

1. PRODUCT

STANDARD SURGICAL GOWN

2. 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

3. DESCRIPTION

Nonwoven , 3 layers SMS 35 gsm, Velcro at the Neck, two ties , Elastic Cuff
Antiallergenic, AirPermeable, Non-Linting
Water Repellent , latex free

4. PACKING

The product is individually 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.

5. STORAGE

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

6. Validity

Sterile. 3 years from the date of production

Size	Length (cm)
S (SMALL)	115-120
M (MEDIUM)	120-127
L (LARGE)	127-135
XL (XLARGE)	135-142
2XL (XXLARGE)	142-152

[illegible]

1. PRODUCT

FULL REINFORCED SURGICAL GOWN

2. 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

3. DESCRIPTION

Nonwoven , 3 layers SMS 35 gsm, 3 gsm medical glue, 15 gsm white lamination, full reinforced on front and sleeves
Velcro at the Neck, two ties , Elastic Cuff
Antiallergenic, AirPermeable, Non-Linting
Water Repellent , latex free

4. PACKING

The product is individually 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.

5. STORAGE

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

6. Term of validity

Sterile. 3 years from the date of production

Size	Length (cm)
S (SMALL)	115-120
M (MEDIUM)	120-127
L (LARGE)	127-135
XL (XLARGE)	135-142
2XL (XXLARGE)	142-152





Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Prodicatorul	Reprezentant	Ordin	Data	Cod vamal
DM000359000	CEARSAF MEDICAL STERIL			101-001S	Turcia	ZEYNI MEDIKAL TEKSTIL INSAAT SAN. VE TIC. LTD. STI	BIO ANALITICA S.R.L.	Rg04-000155	30-06-2022	

✓ [Сопрежм\(Prodicatorul\) „zeyni”](#)

Очистить



***“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.

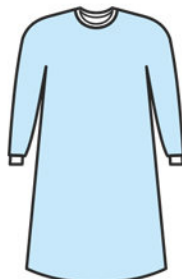
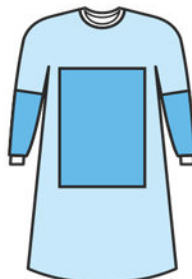
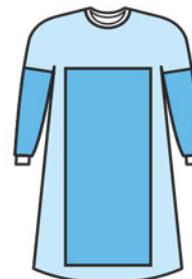
Örtü setlerini sterilizasyon prosesi süresince korumayı sağlar, ayrıca hijyen ve sıkı bir paketlenme sağlar.



STERILE PRODUCTS	STERİL ÜRÜNLER	PAGE SAYFA
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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



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ISO 9001:2015

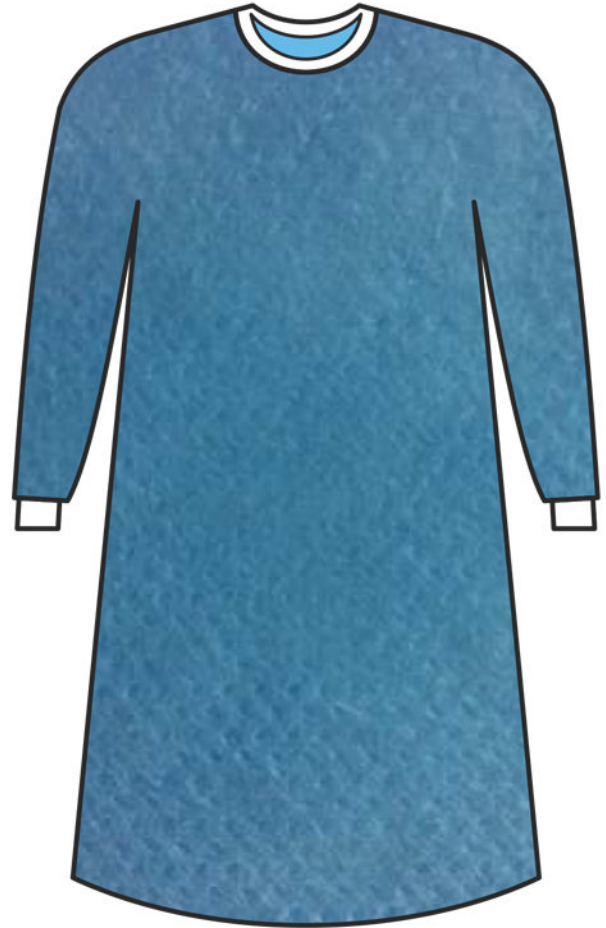


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SURGICAL GOWN COMFORT

- 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

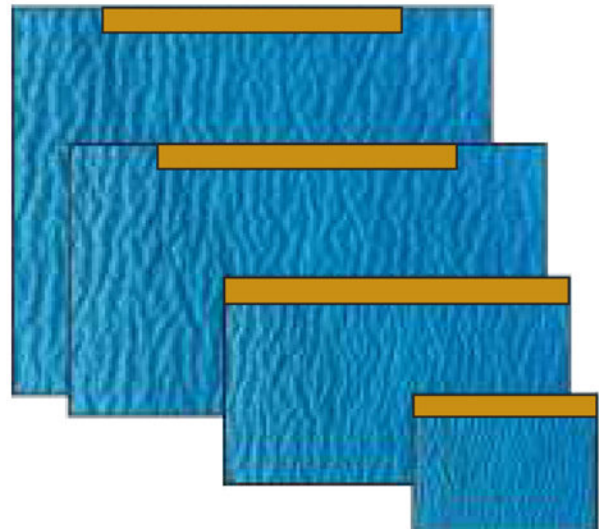
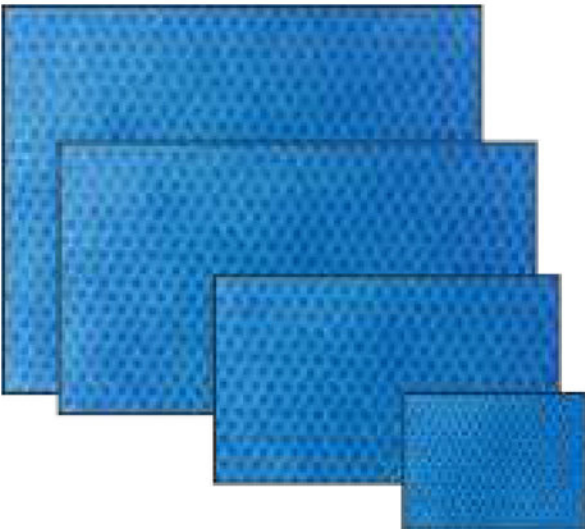


Plain Drapes

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

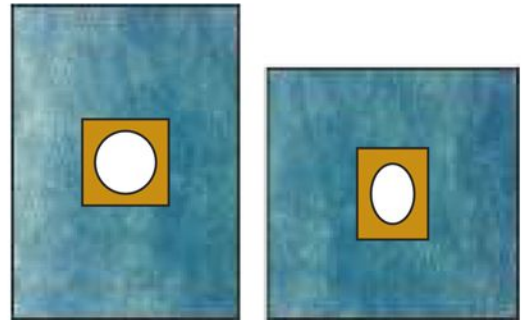
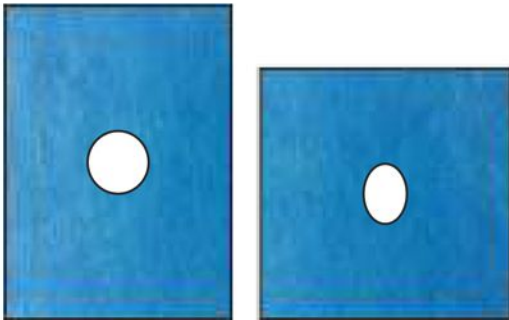


