

DECLARATION OF CONFORMITY

Section No	TD-06/5.2-1-En
Rev Date	29.12.2021
Rev. No	01
Page No	1/1

Company Name : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A.Ş.
 Address : Orhangazi mah. 1673. Sok No:20 Esenyurt İstanbul
 Tel : +90 212 320 37 53
 Fax : +90 212 320 53 51
 Web : www.submed.com.tr
 E-mail : info@submed.com.tr

L.279

Product Name	Reference No	GMDN Code	Class and Rule
ANGIOGRAPHY SURGERY PACK	ASP-001-4	33961	Class 2a Rule 6

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

We herewith declare on our own responsibility that the above mentioned meet the provisions of the Council Directive 93/42/EEC with amended directive 2007/47/EC for Medical Device Directive.

Notified Body : KIWA Belgelendirme Hizmetleri A.Ş.
 NB Address : İTOSB 9. Cad. No :15 Tepeören, Tuzla - İstanbul TÜRKİYE
 NB Identification Number : 1984
 EC Certificate Number : 1984-MDD-14-266
 Expiry Date : 27 May 2024

Signature, Stamp

City Date : İstanbul, 29.12.2021
 Name : Yusuf Yiğit Akkuş
 Position : General Manager

SU BİYOMEDİKAL SİSTEMLER VE
 SAĞLIK HİZMETLERİ SANAYİ VE TİCARET A.Ş.
 Orhangazi Mah. 1673 Sk. No:20 Esenyurt / İSTANBUL
 Tel: 0212 320 37 53 Faks: 0212 320 53 51
 Yenikapı V.D.: 7810897506 Tic.Sic. No: 749756-0

Ürün Grubu / Product Group

Cerrahi Setler
Surgical Sets

Ürün Adı / Product Name

Anjiyografi Cerrahi Seti
Diagnostic Interventions Pack

Referans No / Reference No

ASP-001-4

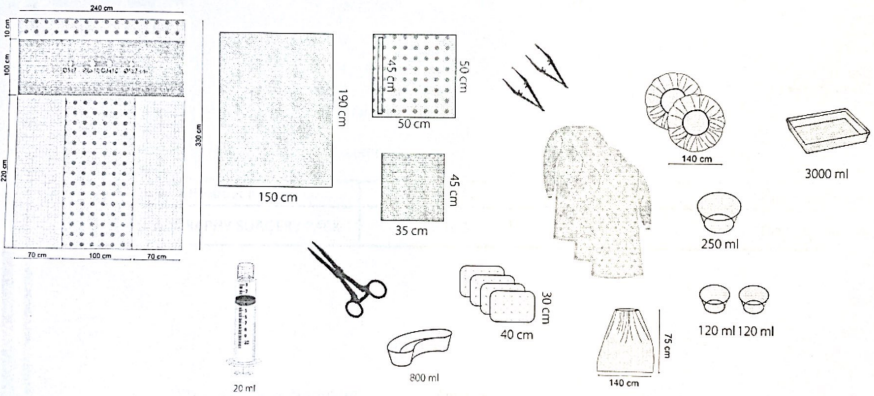
1. Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

L. 242

Ürün Teknik Çizimi

Product Technical Drawing



Ürün Malzeme Bilgileri

Product Material Information

1x Anjiyografi Örtüsü - Angiography Drape	240x330 cm
1x Emici Örtü - Absorbant Drape	35x45 cm 500ml/m ² liquid proof
1x Yan Bantlı Örtü - Adhesive Drape	50x50 cm
1x Alet Masa Örtüsü - Table Cover	150x190 cm
4x El Havlusu - Hand Towel	30x40 cm
3x Standart Cerrahi Önlük - Standard Surgical Gown	XL
1x Tepsi - Tray	3000 ml
1x LL, Şiringa - Syringe, LL	20 ml
2x Skopi Kılıfı - Scopy Cover	ø140 cm
1x C Skopi Kılıfı - C-Arm Scopy Cover	ø75 cm
2x Plastik Kap - Bowl	120 ml
1x Plastik Kap - Bowl	250 ml
1x Böbrek Kabı - Kidney Bowl	800 ml
1x Plastik Forseps - Plastic Forceps	15 cm
2x Plastik Cımbız - Plastic Tweezers	10 cm

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Page No	1/1

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L.273

Product Name	Reference No	GMDN Code	Class and Rule
ANGIOGRAPHY SURGERY PACK	ASP-001-3	33961	Class 2a Rule 6

Conformity Assessment Procedure : Annex V
Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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City Date : İstanbul, 29.12.2021
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Position : General Manager

