x75	1 Pc.

25 IMPLANT PACK / İMPLANT ÖRTÜ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Patient Upper Drape / Hasta Üst Örtüsü	75x90	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	75x75	1 Pc.
3. Reflector Drape / Reflektör Örtüsü	15x15	2 Pc.
4. Transparent Hose Cover / Şeffaf Hortum Kılıfı		2 Pc.
5. Sponge / Spanç	7.5x7.5	5 Pc.
6. Medical Towel / Medikal Havlu	40x40	1 Pc.
7. Universal Bag / Universal Torba	30x35	1 Pc.
8. Sterilization Wrap / Sterilizasyon Bohçası	75x75	1 Pc.

Chemotherapy & Plastic Surgery Packs Kemoterapi & Plastik Cerrahi Setleri



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ISO 13485:2016



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ISO 9001:2015

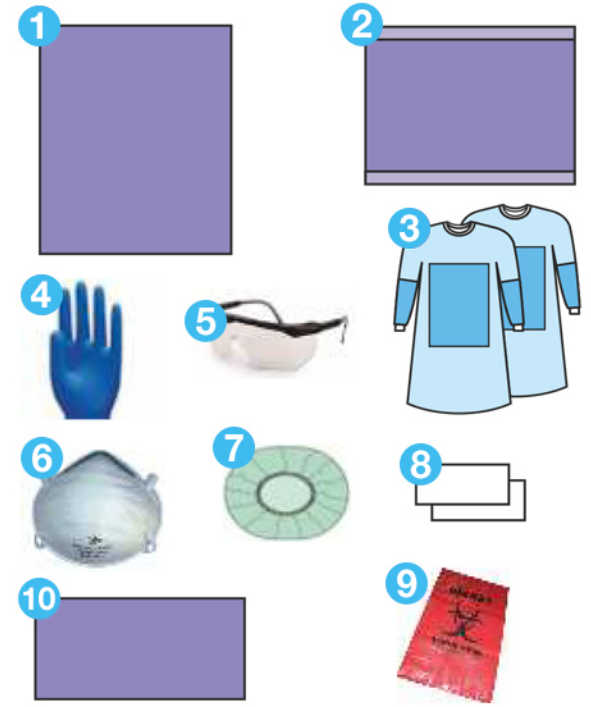


CE 1023

"Hygiene for health, Disposable Sterile Products for hygiene"

CHEMOTHERAPY PACK / KEMOTERAPİ ÖRTÜ SETİ

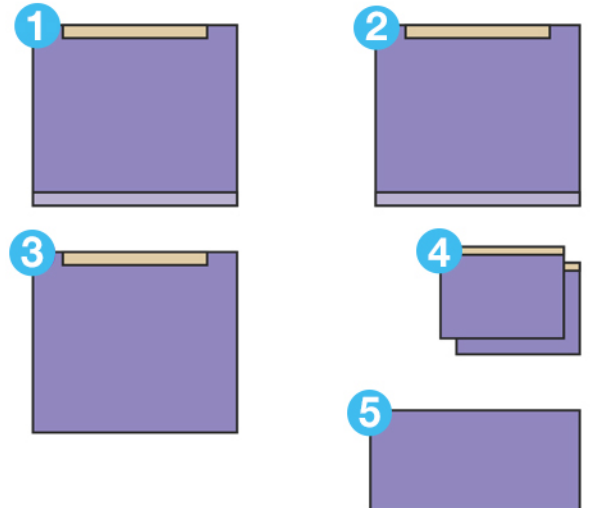
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Chemotherapy Drape / Kemoterapi Örtüsü	50x70	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	50x100	1 Pc.
3. Chemotherapy Gown / Kemoterapi Önlüğü		1 Pc.
4. Chemotherapy Gloves / Kemoterapi Eldiveni		1 Pair/Çift
5. Protective Glasses / Koruyucu Gözlük		1 Pc.
6. Mask / Ventilli		1 Pc.
7. Bonnet / Bone		1 Pc.
8. Medical Towel / Medikal Havlu	40x40	2 Pc.
9. Medical Waste Bag / Tıbbi Atık Torbası		1 Pc.
10. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.