STERILE SURGICAL DRAPES / STERİL CERRAHİ ÖRTÜLER
Fenestrated Drapes

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

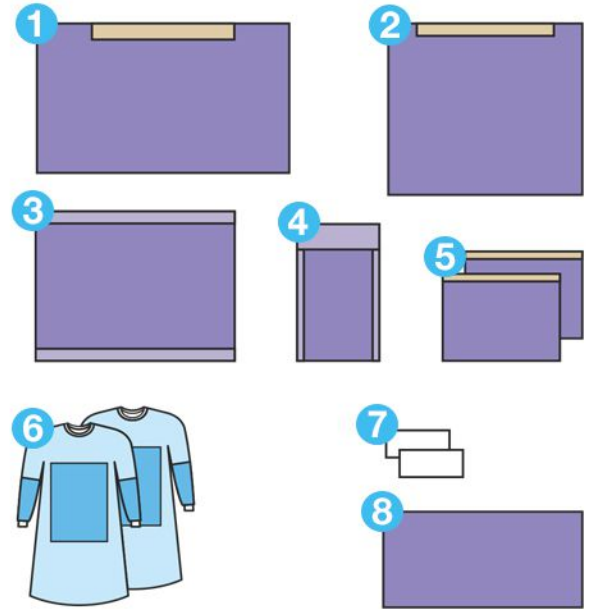
Fenestrated Drapes with Adhesive Tape

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

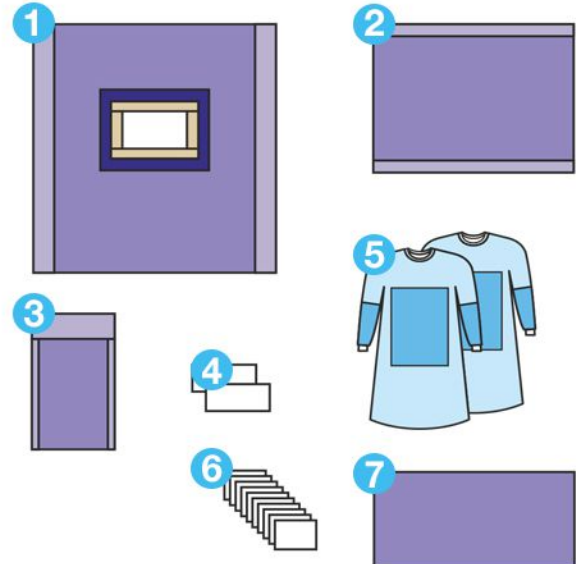


"Hygiene for health, Disposable Sterile Products for hygiene"**GENERAL SURGERY PACK / GENEL CERRAHİ ÖRTÜ SETİ**

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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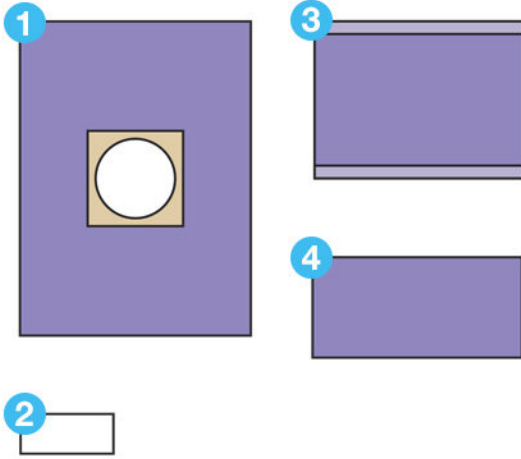
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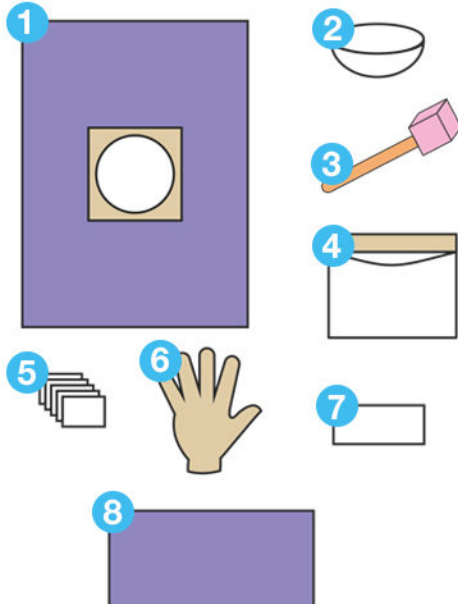
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MINOR SURGERY PACK / MİNÖR CERRAHİ SETİ



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



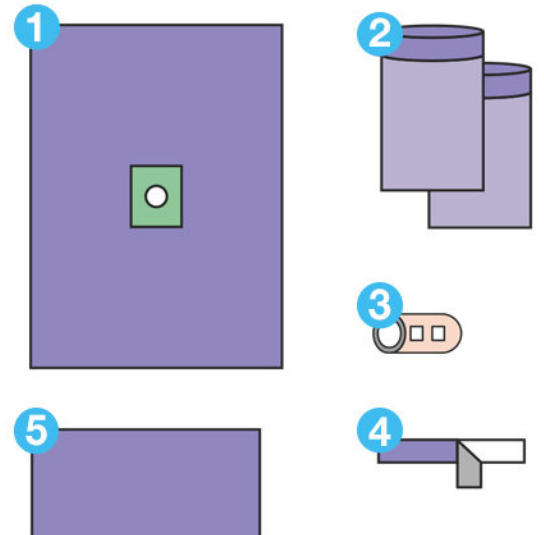
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Fenestrated Drape with Adhesive Tape/Yapışkan Bantlı Delikli Örtü	60x60	1 Pc.
2. 250 cc Solution Cup / Solüsyon Kabi		1 Pc.
3. Betadine Sponge / Boyama Sünger		1 Pc.
4. Universal Bag / Universal Torba	30x35	1 Pc.
5. Sponge / Spanç	7.5x7.5	5 Pc.
6. Gloves /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

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ISO 9001:2015**CE**1023**"Hygiene for health, Disposable Sterile Products for hygiene"****ARTHROSCOPY PACK / ARTROSKOPİ ÖRTÜ SETİ**

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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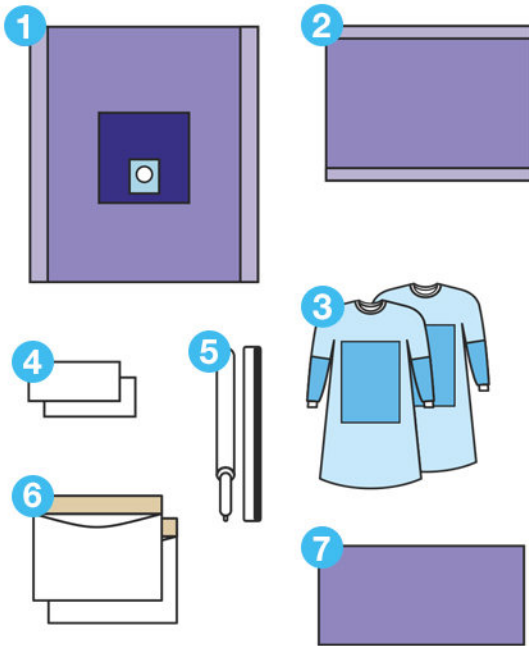
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ISO 9001:2015



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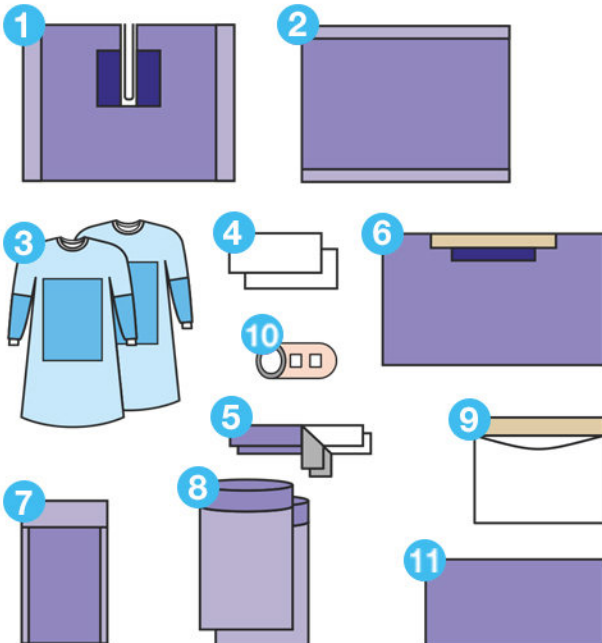
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EXTREMITY PACK / EKSTREMİTE ÖRTÜ SETİ



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.