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Product Name	Reference No	GMDN Code	Class and Rule
CARDIOVASCULAR SURGERY PACK	CVKP-001	33961	Class 1s Rule 4
CARDIOVASCULAR SURGERY PACK	CVKP-002	33961	Class 1s Rule 4
CARDIOVASCULAR SURGERY PACK	CVKP-003	33961	Class 1s Rule 4

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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Ürün Grubu / Product Group

Cerrahi Setler
Surgical Sets

Ürün Adı / Product Name

Kardiyovasküler Cerrahi Seti
Cardiovascular Surgery Pack

Referans No / Reference No

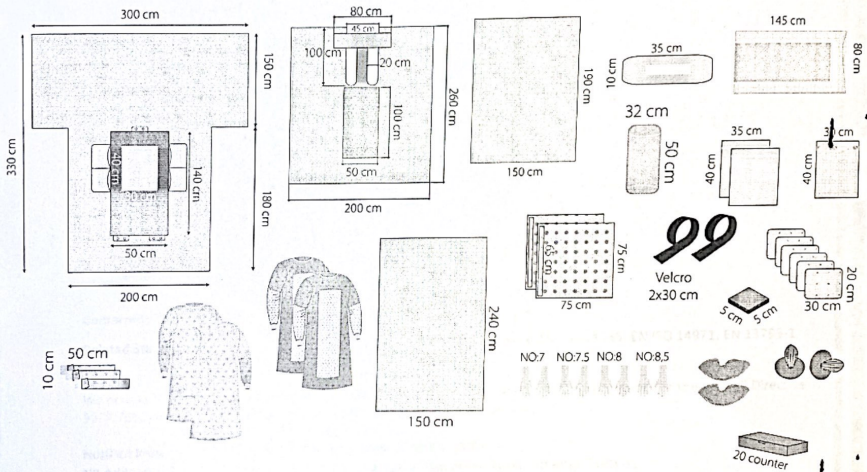
CVKP-002

Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

Ürün Teknik Çizimi

Product Technical Drawing



Ürün Malzeme Bilgileri

Product Material Information

1x Mayo Masa Örtüsü - Mayo Stand Cover	80x145 cm	2x Atık Torbası - Waste Bag	35x40 cm
6x El Havlusu - Hand Towel	20x30 cm	3x OP Tape	10x50 cm
1x Alet Masa Örtüsü - Table Cover	150x190 cm	2x Standart Cerrahi Önlük - Standrad Surgical Gown	XXL
1x PE Torba - Universal PE Bag	30x40 cm	2x Takviyeli Cerrahi Önlük - Reinforced Surgical Gown	XXL
1x Kol Kılıfı - Sleeve Cover	Length : 50 cm	2x Tutamaç Kılıfı - Lamp Handle Cover	
4x Pudrasız Eldiven - Powder-Free Gloves	NO :7-7,5-8-8,5	1x Needle Counter	20 needles
1x Yara Padi - Wound Pad	10x35 cm		
2x Velcro Kablo Tutucu - Velcro Cable Holder	2x30 cm		
1x Koter Zımpara - Instrument Cleaner	5x5 cm		
1x Cerrahi Kütol - Surgical Trunks	30x35 cm		
2x Yan Bantlı Örtü - Side Adhesive Drape	75x75 cm		
1x Perineal Örtü - Perineal Absorbant Drape	200x260 cm		
1x Göğüs Örtüsü - Chest Drape	200x300x330 cm		
1x Alet Masa Örtüsü - Table Cover	150x240 cm		



Cellulose

PE / Spunbond Reinforcement
(2x gsm)

Incise Film Use



Trix Spunbond / PE / Viscone
70 gsm



SMS 43 gsm

Transparent PE Film

PE / Viscone 110 gsm 3-layered
(Highly Absorbent Patch)

SMS 20 gsm

Spunbond

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Product Name	Reference No	GMDN Code	Class and Rule
GENERAL SURGERY PACK	GSP-014-2	33961	Class 1s Rule 4

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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Ürün Grubu / Product Group

Cerrahi Setler
Surgical Sets

Ürün Adı / Product Name

Genel Cerrahi Seti
General Surgery Pack

Referans No. / Reference No.

