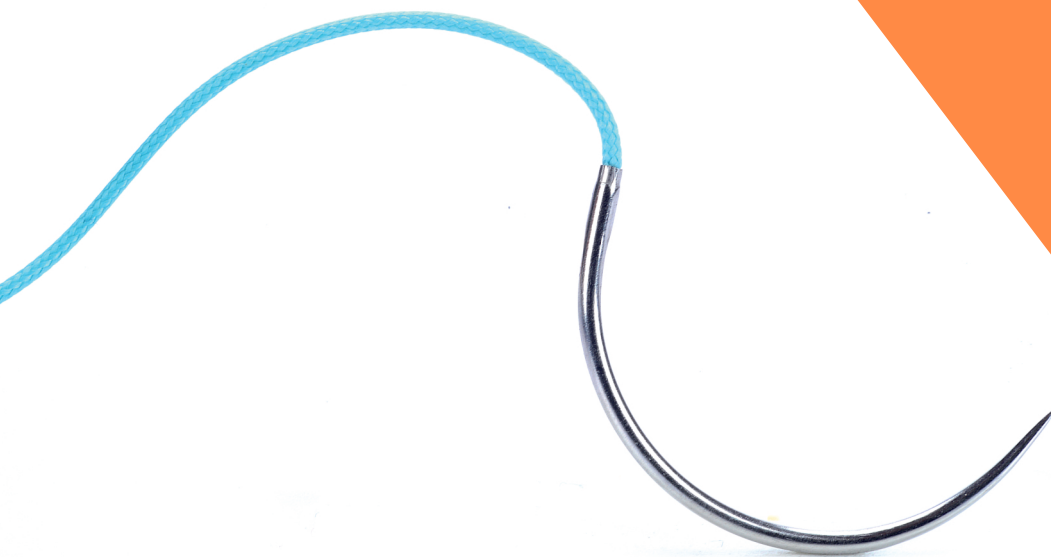


Polisil

Surgical Suture, Braided Polyester, Silicone Coated (PET)
Nonabsorbable, Synthetic

Surgical Sutures
Non-Absorbable

Boz®



Definition

Synthetic Non- Absorbable

Material

Polyester Polyethylene Terephthalate (PET)

Coating

Silicone, Uncoated

Structure

Braided

Colour

Green, White

Size

EP : 0.5 to 7
USP : 7/0 to 5

Tensile Strenght Retention

Permanent

Mass Absorption

Permanent

Sterilization Method

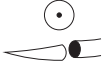
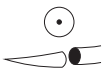





Ethylene Oxide Gas



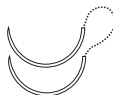
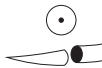








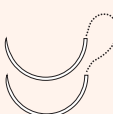
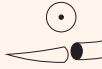
Main Indication

Cardiac Valve Repair
General Surgery
Cardiovascular Procedures
Neurosurgical Procedures

Polisil

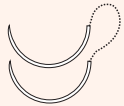


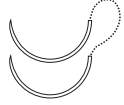


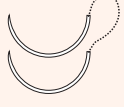






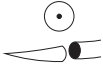

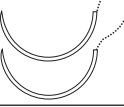
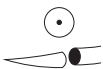
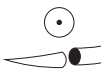
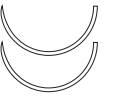
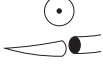
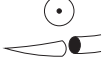
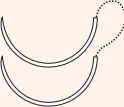


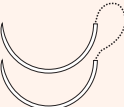


Surgical Suture, Braided Polyester, Silicone Coated (PET) Nonabsorbable, Synthetic

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
8 mm							
1/2 Spatula 340 Micron			PS1756	5/0 1,0	45	12	Green
1/4 Spatula 340 Micron			PS1408	6/0 0,7	45	12	Green
			PS1765	5/0 1,0	45	12	White
			PS1766	5/0 1,0	45	12	Green
3/8 Round Body, Taper Point 280 Micron			PS1302	7/0 0,5	45	12	Green
8,1 mm							
1/4 Sabre 380 Micron			PS5531	4/0 1,5	60	12	Green
10 mm							
3/8 Round Body, Taper Point 280 Micron			PS1482	6/0 0,7	75	12	Green
3/8 Spatula 280 Micron			PS1452	6/0 0,7	45	12	Green
13 mm							
3/8 Round Body, Taper Point 280 Micron			PS1573	6/0 0,7	75	12	Green
3/8 Round Body, Taper Point 320 Micron			PS1903	5/0 1,0	75	12	Green
3/8 Round Body, Taper Point 330 Micron			PS1587	6/0 0,7	75	12	Green
3/8 Round Body, Taper Point 330 Micron 6mm x 3mm x 3mm Teflon Pledget			PS1916	5/0 1,0	75	12	Green
3/8 Reverse Cutting 560 Micron			PS2455	4/0 1,5	45	12	White
3/8 Spatula 280 Micron			PS1604	6/0 0,7	45	12	Green