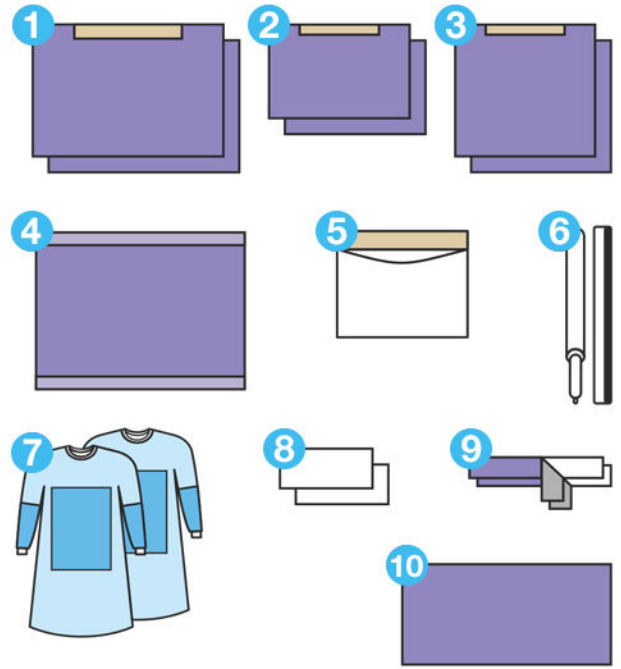
13 HIP PACK / KALÇA ÖRTÜ SETİ



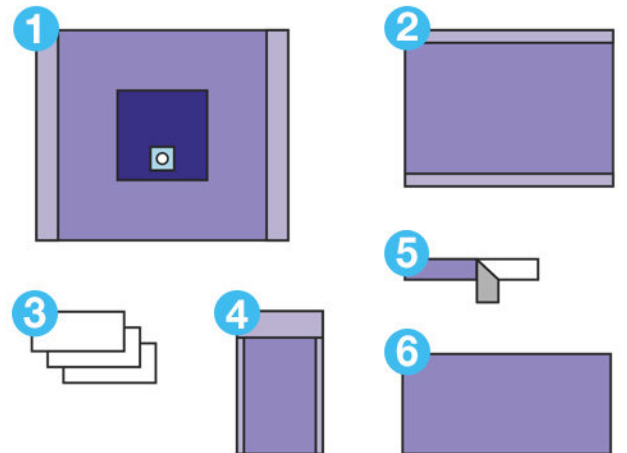
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Drape with U Aperture / U Yankılı Örtü	200x240	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü XL	150x200	1 Pc.
3. Reinforced Surgical Gown / Korumalı Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Nonwoven Op-Tape / Nonwoven Yapışkan Bant	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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ISO 13485:2016**UNICERT**
ISO 9001:2015**CE**1023**"Hygiene for health, Disposable Sterile Products for hygiene"****VERTEBRA PACK / VERTEBRA ÖRTÜ SETİ**

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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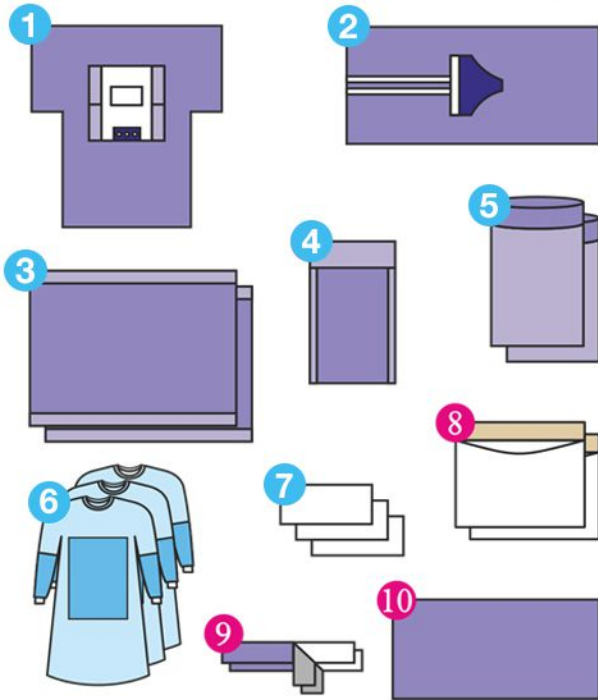
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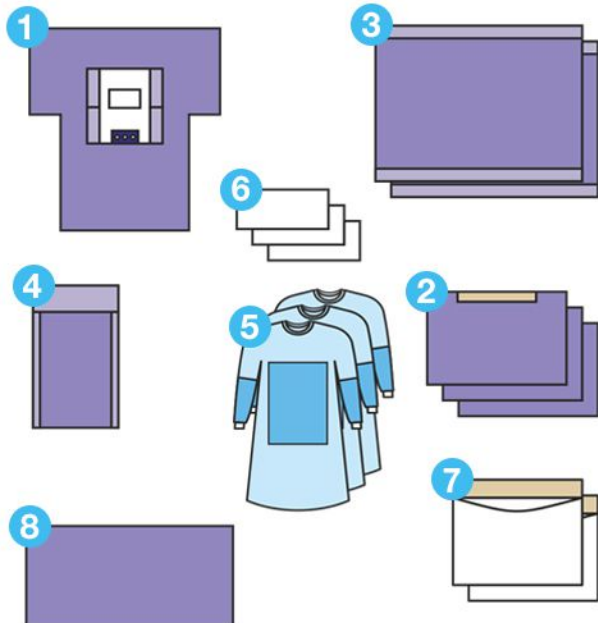
"Hygiene for health, Disposable Sterile Products for hygiene"

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.

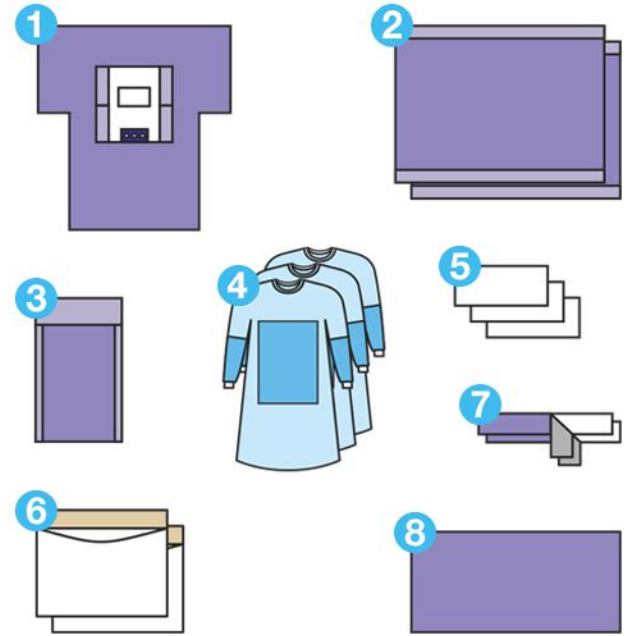
15 CARDIOVASCULAR PACK / KARDİOVASKÜLER ÖRTÜ SETİ



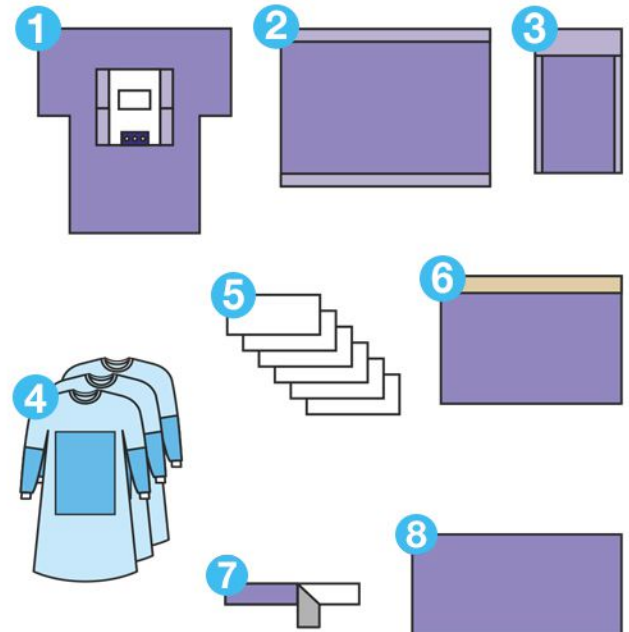
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. C.V.C Drape / K.V.C Örtüsü	200x300	1 Pc.
2. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	75x90	3 Pc.
3. Back Table Cover / Alet Masa Örtüsü	150x200	2 Pc.
4. Mayo Stand Cover / Mayo Masa Örtüsü XXL	78x145	1 Pc.
5. Reinforced Surgical Gown / Korumalı Cerrahi 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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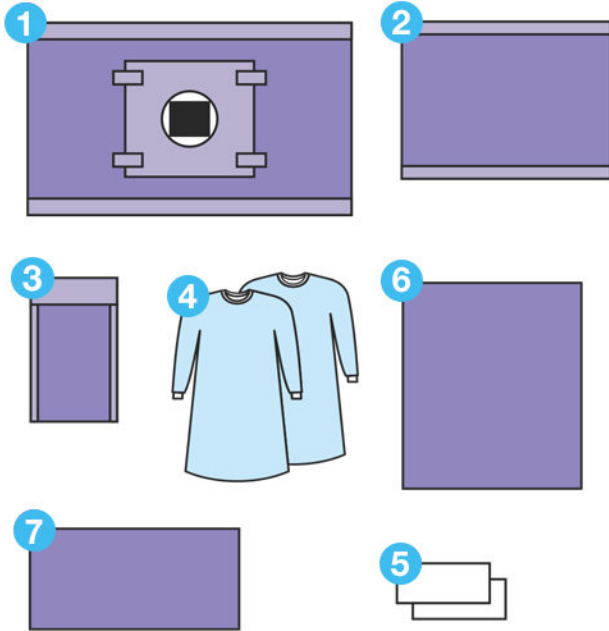
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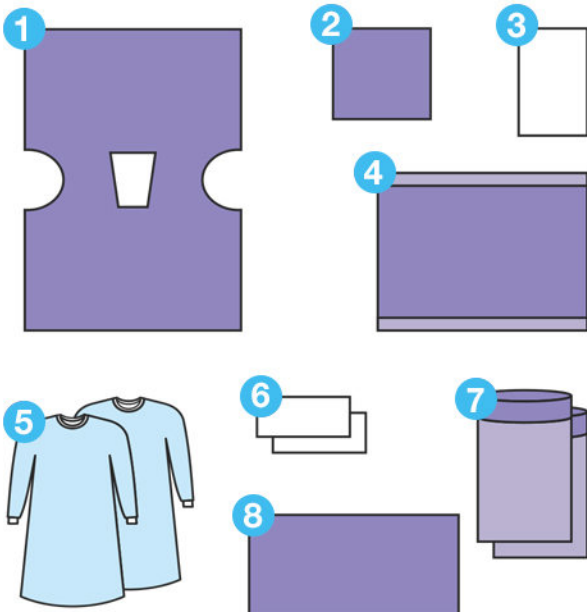
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CAESAREAN SECTION PACK / SEZERYAN ÖRTÜ SETİ