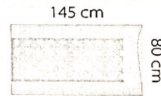
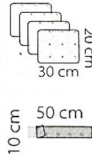
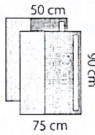
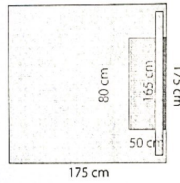
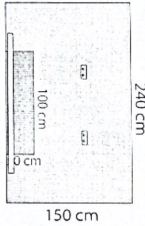
GSP-014-2

Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

Ürün Teknik Çizimi

Product Technical Drawing



Ürün Malzeme Bilgileri

Product Material Information

1x Mayo Masa Örtüsü - Mayo Stand Cover	80x145 cm
2x Takviyeli Yan Bantlı Örtü - Reinforced Side Adhesive Drape	90x75 cm
4x El Havlusu - Hand Towel	20x30 cm
1x OP Tape	10x50 cm
1x Takviyeli Yan Bantlı Örtü - Reinforced Side Adhesive Drape	175x175 cm
1x Takviyeli Anestezi Örtüsü - Reinforced Anesthesia Drape	150x240 cm



Cellulose



Adhesive

Hydrophilic Spunbond
40 gsm

Transparent PE Film



SMS 43 gsm

PL / Wiscons 110 gsm 2-layered
(Highly Absorbent Patch)

Spunbond

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Rev. No	01
Page No	1/1

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Product Name	Reference No	GMDN Code	Class and Rule
GENERAL SURGERY PACK	GSP-014-3	33961	Class 1s Rule 4

Conformity Assessment Procedure : Annex V
Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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City Date : İstanbul, 29.12.2021
Name : Yusuf Yiğit Akkuş
Position : General Manager

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Yenikapı V.D.: 7810897506 Tic.Sic. No: 749756-0

Ürün Grubu / Product Group

Ürün Adı / Product Name

Referans No / Reference No

Cerrahi Setler
Surgical SetsGenel Cerrahi Seti
General Surgery Pack

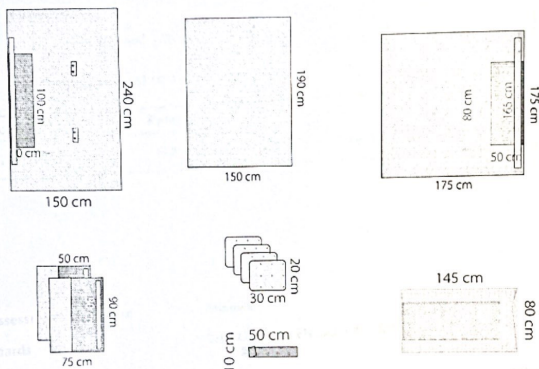
GSP-014-3

Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

Ürün Teknik Çizimi

Product Technical Drawing



Ürün Malzeme Bilgileri

Product Material Information

1x Mayo Masa Örtüsü - Mayo Stand Cover	80x145 cm
2x Takviyeli Yan Bantlı Örtü - Reinforced Side Adhesive Drape	90x75 cm
4x El Havlusu - Hand Towel	20x30 cm
1x OP Tape	10x50 cm
1x Takviyeli Yan Bantlı Örtü - Reinforced Side Adhesive Drape	175x175 cm
1x Takviyeli Anestezi Örtüsü - Reinforced Anesthesia Drape	150x240 cm
1x Alet Masa Örtüsü - Table Cover	150x190 cm



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Product Name	Reference No	GMDN Code	Class and Rule
GENERAL SURGERY PACK	GSP-012-11	33961	Class 1s Rule 4

Conformity Assessment Procedure : Annex V

Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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Position : General Manager

Signature, Stamp

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Ürün Grubu / Product Group

Cerrahi Setler
Surgical Sets

Ürün Adı / Product Name

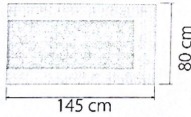
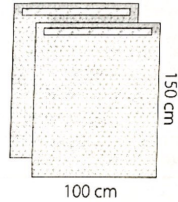
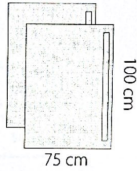
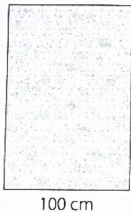
Genel Cerrahi Seti
General Surgery Pack

Referans No / Reference No

GSP-012-11

Ürün İçerik ve Teknik Çizimi
Product Content and Technical Drawing

Ürün Teknik Çizimi
Product Technical Drawing



Ürün Malzeme Bilgileri
Product Material Information

- 1x Mayo Masa Örtüsü - Mayo Stand Cover
- 1x Alet Masa Örtüsü - Table Cover
- 2x Yan Bantlı Örtü - Side Adhesive Drape
- 2x Yan Bantlı Örtü - Side Adhesive Drape
- 2x El Havlusu - Hand Towel

- 80x145 cm
- 100x200 cm
- 100x150 cm
- 75x100 cm
- 20x30 cm

Transparent PE Film

Spunbond

Hydrophilic Spunbond
2 Layered
56 gsm

Adhesive

SMS 40 gsm

Cellulose

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Product Name	Reference No	GMDN Code	Class and Rule
ADHESIVE FENESTRATED DRAPE 75X90 CM	SAFD-078	47783	Class Is Rule 4

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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Ürün Grubu / Product Group