PLASTIC SURGERY PACKS / PLASTİK CERRAHİ ÖRTÜ SETLERİ

26

Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Adhesive Drape / Yapışkan Bantlı Örtü	150x170	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	100x150	1 Pc.
3. Anesthesia Drape / Anestezi Örtüsü	150x240	1 Pc.
4. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	75x90	2 Pc.
5. Sterilization Wrap / Sterilizasyon Bohçası	75x75	1 Pc.



Paediatric Packs Pediatrik Setler



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ISO 13485:2016



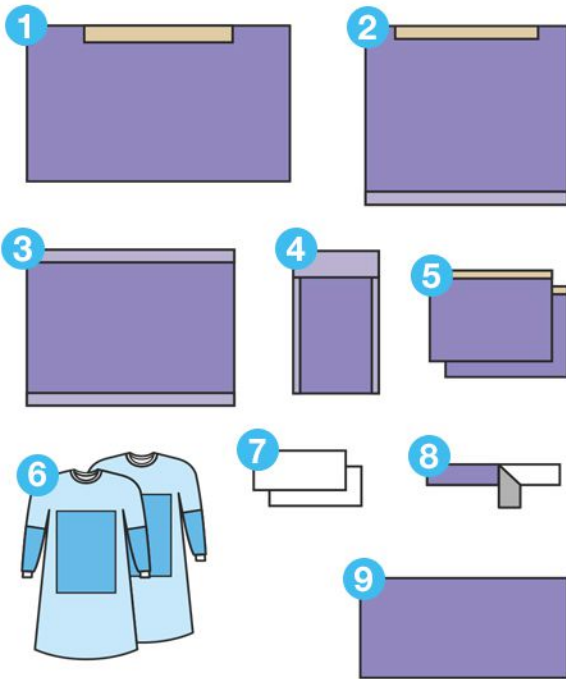
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ISO 9001:2015



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"Hygiene for health, Disposable Sterile Products for hygiene"

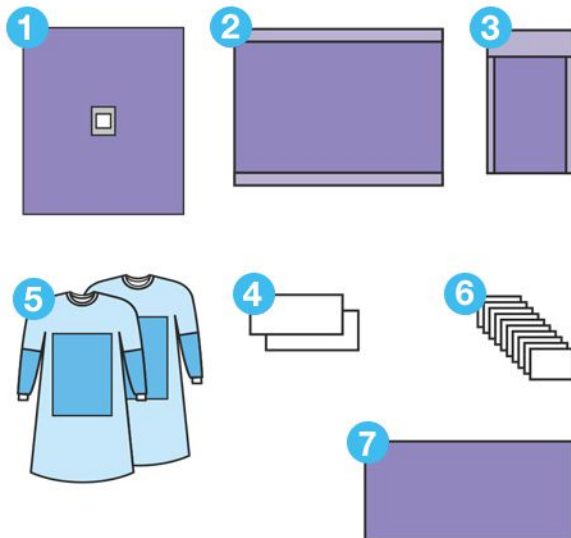
PEDIATRIC UNIVERSAL PACK / PEDIATRİK GENEL CERRAHİ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Anesthesia Drape / Anestezi Örtüsü	150x240	1 Pc.
2. Foot Drape with Adhesive Tape / Yapışkan Bantlı Ayak Örtüsü	175x175	1 Pc.
3. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
4. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
5. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	75x75	2 Pc.
6. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		2 Pc.
7. Medical Towel / Medikal Havlu	33x34	2 Pc.
8. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	10x50	1 Pc.
9. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

27

PAEDIATRIC LAPAROSCOPY PACK / PEDIATRİK LAPAROSKOPİ SETİ



Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Paediatric Laparoscopy Drape (10x10 Ins. Film) / Pediatrik Laparoskopî Örtüsü (10x10 Ins. Film)	150x180	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
3. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Reinforced Surgical Gown / Korumalı Önlük		2 Pc.
6. Sponge / Spanç	7.5x7.5	10 Pc.
7. Sterilization Wrap / Sterilizasyon Bohçası	100x100	1 Pc.