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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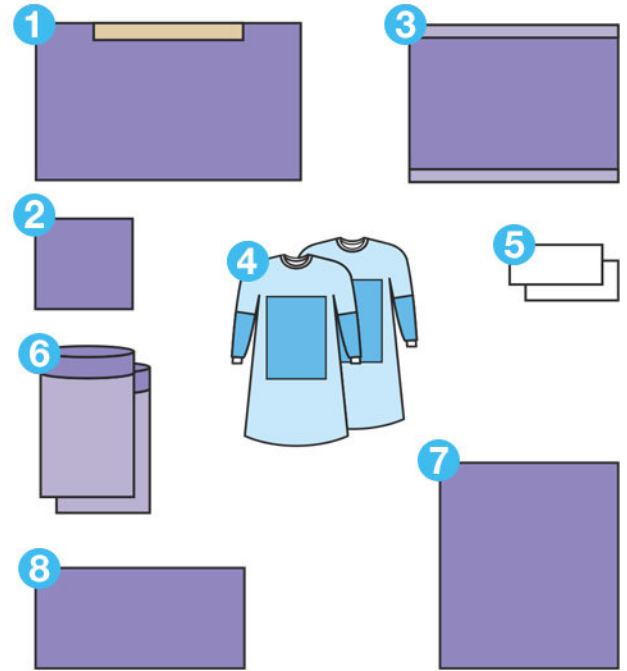


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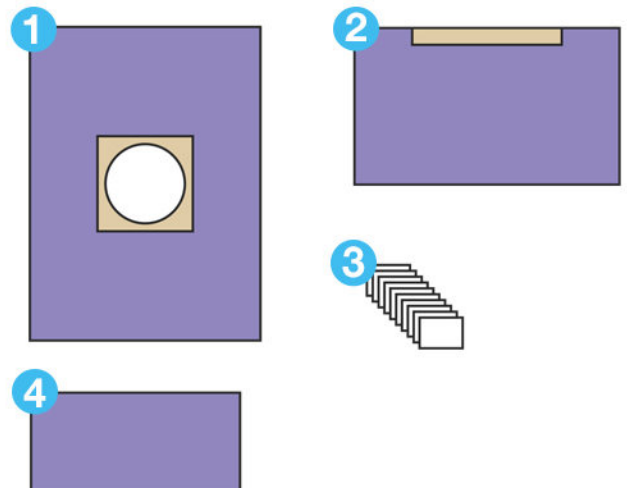
DELIVERY DRAPE PACK / DOĞUM ÖRTÜ SETİ

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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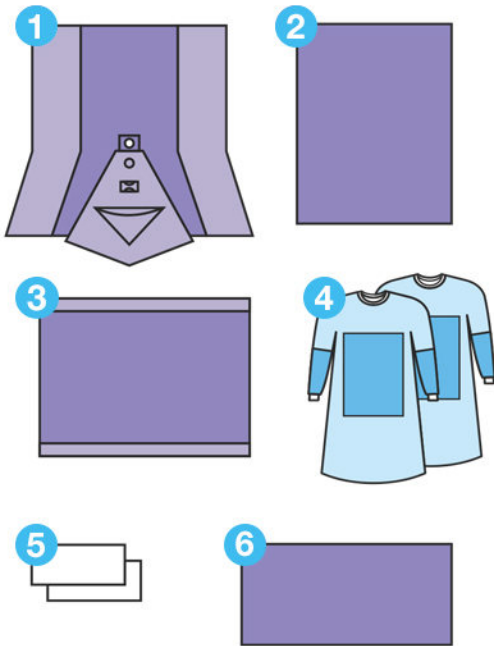
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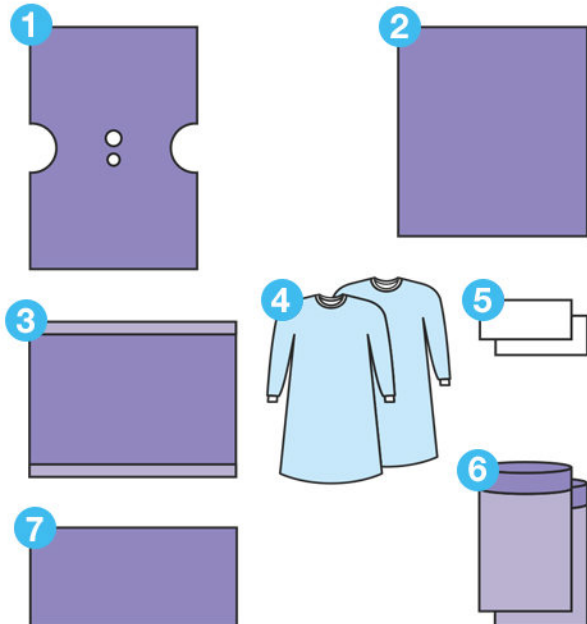
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T.U.R DRAPE PACK / T.U.R ÖRTÜ SETİ



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.

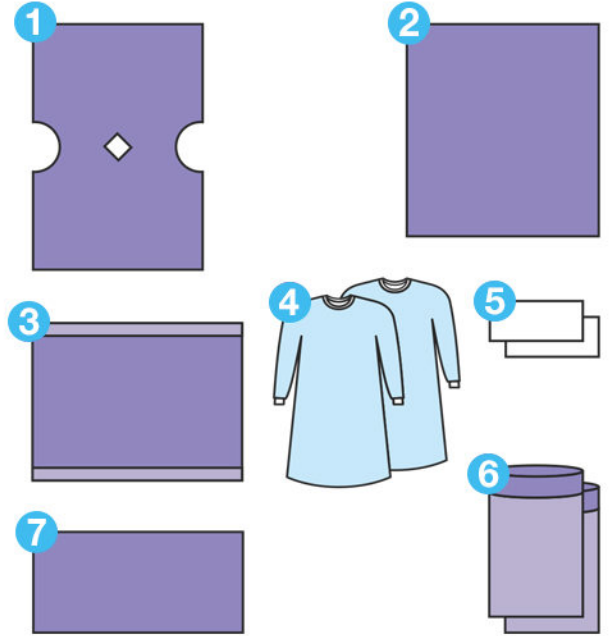
19 UROLOGY DRAPE PACK / ÜROLOJİ ÖRTÜ SETİ