Cerrahi Örtüler
Surgical Drapes

Ürün Adı / Product Name

Delikli Bantlı Örtü
Adhesive Fenestrated Drape

Referans No / Reference No

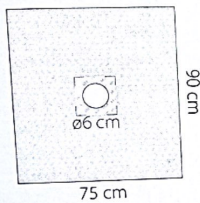
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1. Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

Ürün Teknik Çizimi

Product Technical Drawing



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Reason: MoldSign Signature
Location: Moldova




Ürün Malzeme Bilgileri

Product Material Information

1x Delikli Bantlı Örtü - Adhesive Fenestrated Drape

75x90 cm



Hydrophilic Spunbond
2 Layered
54 gsm



Adhesive

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Section No	TD-06/S.2-1-En
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Page No	1/1

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Product Name	Reference No	GMDN Code	Class and Rule
SURGICAL DRAPE PACK	SDP-002	33961	Class Is Rule 4

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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Ürün Grubu / Product Group

Cerrahi Örtüler
Surgical Drapes

Ürün Adı / Product Name

Yan Bantlı Takviyeli Örtü
Reinforced Adhesive Drape

Referans No / Reference No

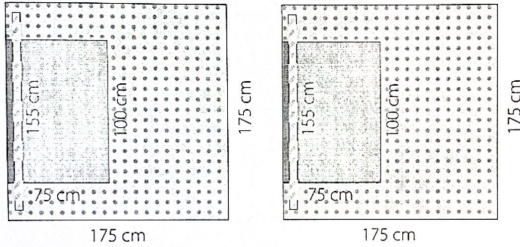
SDP-002

1. Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

Ürün Teknik Çizimi

Product Technical Drawing



Ürün Malzeme Bilgileri

Product Material Information

2x Takviyeli Yan Bantlı Örtü - Reinforced Adhesive Drape

175x175 cm

Ürün Grubu / Product Group

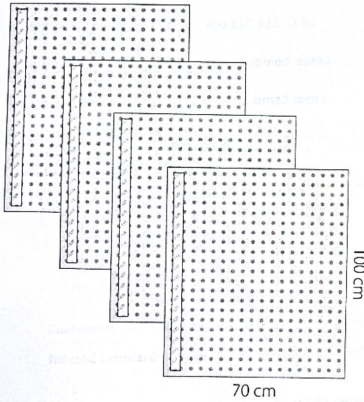
Cerrahi Örtüler
Surgical Drapes

Ürün Adı / Product Name

Yan Bantlı Düz Örtüler
Adhesive Drape

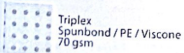
Referans No. / Reference No.

SDP-001

1. Ürün İçerik ve Teknik Çizimi
Product Content and Technical DrawingÜrün Teknik Çizimi
Product Technical DrawingÜrün Malzeme Bilgileri
Product Material Information

4x Yan Bantlı Düz Örtü - Absorbant Adhesive Drape

70x100 cm

Triplex
Spunbond / PE / Viscone
70 gsm

Adhesive

DECLARATION OF CONFORMITY

Section No	TD-06/5.2-1-En
Rev Date	29.12.2021
Rev. No	01
Page No	1/1

Company Name : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A.Ş.
 Address : Orhangazi mah. 1673. Sok No:20 Esenyurt İstanbul
 Tel : +90 212 320 37 53
 Fax : +90 212 320 53 51
 Web : www.submed.com.tr
 E-mail : info@submed.com.tr

Product Name	Reference No	GMDN Code	Class and Rule
PLAIN DRAPE 50X70 CM	SPD-085	47783	Class Is Rule 1

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

We herewith declare on our own responsibility that the above mentioned meet the provisions of the Council Directive 93/42/EEC with amended directive 2007/47/EC for Medical Device Directive.

Notified Body : KIWA Belgelendirme Hizmetleri A.Ş.
 NB Address : İTOSB 9. Cad. No :15 Tepeören, Tuzla - İstanbul TÜRKİYE
 NB Identification Number : 1984
 EC Certificate Number : 1984-MDD-14-266
 Expiry Date : 27 May 2024

Signature, Stamp

City Date : İstanbul, 29.12.2021
 Name : Yusuf Yiğit Akkuş
 Position : General Manager

SU BİYOMEDİKAL SİSTEMLER VE
 SAĞLIK HİZMETLERİ SANAYİ VE TİCARET A.Ş.
 Orhangazi Mah. 1673 Sk. No:20 Esenyurt / İSTANBUL
 Tel: 0212 320 37 53 Faks: 0212 320 53 51
 Yenikapı V.D.: 7810897506 Tic.Sic. No: 749756-0