Patient Gown*Long Sleeve Patient Gown*

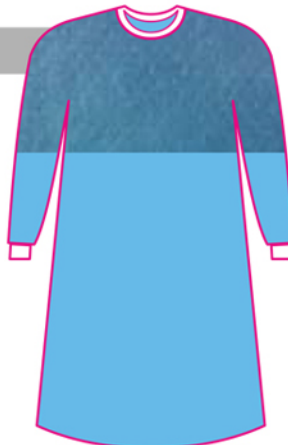
Patient Gown (Long Sleeve)	M
	L
	XL
	XXL

*Short Sleeve Patient Gown*

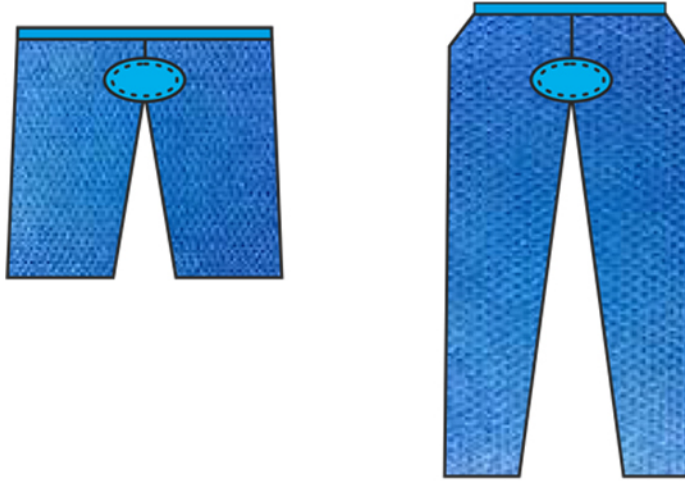
Patient Gown (Short Sleeve)	M
	L
	XL
	XXL

Chemotherapy Gown

Chemotherapy Gown	M
	L
	XL
	XXL

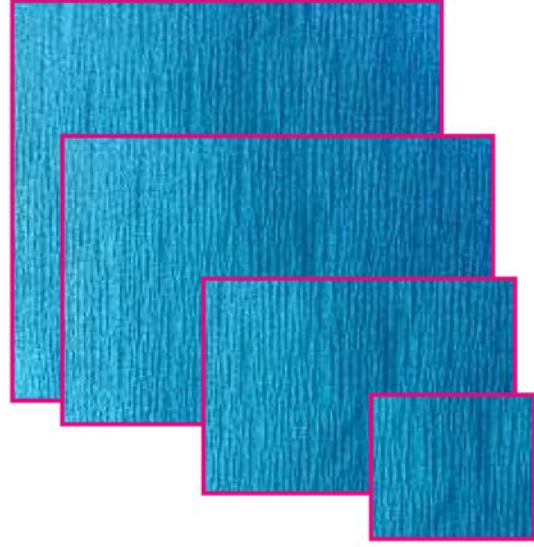
Urology Gown

Urology Gown	M
	L
	XL
	XXL

COLONOSCOPY PANTS/SHORTS / KOLONOSKOPİ PANTOLONU / ŞORTU

Colonoscopy Pants	L
	XL
Colonoscopy Shorts	L
	XL

STERILIZATION WRAP / STERİLİZASYON BOHÇALARI



Sterilization Wrap	50x50
	75x75
	90x90
	100x100
	120x120
	130x150

BED SHEETS / YATAK ÖRTÜSÜ

30

SMS	80x220
	150x220
Trilaminate Green	80x220
	150x220
Trilaminate Blue	80x220
	150x220
Patient Bed Set	Bed Sheet+Pillow Cover+ Blanket Cover



UNICERT
ISO 13485:2016



UNICERT
ISO 9001:2015



CE₁₀₂₃

Yunusemre Mh. 12. Yıldırım Sk. No:17 Yıldırım / Bursa
Tel. : 0224. 369 32 32 Faks : 0224. 369 32 36
E-mail : info@zeynimedical.com.tr





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

**ZEYİNİ MEDİKAL TEKSTİL İNŞAAT
SANAYİ VE TİCARET LİMİTED ŞİRKETİ**

**YUNUSEMRE MAHALLESİ 12. YILDIRIM SOKAK NO:17
YILDIRIM / BURSA / TÜRKİYE**

In recognition of the organization's Management System
which complies with

EN 13795-1:2019

The scope of activities covered by this certificate is defined below

**MANUFACTURING, SALES OF DISPOSABLE, STERILE AND NON-STERILE
SURGICAL GOWNS, INSULATED VISITOR GOWNS AND COVERS**

**TEK KULLANIMLIK, STERİL VE STERİL OLMAYAN CERRAHİ ÖNLÜK,
İZOLASYONLU ZİYARETÇİ ÖNLÜĞÜ VE ÖRTÜLERİN İMALATI, SATIŞI**

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

Certificate Number: **SISTUREN082020161**

Date of Issue of Original Certificate: **21.08.2020**

Date of Issue of latest certificate: **23.09.2021**

Expiry Date: **20.08.2022**

Re-certification Due on: **21.07.2023**


Managing Director

Note: This certificate is valid only if produced with the
continuation letter after the surveillance is carried out successfully.