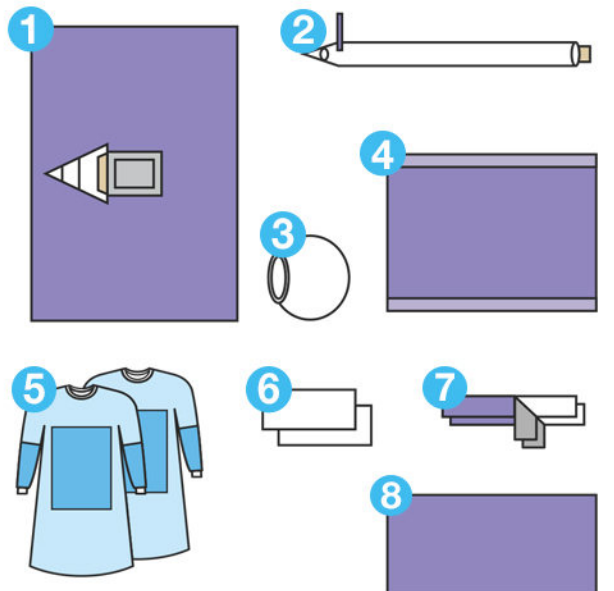
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Urology Drape / Üroloji Örtüsü	100x150	1 Pc.
2. Plain Drape / Düz Örtü	100x120	1 Pc.
3. Back Table Cover Standart / Alet Masa Örtüsü	150x200	1 Pc.
4. Surgical Gown XL / Standart Cerrahi Önlük XL		2 Pc.
5. Medical Towel / Medikal Havlu	40x40	2 Pc.
6. Leg Cover / 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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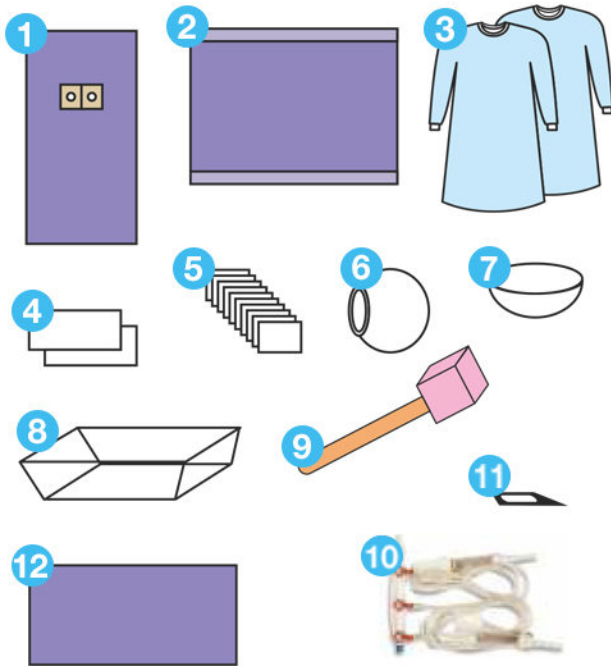
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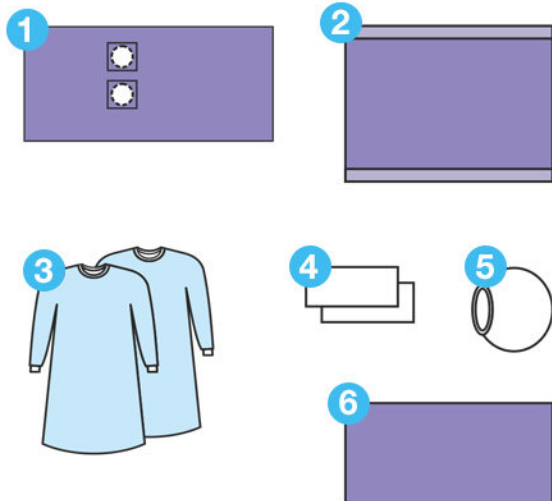
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ANGIOGRAPHY PACK / ANJİOGRAFİ ÖRTÜ SETİ -I-



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.

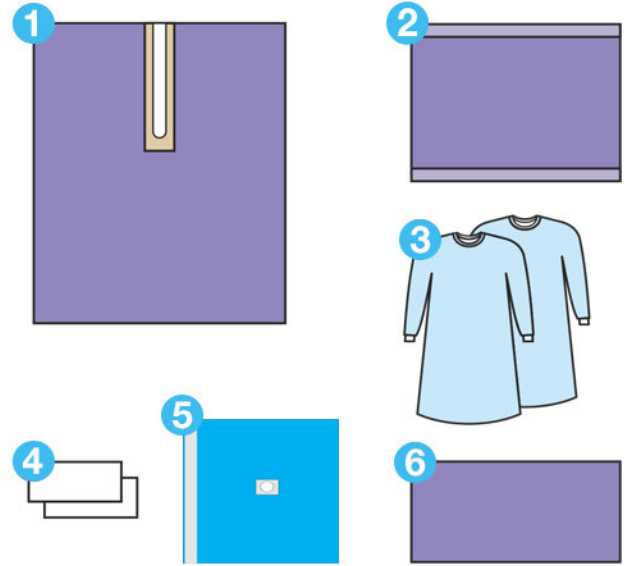
21 ANGIOGRAPHY PACK / ANJİOGRAFİ ÖRTÜ SETİ -II-



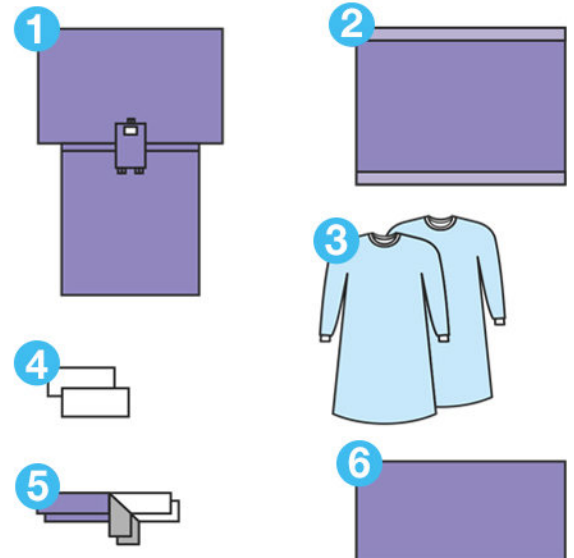
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Angiography Drape / Anjio Örtüsü	150x300	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü XL	100x150	1 Pc.
3. Standard Surgical Gown / Standart Cerrahi Önlük		2 Pc.
4. Medical Towel / Medikal Havlu	40x40	2 Pc.
5. Fluoroscopy Cover 86cm / Fluoroscopi Kılıfı 86cm		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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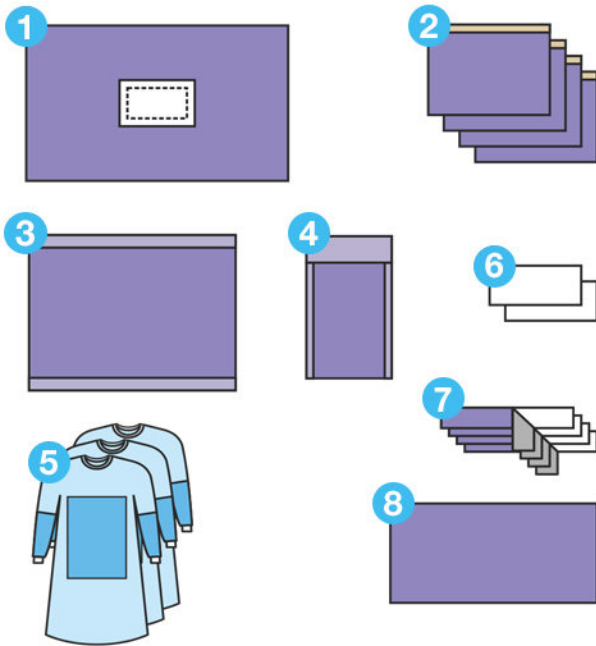
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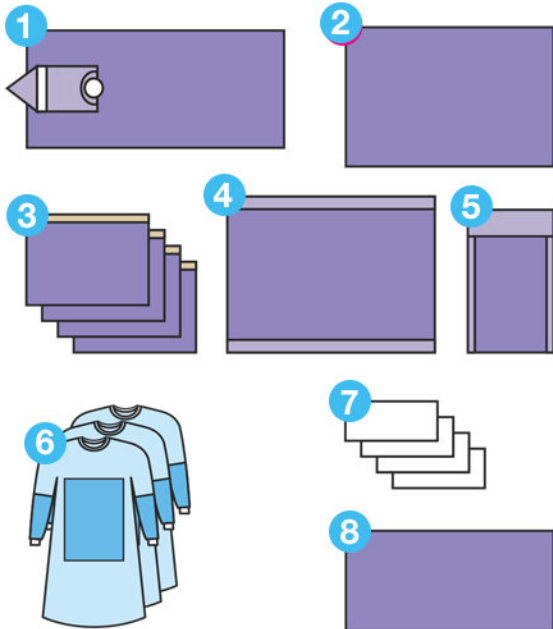
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SPINAL (LAMINECTOMY) PACK / SPİNAL (LAMİNEKTOMİ) ÖRTÜ SETİ



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.