Ürün Grubu / Product Group

Ürün Adı / Product Name

Referans No / Reference No

Cerrahi Örtüler
Surgical Drapes

Emici Örtü
Absorbant Drape

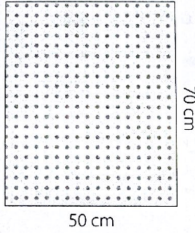
SPD-085

1. Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

Ürün Teknik Çizimi

Product Technical Drawing



Ürün Malzeme Bilgileri

Product Material Information

1x Emici Örtü - Absorbant Drape

50x70 cm

Triplex
Spunbond / PE / Viscone
70 gsm ±5

DECLARATION OF CONFORMITY

Section No	TD-06/5.2-1-En
Rev Date	29.12.2021
Rev. No	01
Page No	1/1

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 Web : www.submed.com.tr
 E-mail : info@submed.com.tr

Product Name	Reference No	GMDN Code	Class and Rule
INSTRUMENT TABLE COVER	STC-014	47783	Class Is Rule 1

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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Signature, Stamp

City Date : İstanbul, 29.12.2021
 Name : Yusuf Yiğit Akkuş
 Position : General Manager

SU BİYOMEDİKAL SİSTEMLER VE
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 Orhangazi Mah. 1673 Sk. No:20 Esenyurt / İSTANBUL
 Tel: 0212 320 37 53 Faks: 0212 320 53 51
 Yenikapı V.D.: 7810997506 Tic.Sic. No: 749756-0

submed SAFE EASY

ÜRÜN TEKNİK BİLGİLERİ
PRODUCT TECHNICAL INFORMATION

L 114

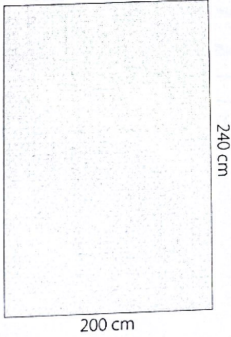
Ürün Grubu / Product Group

Ürün Adı / Product Name

Referans No / Reference No

Cerrahi Örtüler
Surgical DrapesAlet Masa Örtüsü
Table Cover

STC-014

1. Ürün İçerik ve Teknik Çizimi
Product Content and Technical DrawingÜrün Teknik Çizimi
Product Technical DrawingÜrün Malzeme Bilgileri
Product Material Information

1x Alet Masa Örtüsü - Table Cover

200x240 cm

Hydrophilic Spunbond
2 Layered
56 gsm

DECLARATION OF CONFORMITY

Section No	TD-06/5.2-1-En
Rev Date	29.12.2021
Rev. No	01
Page No	1/1

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 Web : www.submed .com.tr
 E-mail : info@submed.com.tr

Product Name	Reference No	GMDN Code	Class and Rule
NEPHRECTOMY PROCEDURE SET	UNSP-001	33961	Class 2a Rule 6

Conformity Assessment Procedure : Annex V

Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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 NB Identification Number : 1984
 EC Certificate Number : 1984-MDD-14-266
 Expiry Date : 27 May 2024

Signature, Stamp

City Date : İstanbul, 29.12.2021
 Name : Yusuf Yiğit Akkuş
 Position : General Manager

SU BİYOMEDİKAL SİSTEMLER VE
SAĞLIK HİZMETLERİ SANAYİ VE TİCARET A.Ş.
 Orhangazi Mah. 1673 Sk. No:20 Esenyurt / İSTANBUL
 Tel: 0212 320 37 53 Faks: 0212 320 53 51
 Yenikapı V.D.: 7810897503 Tic.Sic. No: 749756-0

Ürün Grubu / Product Group

Ürün Adı / Product Name

Referans No / Reference No

Cerrahi Setler
Surgical Sets

Perkütan Nefrostomi Seti
Percutan Nephrostomy Pack

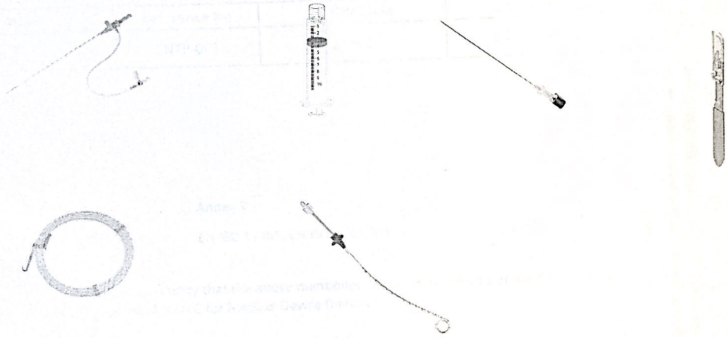
UNPS-001

Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

Ürün Teknik Çizimi

Product Technical Drawing



Ürün Malzeme Bilgileri

Product Material Information

- 1x Pigtail Tip Catheter - Pigtail Type Catheter
- 1x Dilator
- 1x Kılavuz Tel - Guidewire
- 1x Puncture İğne - Puncture Needle
- 1x LL, Şiringa - Syringe, LL
- 1x Bistüri - Scalpel