The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Compliance is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid

Corporate office(SIS): Unit No. 514, 5th Floor, Vipul Business Park, Sohna Road, Sector-48, Gurgaon-122018, Haryana, India.
International office(SIS):- URB. Santa Ana Cal. German, Schrieber 276, San Isidro, Lima, Peru 15047.
Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91 99105 01396, + 91 96430 73391
The status of this certificate can be verified on "http://www.siscertifications.com/verify/"
Web:- http://www.siscertifications.co.in, www.siscertifications.com

Issue No.: 03



ZEYİNİ MEDİKAL TEKSTİL İNŞ.SAN. VE TİC. LTD. ŞTİ.

YUNUSEMRE MAH. 12 YILDIRIM SOKAK NO:17 YILDIRIM/BURSA

Report No. 111699085
Buyer /
Test Item. : Nonwoven fabric,3-layer, SMS
Item No. : /
Colour Name. : /
Condition at delivery. : Samples tested as received.
Test Scope. : Parameters selected by customer
Test Specification : Determination of hydrostatic pressure

**Applicant's Provided
Care Instruction/Label:** -

Sample Receiving date: 2021-10-18 (p.m)
Testing Period: 2021-10-21 to 2021-10-25
Test Result: No Comment

For and on behalf of
TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş

Tomris Hasağcebi / Customer
Relations Manager

Abdullah Akil / Physical
Laboratory Manager

TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş.

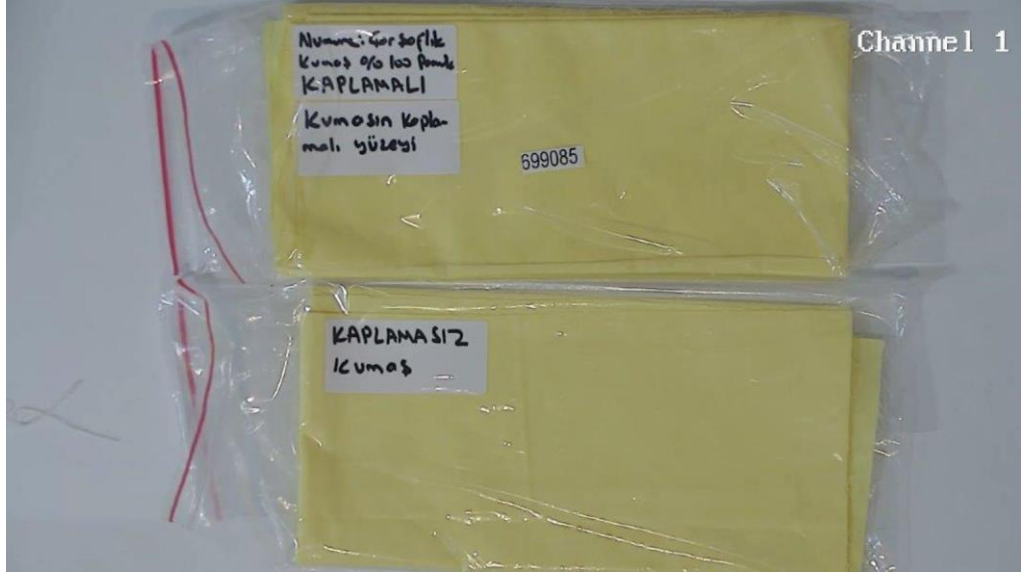
Kozyatagi Mah. Saniye Ermutlu Sok. No:12
Colakoglu Plaza B Blok 34742 Kadikoy Istanbul,
Tel. +902166653200, Fax +902166653299, e-mail: info@tr.tuv.com

*The results given in this report belong to the received sample by vendor.
This test 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.
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.*

Products

Report No.: 111699085

Date: 10.25.2021



Products

Report No.: 111699085

Date: 10.25.2021

Material List:

Page 3 of 6

Material No.	Material	Color	Location
M001	Textile	-	Textile
M002	Textile + coating	-	Textile w /coating

Products

Report No.: 111699085

Date: 10.25.2021

Conclusion:

TEST PROPERTY

Hydrostatic Pressure Test

M001

#

M002

#



TÜVRheinland®

Precisely Right.