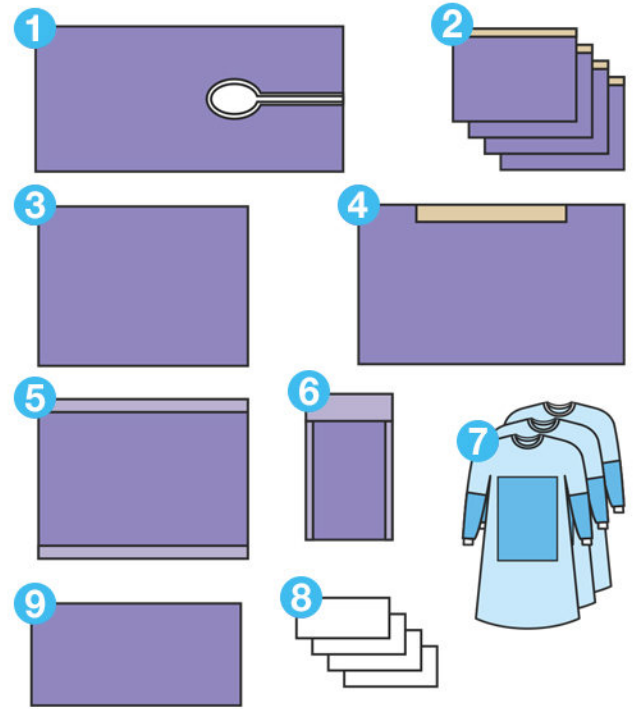
23 CRANIOTOMY PACK / KRANIOTOMİ ÖRTÜ SETİ



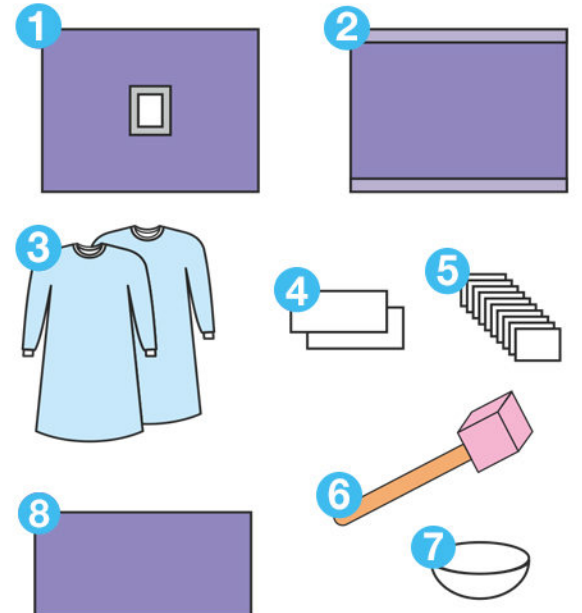
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Craniotomy Drape / Kraniotomi Örtüsü	220x350	1 Pc.
2. Plain Drape / Düz Örtü	150x250	1 Pc.
3. Drape with Adhesive Tape / Yapışkan Bantlı Örtü	100x100	4 Pc.
4. Back Table Cover / Alet Masa Örtüsü	150x200	1 Pc.
5. Mayo Stand Cover / Mayo Masa Örtüsü	78x145	1 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.

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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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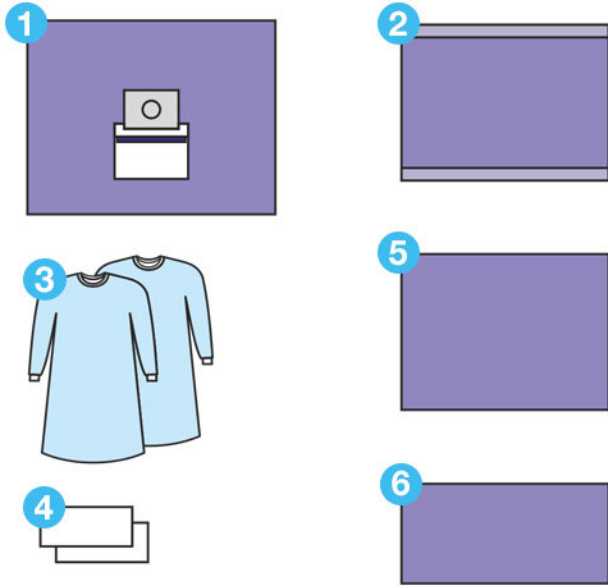
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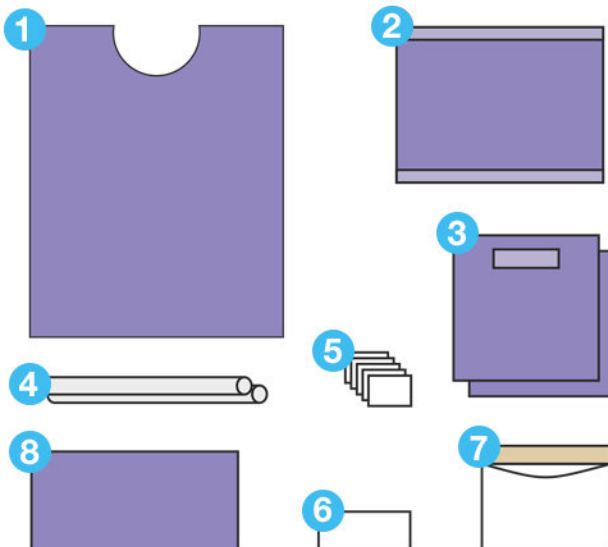
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OPHTHALMIC DRAPE PACK / GÖZ ÖRTÜ SETİ



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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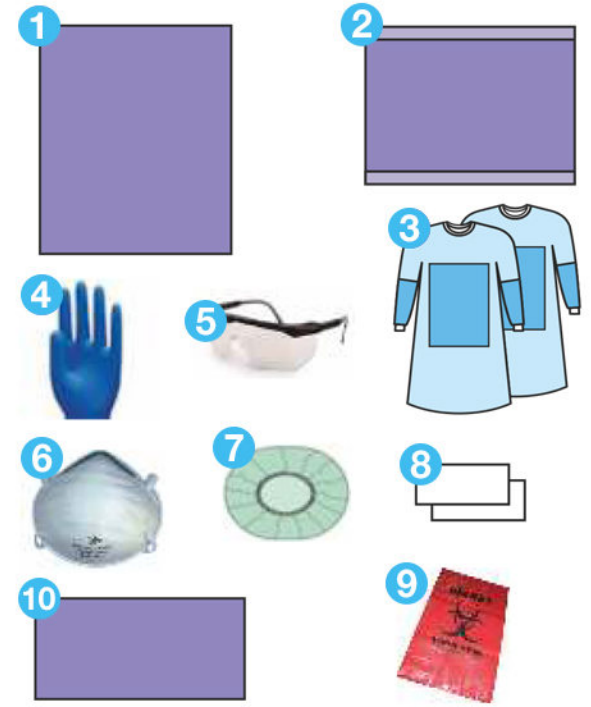


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"Hygiene for health, Disposable Sterile Products for hygiene"

CHEMOTHERAPY PACK / KEMOTERAPİ ÖRTÜ SETİ

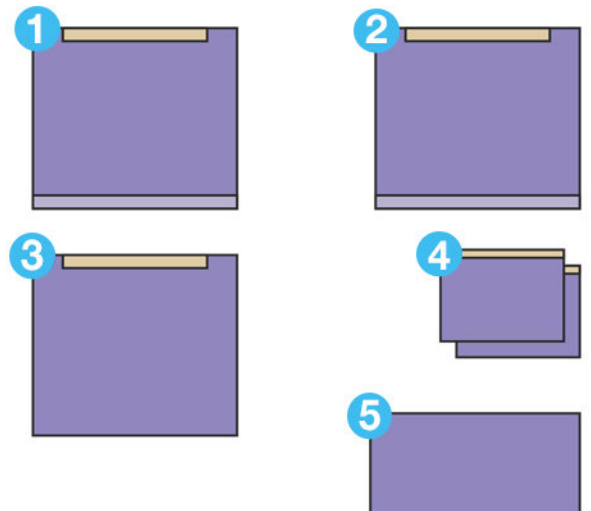
Product Name Ürün Adı	Size Ebat	Pcs. Adet
1. Chemotherapy Drape / Kemoterapi Örtüsü	50x70	1 Pc.
2. Back Table Cover / Alet Masa Örtüsü	50x100	1 Pc.
3. Chemotherapy Gown / Kemoterapi Önlüğü		1 Pc.
4. Chemotherapy Gloves / Kemoterapi Eldiveni		1 Pair/Çift
5. Protective Glasses / Koruyucu Gözlük		1 Pc.
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