0.38x80 cm
185x20 cm
10 ml
NO: 11

ORL

DECLARATION OF CONFORMITY

Section No	TD-06/5.2-1-En
Rev Date	29.12.2021
Rev. No	01
Page No	1/1

Company Name : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A.Ş.
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 Web : www.submed.com.tr
 E-mail : info@submed.com.tr

Product Name	Reference No	GMDN Code	Class and Rule
ENT SURGERY PACK	ENTP-001	33961	Class 1s Rule 4

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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SU BİYOMEDİKAL SİSTEMLER VE
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 Orhangazi Mah. 1673 Sok. No:20 Esenyurt / İSTANBUL
 Tel: 0212 320 37 53 Paks: 0212 320 53 51
 Yenikapı V.D.: 781087505 Tic.Sic. No: 749756-0

Ürün Grubu / Product Group

Ürün Adı / Product Name

Referans No / Reference No

Cerrahi Setler
Surgical Sets

KBB Cerrahi Seti
ENT Surgery Pack

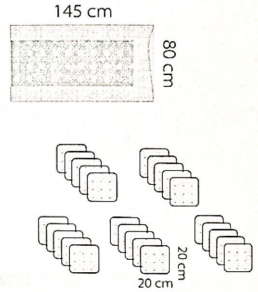
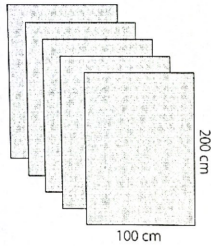
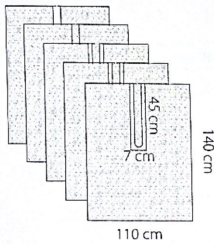
ENTP-001

Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

Ürün Teknik Çizimi

Product Technical Drawing



Ürün Malzeme Bilgileri

Product Material Information

- 5x U Yarıklı Örtü - U Split Drape
- 5x Alet Masa Örtüsü - Table Cover
- 20x El Havlusu - Hand Towel
- 1x Mayo Masa Örtüsü - Mayo Stand Cover

- 110x140 cm
- 100x200 cm
- 20x30 cm
- 80x145 cm

Cellulose

DECLARATION OF CONFORMITY

Section No	TD-06/5.2-1-En
Rev Date	29.12.2021
Rev. No	01
Page No	1/1

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 Fax : +90 212 320 53 51
 Web : www.submed.com.tr
 E-mail : info@submed.com.tr

Product Name	Reference No	GMDN Code	Class and Rule
TUR PACK	UTSP-004	33961	Class 1s Rule 4

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

We herewith declare on our own responsibility that the above mentioned meet the provisions of the Council Directive 93/42/EEC with amended directive 2007/47/EC for Medical Device Directive.

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 NB Identification Number : 1984
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 Expiry Date : 27 May 2024

Signature, Stamp

City Date : İstanbul, 29.12.2021
 Name : Yusuf Yiğit Akkuş
 Position : General Manager

**SU BİYOMEDİKAL SİSTEMLER VE
 SAĞLIK HİZMETLERİ SANAYİ VE TİCARET A.Ş.**
 Orhangazi Mah. 1673 Sk. No:20 Esenyurt / İSTANBUL
 Tel: 0212 320 37 53 Faks: 0212 320 53 51
 Yenikapı V.D.: 7810897506 Tic.Sic. No: 749756-0

Ürün Grubu / Product Group

Ürün Adı / Product Name

Referans No / Reference No

Cerrahi Setler
Surgical Sets

TUR Cerrahi Seti
TUR Surgery Pack

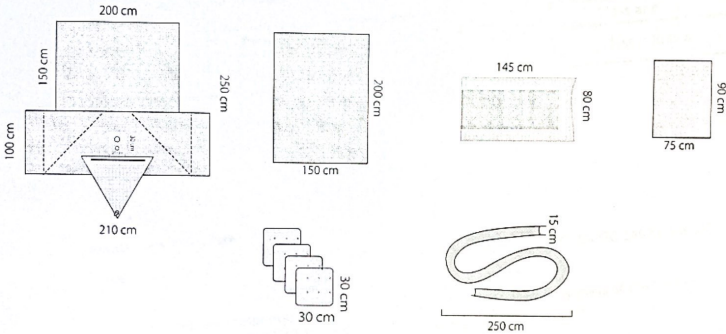
UTSP-004

Ürün İçerik ve Teknik Çizimi

Product Content and Technical Drawing

Ürün Teknik Çizimi

Product Technical Drawing



Ürün Malzeme Bilgileri

Product Material Information

1x TUR Örtüsü - TUR Drape	200x250 cm
1x Alet Masa Örtüsü - Table Cover	150x200 cm
1x Mayo Masa Örtüsü - Mayo Stand Cover	80x145 cm
1x Düz Örtü - Plain Drape	75x90 cm
4x El Havlusu - Hand Towel	30x30 cm
1x Kamera Kılıfı - Camera Cover	15x250 cm