Page 4 of 6

Products

Report No.: 111699085

Date: 10.25.2021

1.Hydrostatic Pressure Test

Test method : EN 20811:1993

Face Side: Original
Test Conditions: 65 cm2 Test
Speed:65 cmH2O/dak

	<u>M001</u>	<u>M002</u>	<u>Requirement</u>
<u>Pressure</u>			
Average	65 cm H2O	65cm H2O	-

- END -

Products

Report No.: 111699085
Date: 10.25.2021

1. PRODUCT

ANGIOGRAPHY SET

2. CODE

Model 601-001-S.

3. PRODUCT CONFIRMITIES

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009, ISO 10993-7:2008, EN 20811

4. CONTENT

Angiography Drape 240 CM X 370 CM 1 Pc.

Adhesive Drape 50 CM X 50 CM 1 Pc.

C-Arm Cover 140 CM 1 Pc.

Superabsorbent Drape 35 CM X 50 CM 1 Pc.

Instrument Table Field 150 CM X 190 CM 1 Pc.

5. PACKING

The product is individual packaged. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, validity date, lot number, etc.

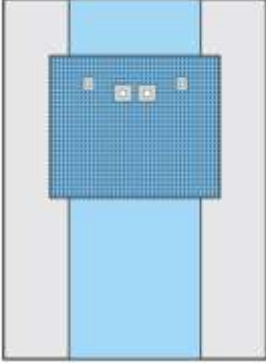
6. STORAGE

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

7. Validity

Sterile EO. 3 years from the date of production

Content



ZEYNI MEDİKAL
TEKSTİL, İNŞAAT SAN. VE TİC. LTD. ŞTİ.
Yenimahalle Mh. No. 17 Çankaya Sk. No.17
Yenimahalle / ANKARA
Yatırım Yönetimi: Dr. Sinan Yılmaz
Mersis: 080300141040300001



SCIENTIFIC AND TECHNOLOGICAL RESEARCH COUNCIL OF TURKEY
MARMARA RESEARCH CENTER
GENETIC ENGINEERING and BIOTECHNOLOGY INSTITUTE

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T02626772000 F02626412309
<http://www.mam.gov.tr>

CERTIFICATE OF ANALYSIS
(Industrial Technical Support Service)

Report no :16563500-125.05-89 /4654
Report date :23.08.2017
Applicant : ZEYİNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.
Address : YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA
Subject :CYTOTOXICITY TEST CARRIED OUT for 'SURGERY DRAPE' IN THE SCOPE OF BIOCOMPATIBILITY TESTS

The results included in this report are related to only the sample analyzed.

Approved by

Assoc. Prof. Dr. Fatima YÜCEL
GMBE Industrial Services Officer

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The unsigned analysis reports are not valid.

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Page 1/6





Report no:16563500-125.05-89/4654

Sample	Specifications	Item
Surgery Set		3

Table1 (contd.).Product tested.

Descriptions:

Signatories:

53192



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Report no:16563500-125.05-89/4654

Cytotoxicity Test

The cytotoxicity tests were carried out in accordance with 'Biological evaluation of medical products: ISO 10993-5: 2009 Tests for in vitro cytotoxicity' standards.

Beginning date of test:

Expiry date of test:

Sample description: The sample characteristics are as explained in the Part 1. The samples were provided by 'ZEYİN MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.' firm. The tests were carried out by taking parts from surgery set selected as representing the product.

Explanation of cell strain used and its reasons: L929 rat cell strain was used. It was selected since it is one of the cell strains recommended by ISO 10993-5 and appropriate for representation of mammals system.

Explanation of cell strain used and its reasons: L929 rat cell strain was used. It was selected since it is one of the cell strains recommended by ISO 10993-5 and appropriate for representation of mammals system.