UNICERT
ISO 13485:2016



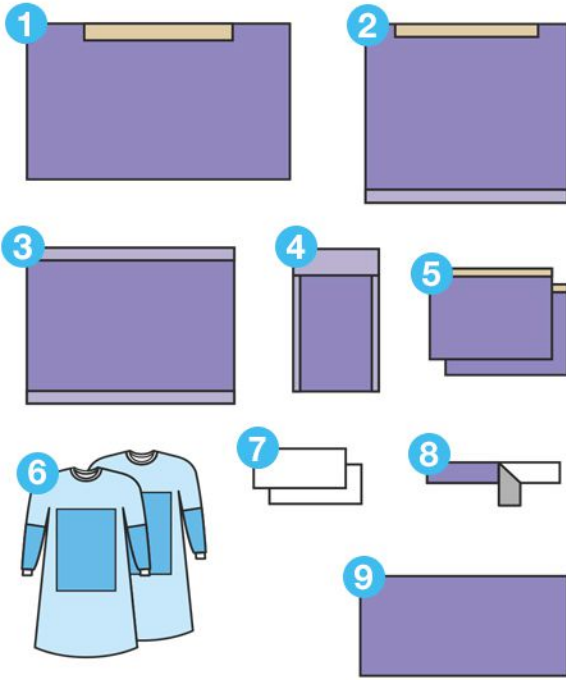
UNICERT
ISO 9001:2015



CE 1023

"Hygiene for health, Disposable Sterile Products for hygiene"

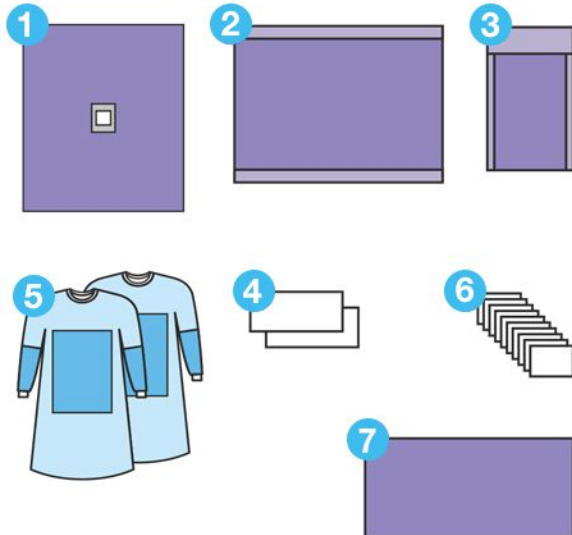
PEDIATRIC UNIVERSAL PACK / PEDIATRİK GENEL CERRAHİ SETİ



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*

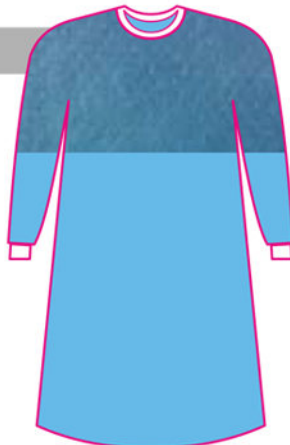
Patient Gown (Long Sleeve)	M
	L
	XL
	XXL

*Short Sleeve Patient Gown*

Patient Gown (Short Sleeve)	M
	L
	XL
	XXL

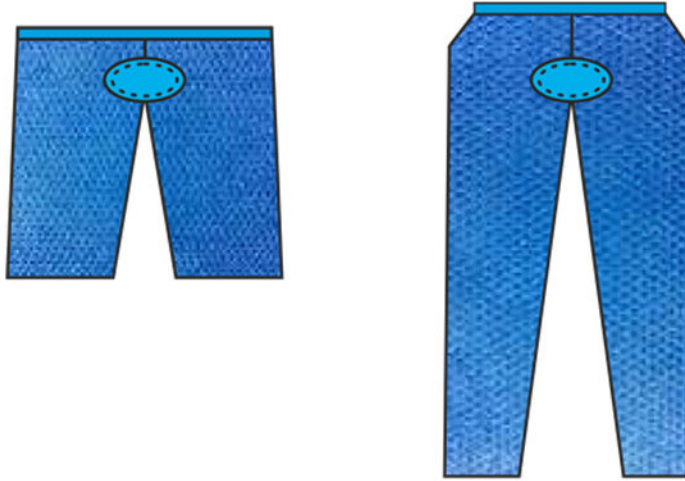
Chemotherapy Gown

Chemotherapy Gown	M
	L
	XL
	XXL

Urology Gown

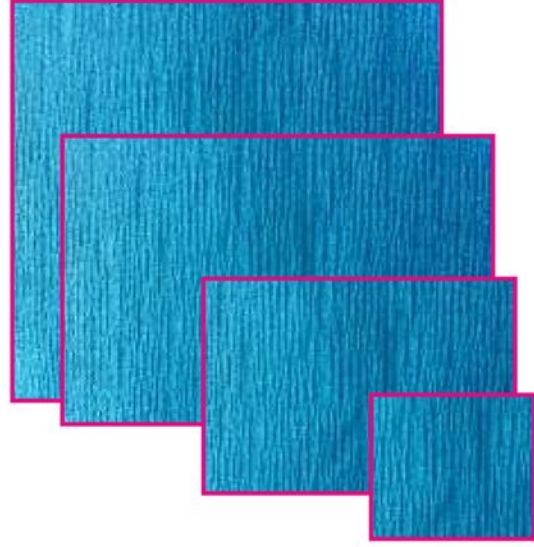
Urology Gown	M
	L
	XL
	XXL

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

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





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



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 9001:2015

Certificate No : QMS 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)



Deutsche
Akkreditierungsstelle
D-ZM-16058-01-00

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



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

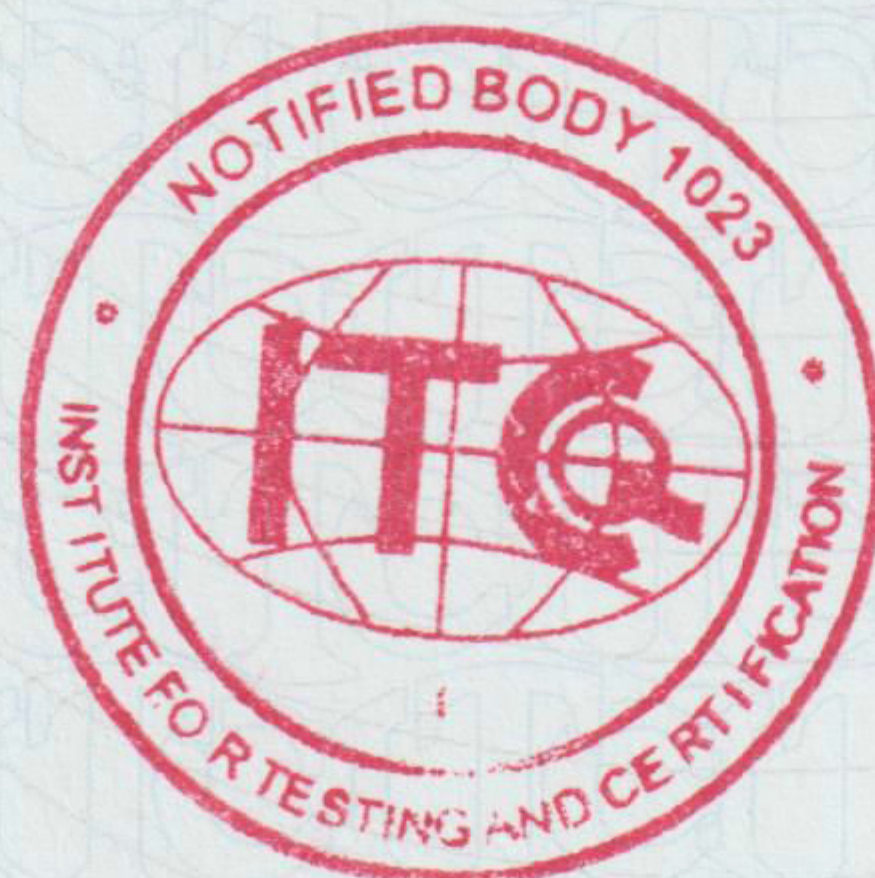
The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects 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