PVC

Rubber

Spunbond

Hydrophilic Spunbond
2 Layered
56 gsm

Transparent PE Film

Cellulose

Transparent PE Film

DECLARATION OF CONFORMITY

Section No	TD-06/5.2-1-En
Rev Date	29.12.2021
Rev. No	01
Page No	1/1

Company Name : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A.Ş.
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Product Name	Reference No	GMDN Code	Class and Rule
SURGICAL DRAPE PACK	SDP-001	33961	Class Is Rule 4

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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 NB Address : İTOSB 9. Cad. No :15 Tepeören, Tuzla - İstanbul TÜRKİYE
 NB Identification Number : 1984
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 Expiry Date : 27 May 2024

Signature, Stamp

City Date : İstanbul, 29.12.2021
 Name : Yusuf Yiğit Akkuş
 Position : General Manager

SU BIYOMEDİKAL SİSTEMLER VE
 SAĞLIK HİZMETLERİ SANAYİ VE TİCARET A.Ş.
 Orhangazi Mah. 1673 Sk. No:20 Esenyurt / İSTANBUL
 Tel: 0212 320 37 53 Paks: 0212 320 53 51
 Yenikapı V.D.: 7810897506 Tic.Sic. No: 749758-0

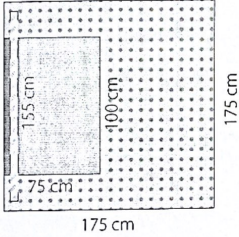
Ürün Grubu / Product Group

Ürün Adı / Product Name

Referans No / Reference No

Cerrahi Örtüler
Surgical DrapesYan Bantlı Takviyeli Örtü
Reinforced Adhesive Drape

XXXXXXXXXX

1. Ürün İçerik ve Teknik Çizimi
Product Content and Technical DrawingÜrün Teknik Çizimi
Product Technical Drawing

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Date: 2021.12.27 17:09:45 MSK
Reason: MoldSign Signature
Location: Moldova

Ürün Malzeme Bilgileri
Product Material Information

1x Takviyeli Yan Bantlı Örtü - Reinforced Adhesive Drape

175x175 cm



PE / Viscone 110 gsm 2-layered
(Highly Absorbent Patch)



Adhesive



Triplex
Spunbond / PE / Viscone
70 gsm

DECLARATION OF CONFORMITY

Section No	TD-06/5.2-1-En
Rev Date	29.12.2021
Rev. No	01
Page No	1/1

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113

Product Name	Reference No	GMDN Code	Class and Rule
CRANIOTOMY SURGERY PACK	NCSP-003	33961	Class 2a Rule 6

Conformity Assessment Procedure : Annex V
 Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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City Date : İstanbul, 29.12.2021
 Name : Yusuf Yiğit Akkuş
 Position : General Manager

SU BİYOMEDİKAL SİSTEMLER VE
 SAĞLIK HİZMETLERİ SANAYİ VE TİCARET A.Ş.
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 Yenikapı V.D.: 7810897505 Tic.Sic. No: 749756-0