Name and batch number of the firm provided the feed used and the serum and antibiotics added: DMEM/F12 (Sigma cat # D0547-10X-1, lot #SLBH4393) + 10% Fetal bovine serum (Gibco Life Sciences Cat # 10270-106, lot #41G2943K)+ penicillinle streptomycin (Gibco Life Sciences, Cat # 15140-122, lot # 1688254) were used as feed lot.

Test method: Direct contact method.

Rational: The analyses of toxic effect of solid matters, dissolved in liquid, as a result of contact with cell.

Direct contact protocol: The 'Surgical Drape' was provided as sterile and not subjected to a sterilization process once again. The 'Surgical Drape' was cut to the extent of 1/10 of total surface area of cells and put into middle of pits over the cells.

Test protocol: L929 cells were counted and implanted in 8 pits as 4×10^5 cell/pit and incubated for 24 hours at 37°C and 5% CO₂. The samples prepared as explained above and the controls were immediately added on cells and incubated for 24 hours at 37°C and 5% CO₂. The samples were contacted with cells for 24 hours and then observed microscopically. Following this process, WST-1 agent at 1:50 rate was added onto the cells and the color formation was waited for 2 hours. 100 µ liquid from each pit was taken and poured into 3 pits in 96 sizes so that the absorbance measure was realized at microplate reader, at 450 nm and 650 nm reference wave length for viability test.

Cytotoxicity Measure method: WST-1 cell viability analyses (Colorimetric)

Rational: The consistent and sensitive measurement of cell viability.

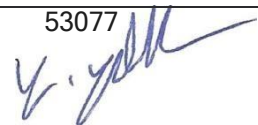
Descriptions:

Signatories:

52966



53077



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Report no:16563500-125.05-89/4654

Negative, positive and other controls:

Controls:

Control 1- The plates on which any material was not put but only the cells were implanted

Control 2- The sterile and dry whatmann paper cut in 1 cm X 1 cm sizes.

Negative Control: Whatmann paper saturated with PBS (25µl) and cut in 1cm X 1cm sizes.

Positive Control: Whatmann paper saturated with EMS (Ethyl methanesulfonate, Merck Millipore, 820774) (25µl) and cut in 1cm X 1cm sizes.

RESULT:

Cell response and other observations:

Quantitative Evaluation

It was observed that there was no cell direct under the sample. However, the same result was observed in PBS saturated whatmann paper samples. A zonal toxic effect was not observed around the sample. This observation was reflected in qualitative evaluation.

	Degree		Degree
Sample		Control 1, Empty	0
Surgery Drape	0	Control 2, dry Whatmann paper	0
		Negative Control, PBS saturated Whatmann paper	0
		Positive Control, EMS saturated Whatmann paper	4

Table 2. Quantitative Evaluation.

Degree	Reactivity	Situation
0	None	Clear intracytoplasmic granuls, no any cell lysis, no impact on cell growth.
1	Less	The rate of cells, which are become rounded, representing poor adhesion and/or having no intracytoplasmic granules, showing morphological changes and partly lysis, is below 20%.
2	Slight	The rate of cells, which are become rounded and having no intracytoplasmic garnuls, is below 50%, there is no extensive cell lysis; growth inhibition is below 50%.
3	Moderate	Less than 70% of cells are rounded or showing lysis and growth inhibition is not more than 50%.
4	Serious	All or almost all of the cells are showing lysis.

Table 3. Evaluation criteria and scoring for cytotoxicity test.

Descriptions:

Signatories:

52966

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**MAM**

Report no: 16563500-125.05-89/4654

According to the evaluation criteria given in the Table 3, L929 cell culture was exposed to 'Surgical Drape' for 24 hours in order to examine its potential for causing to cell death according to the control and the cell viability was found as 98.11 ± 1.31 according to the control as a result of ISO 10993-5 cytotoxicity test carried out in the scope of biocompatibility.