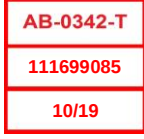
First Issued: 2009-11-26

Revision: f



Date: 2020-06-23

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



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

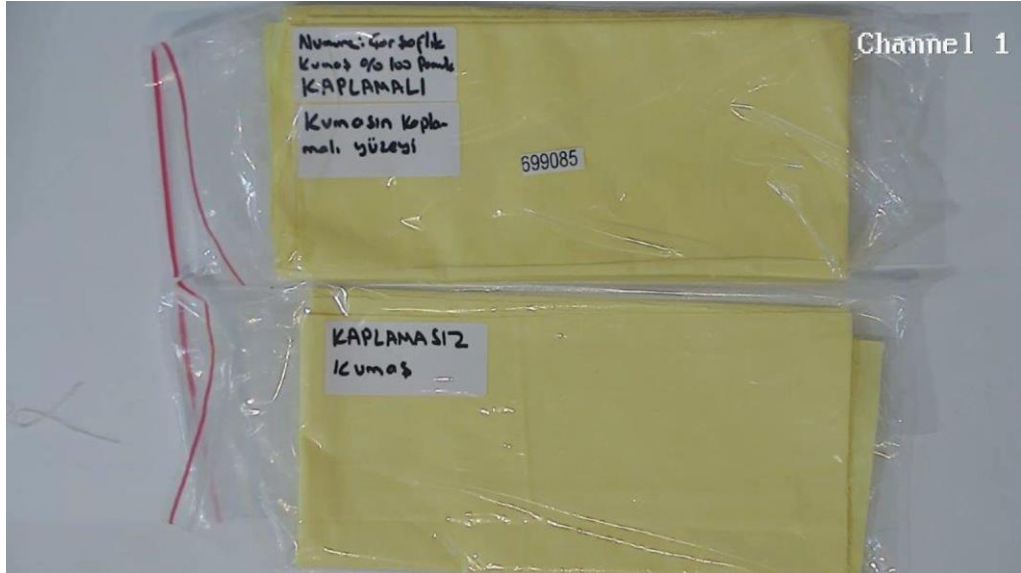
Tomris Hasançebi / Customer
Relations Manager

Abdullah Akil / Physical
Laboratory Manager

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:

Page 4 of 6

TEST PROPERTY

M001

M002

Hydrostatic Pressure Test

#

#



TÜVRheinland®

Precisely Right.

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



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

CERTIFICATE OF COMPLIANCE



REPORT NUMBER
Rapor Numarası

SA2-5076

STANDARD(S)
Standardlar

93/42/EEC

DATE OF REPORT
Rapor Tarihi

23.03.2022

AUDIT REPORT
DENETİM RAPORU

Zeyni Medikal Tekstil İnş. San. Ve Tic. Ltd. Şti.
ORGANIZATION'S NAME IN FULL (BLOCK CAPITALS)

Kuruluşun Tam Adı (Büyük Harflerle)

Bursa

TOWN/Şehir

TURKEY

COUNTRY/Ülke

16

TOTAL NUMBER OF EMPLOYEES COVERED BY SYSTEM
Sistem İçinde Yer Alan Toplam Çalışan Sayısı

SITE VISITED IF A MULTI-SITE LOCATION(S)
Çok İşletmeli Kuruluş ise Ziyaret Edilen Yerler

Manufacture And Sale Of Sterile Disposable Gowns And Drapes

SCOPE/Kapsam

The contents of this report are confidential to the organization as detailed above and to UNIVERSAL. Distribution of this report in whole, or in part, to any person other than employees of the organization or UNIVERSAL must be agreed in writing prior to circulation (with the exception of the regulators, such as DAKKS).

Bu raporun içeriği, aşağıda açıklandığı gibi, kuruluşun kendisi ve UNIVERSAL dışında gizlidir. Bu raporun tamamı veya bir kısmının kuruluşun çalışanları veya UNIVERSAL dışında çoğaltılması ve dağıtılması, dağıtımdan önce yazılı mutabakat ile mümkündür(DAKKS gibi kurumlar hariç).

The Non-Compliance points contained within this report are the result of limited sampling and it can not, therefore, be assumed others do not exist.

Bu raporda yer alan uygunsuzluklar, örnekleme usulü yapılan çalışma sonucunu yansıtır ve bu sebeple başka uygunsuzluk olmadığı anlamını taşımaz.

Baris AVCI

LEAD AUDITOR

Başdenetçi

REPORT NUMBER
Rapor Numarası

SA2-5076

STANDARD(S)
Standardlar

93/42/EEC

DATE OF REPORT
Rapor Tarihi

23.03.2022

Date of Audit(s) Denetim Tarih(ler)i	23.03.2022		
Audit Team Denetim Ekibi	Name Adı	Man-Days Adam-Gün	
Lead Auditor Başdenetçi	Baris AVCI	1 man/day	
Auditor Denetçi			
Technical Expert Teknik Uzman			
Total Man-days for Audit Denetim İçin Toplam Adam –Gün Sayısı		1,0 man/day	

REPORT SUMMARY
Rapor Özeti

Management responsibility
Yönetimin sorumluluğu

Quality Manual KEK-00 Rev Date: 18.01.2022, Revision No: 02 (for No. 090816 QS/NB documentation has issued)
Management Review meeting according to 93/42/EEC requirements has been performed constinously.

Policy, objective(s)/target (s)
Politika, amaç / hedefler

Quality Manual KEK-00 Rev Date: 18.01.2022, Revision No: 02
2021-2022 Quality objectives of the firm has been determined as measurably.
Targets of the company has been following by process responsables and QMR.

Accordance to regulatory requirements
Yasal şartlara uyum

The company is following the legal requirements updates strictly by General Manager and by process responsables.

Responsibilities and employee's competence
Sorumluluklar ve personelin yeterliliği

Quality Manual KEK-00 Rev Date: 18.01.2022, Revision No: 02
Organizational Manual OEK- Job descriptions Rev date 19.02.2022, Rev 02 (according to ISO 13485:2016 requirements responsibilities have been issued)
Organizational chart Rev.Date./No :30.12.2021/02 Doc No : ŞM. 01have been issued at 18.05.2021.
On organizational chart Top Management, Quality Management, Sale and Marketing, Human Resources, Purchasing departments have been showned.
Mehmet İŞMAN is appointed for Quality Department and same working on Quality Management responsibility.

Complaints and suggestions of interested parties, incidents:
İlgili Tarafların Şikayet ve Tavsiyeleri

NA

REPORT NUMBER
Rapor Numarası

SA2-5076

STANDARD(S)
Standartlar

93/42/EEC

DATE OF REPORT
Rapor Tarihi

23.03.2022

Design and Development
Tasarım ve Geliştirme

NA

Risk Management, Risk Analysis
Risk Yönetimi, Risk Analizi

NA

Purchasing
Satın alma

NA

Labels and Instruction For Use
Etiketleme ve Kullanım Kılavuzu

NA

Operational control of processes
Proseslerin operasyonel kontrolü

NA

Findings of the conducted Internal Audits and Management Review
İç denetimler ve yönetimin gözden geçirmesine ait bulgular

NA

REPORT NUMBER
Rapor Numarası

SA2-5076

STANDARD(S)
Standardlar

93/42/EEC

DATE OF REPORT
Rapor Tarihi

23.03.2022

Product Conformity Assessment Information

Ürün Uygunluk Değerlendirme Bilgisi

NA

Site and clauses requested to be audited in the next audit

NA

Observations (Positive and developable matters)

Gözlemler (Olumlu ve geliştirilebilecek hususlar)

NA

1.	Have all mandatory clauses been audited (✓) as appropriate Y ☐ N ☐ If NO, state why in the summary above Mecburi olan bütün maddeler denetlendi mi? E ☒ Cevap H ise yukarıda yer alan özetle sebebini belirtiniz.
2.	If YES, but audit was not satisfactory for these clauses, state why in the summary above Cevabınız evet ise, ancak denetimde bu maddelerle ilgili uygunsuzluk bulunmuşsa, yukarıda yer alan özetle sebebini belirtiniz.
3.	Have all NC points raised from previous visits been effectively closed (✓) as appropriate Y ☐ N ☐ Daha önceki denetimde belirtilen uygunsuzluklar, başarılı şekilde kapatılmış mı? E ☒
4.	If NO, state why in the summary above Eğer cevap hayır ise yukarıda yer alan özetle sebebini belirtiniz.

RECOMMENDATION (PLEASE TICK ONE)

Tavsiye (Lütfen Uygun Olanı İşaretleyiniz)

Proceed To Extending Certificate Belge Düzenlenmesi ve Uzatılması	☒	Proceed To Follow Up Audit Takip Denetimi	☐
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Note: 1) When more than one standard is being audited at the same time, the standard must be shown against each item number.

Not: 1) Aynı anda birden fazla standard denetlenecekse, her maddenin karşısına standard adı belirtilmelidir.

Barış AVCI

LEAD AUDITOR

Başdenetçi