Ürün Grubu / Product Group

Cerrahi Setler
Surgical Sets

Ürün Adı / Product Name

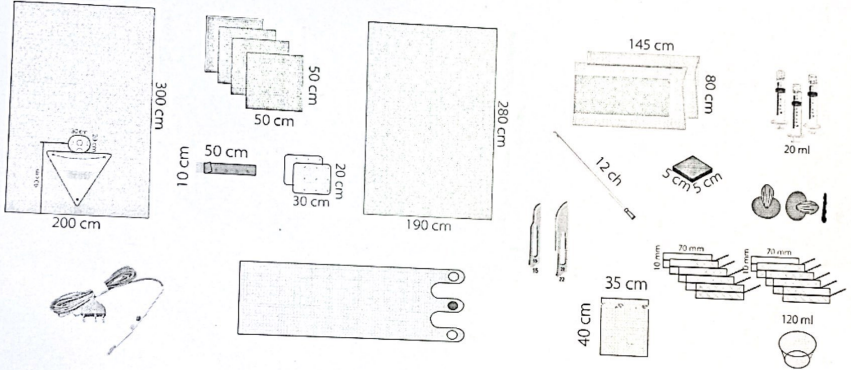
Beyin Cerrahi Seti
Brain Surgery Pack

Referans No / Reference No

NCSP-003

1. Ürün İçerik ve Teknik Çizimi
Product Content and Technical Drawing

Ürün Teknik Çizimi
Product Technical Drawing



Ürün Malzeme Bilgileri
Product Material Information

- 1x Kraniyotomi Örtüsü - Craniotomy Drape
- 4x Emici Örtü - Absorbant Drape
- 2x El Havlusu - Hand Towel
- 1x OP Tape
- 1x Alet Masa Örtüsü (Bohça) - Table Cover
- 2x Mayo Masa Örtüsü - Mayo Stand Cover
- 1x Suction Kateter - Suction Catheter
- 1x Koter Zımpara - Instrument Cleaner
- 3x LL, Şırınga - Syring, LL
- 2x Tutamaç Koruyucu - Lamp Handle Cover
- 10x Beyin Cerrahi Tamponu - Neuro Surgical Pattie
- 1x Bistüri Ucu - Scalpel Blades
- 1x Bistüri Ucu - Scalpel Blades

- 200x300 cm
- 50x50 cm
- 20x30 cm
- 10x50 cm
- 190x280 cm
- 80x145 cm
- 12 ch
- 5x5 cm
- 20 cm
- 40 cm
- 35 cm
- 70 mm
- 20 mm
- 120 ml
- 1x Alet Torbası - Universal PE Bag
- 1x Plastik Kap - Gallipot
- 1x Mikroskop Kılıfı - Microscope Cover
- 1x Koter - Electrical Koter Pencil

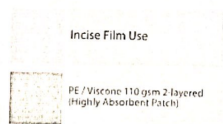
- 35x40 cm
- 120 ml
- 300 cm



Cotton

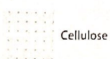


Spunbond



Transparent PE Film

Incise Film Use



Cellulose

Ürün Grubu / Product Group

Cerrahi Setler
Surgical Sets

Ürün Adı / Product Name

Beyin Cerrahi Seti
Brain Surgery Pack

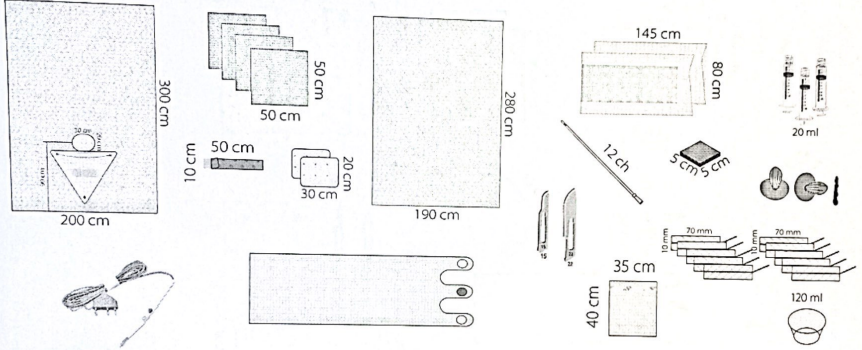
Referans No / Reference No

NCSP-002

1. Ürün İçerik ve Teknik Çizimi
Product Content and Technical Drawing

Ürün Teknik Çizimi
Product Technical Drawing

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Reason: MoldSign Signature
Location: Moldova



Ürün Malzeme Bilgileri
Product Material Information

- 1x Kraniotomi Örtüsü - Craniotomy Drape
- 4x Emici Örtü - Absorbant Drape
- 2x El Havlusu - Hand Towel
- 1x OP Tape
- 1x Alet Masa Örtüsü (Bohça) - Table Cover
- 2x Mayo Masa Örtüsü - Mayo Stand Cover
- 1x Suction Kateter - Suction Catheter
- 1x Koter Zımpara - Instrument Cleaner
- 3x LL, Şiringa - Syring, LL
- 2x Tutamaç Koryuyucu - Lamp Handle Cover
- 10x Beyin Cerrahi Tamponu - Neuro Surgical Pattie
- 1x Bistüri Ucu - Scalpel Blades
- 1x Bistüri Ucu - Scalpel Blades

- 200x300 cm
- 50x50 cm
- 20x30 cm
- 10x50 cm
- 190x280 cm
- 80x145 cm
- 12 ch
- 5x5 cm
- 20 ml
- 190x280 cm
- 80x145 cm
- 12 ch
- 5x5 cm
- 20 ml
- 10x70 mm
- NO 15
- NO 22
- 1x Alet Torbası - Universal PE Bag
- 1x Plastik Kap - Gallipot
- 1x Mikroskop Kılıfı - Microscope Cover
- 1x Koter - Electrical Koter Pencil

- 35x40 cm
- 120 ml
- 300 cm