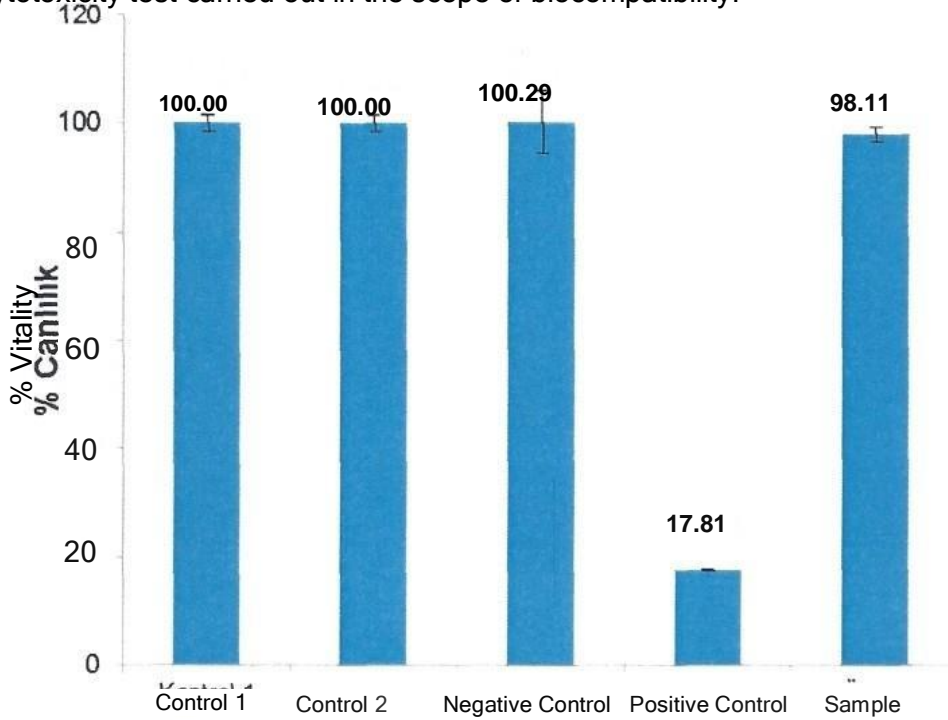


Figure 1. The viability analyses, carried out by using extracts from samples called 'Surgical Drape', are shown in the Figure.

Cytotoxicity of 'Surgical Drape' sample; The absorbance values of samples were normalized by using Negative Control 2 absorbance values in parallel with the samples for 100% viability.

The data, obtained for each sample, was provided as a result of triplicated process in tests of 3 extracts from 3 randomly selected samples.

EVALUATION:

No cytotoxic effect according to the viability test carried out by using 'Surgical Drape' extraction method.

Descriptions:

Signatories:

52966

53077

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SCIENTIFIC AND TECHNOLOGICAL RESEARCH COUNCIL OF TURKEY
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GENETIC ENGINEERING and BIOTECHNOLOGY INSTITUTE

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CERTIFICATE of ANALYSIS-R
(Industrial Technical Support Service)

Report no : 16563500-125.05- 64 / 3882-2
Report date : 22.06.2017
Applicant : ZEYİNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.
Address : YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA
Subject : SENSITIZATION TEST CARRIED OUT FOR 'SURGERY SET' IN THE SCOPE OF BIOCOMPATIBILITY TESTS

The results included in this report are related to only the sample analyzed.

Approved by

Assoc. Prof. Dr. Fatima YÜCEL
GMBE Industrial Services Officer

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Report no : 16563500-125.05- 64 / 3882-2
Applicant : ZEYİNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.
Address of Applicant : YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA

Sample : Standardized sample
Sample number : 3
Delivery type of sample : By Cargo
Situation in delivery time: It was provided in closed sterilization packets under sterile conditions.

Expiry date : 05/2022
Sample registration no at Institution : 17/35-GMBE
Acceptance date and hour 16.05.2017
Analysis date : 07.06.2017 – 21.06.2017

Witness sample information : () Return to customer (x) Witness sample is available () Witness sample was not taken

1- Samples:

The standardized 3 samples, defined as 'Surgery Set', were analyzed for sensitization tests upon the application of ZEYİNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ. dated 16/05/2017 and numbered 2669.

Table 1. The tested product.

Sample	Characteristics	Item
Sterile Surgical Drapes	The product is a set consisted of medical textile products in various sizes and forms used for various purposes during surgeries. 1- Drape (100x150cm) Production date: 05/2017, STERILE EO LOT 000001, Latex Free, Single Use Only	3

Descriptions:

Signatories:

53192

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Sample	Specifications	Item
Surgery Set		3

Table 1 (contd.). The tested product.

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2- Skin Sensitization Test

Sensitization test was carried out in accordance with 'ISO 10993-10: 2010 tests for irritation and delayed-type hypersensitivity' standard protocol.

The extract was provided by applying 6 cm²/ml surface area/volume rate in compliance with the form and structure of the product. For this purpose, the incubation for 72 hours at 37°C was applied. The sensitization test was carried out by using adult female subjects of guinea pig (*Cavia porcellus*) family weighted between 300-500 gr. As stated in the document titled ISO 10993-10:2010, the tests were carried out with 0,1 ml subcutaneous use of material to be tested. The topical application was made to the region to which subcutaneous injection (intradermal induction phase) is not applied as left region of the animal in the 7th day and right region of the animal in the 14th day of the test. The application plan administered on experimental animals is shown in Figure 1.

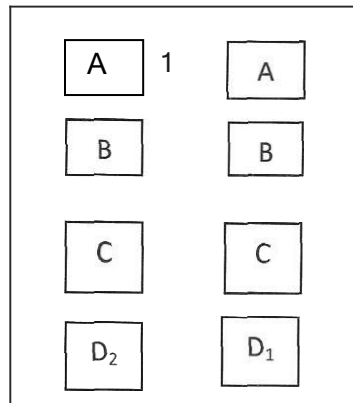


Figure 1.

1- Head of experimental animal.

A- The test regions treated by mixing Freund's Complete Anjuvant (FCA) and serum physiological solution at the rate of 50:50.

B- The test regions treated by using only the test material.

C- The test regions treated by mixing the sample applied in region A and the test material applied in region B at the rate of 50:50.

D- The test material was made as its topical application is 0.3 ml to the intracapsular region.

One pair of 0.1 ml injection was made to the left and right regions of the animal during the applications in A, B and C regions.

In the region D, it was applied to the left region (D₁) in the 7th day and the right topical region (D₂) in the 14th day.

Descriptions:

Signatories:

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Negative Control

Negative control was comparatively carried out in 2 different regions in 2 different applications (Figure 2).

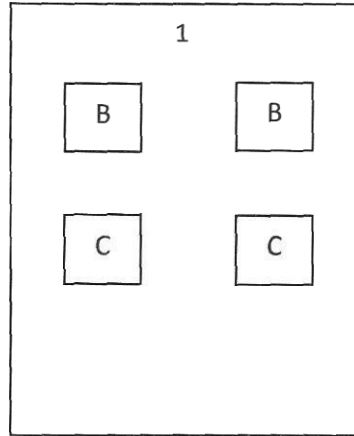


Figure 2.

1- Head of experimental animal.

B- Serum Physiological 0.1 ml.

C- Freund's Complete Anjuvant (FCA) and serum physiological solution at the rate of 50:50 was mixed and applied.

D-0.3 ml serum physiological was applied to the topical regions.

The test materials were applied to experimental animals as shown in Figure 2 one day after they were shaved to provide an application field and to control animals as shown in Figure 3. All applications were made as 0.1 ml to subcutaneous. The regions were not closed in anyway after application. In the topical application, the test material for experimental animals and 0.3 ml serum physiological for control animals were applied to the skin, the application regions were bandaged with gauze bandage and all application regions were wrapped with elastic bandage after application. The gauze bandages were contacted with the regions for 48 hours. At the end of application duration, the bandages were removed and the reactions on the skin were noted. The second topical application was carried out after 7 days and the same experimental processes were followed.

Descriptions:

Signatories:

53006



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Applied test material

10 animals were test material and 5 animals for control were used in the application. Total 15 animals were used in this test since there was only one test material.

Test Material: Surgical Drape

Reaction
No visible change
Clear or patched rash
Moderate or confluent rash
Intensive rash or pocks

Table 2. Evaluation criteria and scoring.

Evaluation Average

Samples	Result
Surgical Drape	0,4
Negative Control Application	0,4

Table 3. Average score values.

Result

As stated in the test carried out for test and control samples, the observations were scored by taking into account the evaluation and scoring criteria given in the Table 2. The rash was seen on the skin of animals in the group to which 'Surgical Drape' extract was applied as a result of evaluation. The sensitization score was found as 0.4 (Table 3) as a result of observations. A significant weight loss and visible negative effects in general health condition were not observed in experimental animals. According to the results obtained, it was determined that the material tested did not have any sensitive (sensitive to matter) effect according to the evaluation criteria and protocol stated in ISO 10993-10:2010 document.

Descriptions:

Signatories:

53006



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