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
16 mm							
1/2 Round Body,Taper Point			PS3008	3/0 2,0	75	12	Green
1/2 Round Body,Taper Point			PS2515	4/0 1,5	90	12	Green
			PS3011	3/0 2,0	90	12	Green
1/2 Round Body,Taper Point			PS3012	3/0 2,0	90	6	5 Green 5 White
			PS5923	3/0 2,0	90	12	Green
6mm x 3mm x 1.5mm Teflon Pledget							
3/8 Inside Cutting			PS2560	4/0 1,5	75	12	Green
			PS3040	3/0 2,0	75	12	Green
17 mm							
1/2 Round Body,Taper Point			PS2582	4/0 1,5	75	12	Green
			PS3609	2/0 3,0	75	12	Green
1/2 Round Body,Taper Point			PS2587	4/0 1,5	90	12	Green
			PS3066	3/0 2,0	90	12	Green
			PS3613	2/0 3,0	90	12	Green
			PS3615	2/0 3,0	90	6	5 Green 5 White
1/2 Round Body,Taper Point			PS2579	4/0 1,5	75	12	Green
			PS3606	2/0 3,0	75	6	5 Green 5 White
			PS3617	2/0 3,0	90	12	Green
3mm x 3mm x 1.5mm Teflon Pledget							


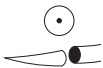
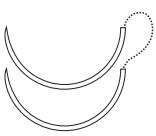
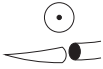
Polisil

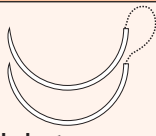

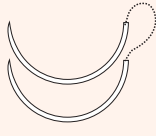


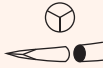
Surgical Suture, Braided Polyester, Silicone Coated (PET) Nonabsorbable, Synthetic



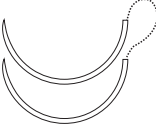
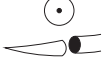
Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
17 mm							
1/2 Round Body, Taper Point 6mm x 3mm x 1.5mm Teflon Pledget	 		PS3067	3/0 2,0	90	6	5 Green 5 White
			PS3616	2/0 3,0	90	6	5 Green 5 White
			PS3618	2/0 3,0	90	12	Green
1/2 Tapercutting	 		PS2570	4/0 1,5	90	12	Green
1/2 Tapercutting 7mm x 3mm x 1.5mm Teflon Pledget	 		PS3592	2/0 3,0	75	6	5 Green 5 White
3/8 Round Body, Taper Point	 		PS5762	3/0 2,0	75	12	Green
20 mm							
1/2 Round Body, Taper Point	 		PS3648	2/0 3,0	75	12	Green
1/2 Round Body, Taper Point	 		PS3650	2/0 3,0	75	12	Green
1/2 Round Body, Taper Point	 		PS2688	4/0 1,5	75	12	Green
			PS2695	4/0 1,5	90	12	Green
			PS5843	3/0 2,0	75	12	Green
			PS3148	3/0 2,0	90	12	Green
1/2 Round Body, Taper Point 6mm x 3mm x 1.5mm Teflon Pledget	 		PS3651	2/0 3,0	75	6	5 Green 5 White
			PS3653	2/0 3,0	90	12	Green
1/2 Round Body, Taper Point 6mm x 3mm x 3mm Teflon Pledget	 		PS2706	4/0 1,5	75	12	Green

Polisil

Surgical Suture, Braided Polyester, Silicone Coated (PET) Nonabsorbable, Synthetic







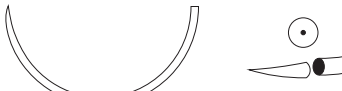

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
25 mm							
1/2 Round Body, Taper Point			PS3727	2/0 3,0	75	12	Green
			PS4191	0 3,5	75	12	Green
1/2 Round Body, Taper Point			PS3258	3/0 2,0	75	12	Green
			PS3262	3/0 2,0	90	12	Green
			PS3730	2/0 3,0	75	6	5 Green 5 White
			PS3733	2/0 3,0	75	12	Green
			PS3737	2/0 3,0	90	6	5 Green 5 White
			PS3741	2/0 3,0	90	12	Green

25 mm							
1/2 Round Body, Taper Point			PS3738	2/0	90	12	Green
				3,0			
3mm x 3mm x 1.5mm Teflon Pledget							
1/2 Round Body, Taper Point			PS3263	3/0	90	12	Green
				2,0			
			PS3729	2/0			
	3,0						
6mm x 3mm x 1.5mm Teflon Pledget			PS3732	2/0	75	12	Green
				3,0			
1/2 Tapercutting			PS5826	2/0	90	6	5 Green 5 White
				3,0			
3mm x 3mm x 1.5mm Teflon Pledget							

26 mm							
1/2 Round Body, Taper Point			PS3788	2/0 3,0	75	12	Green
			PS4217	0 3,5	75	12	Green
1/2 Round Body, Taper Point			PS3322	3/0 2,0	90	12	Green
			PS4221	0 3,5	90	12	Green

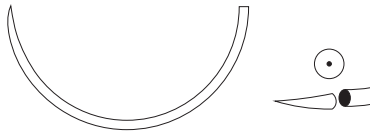

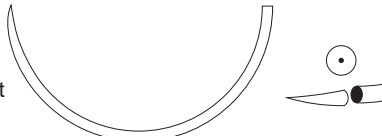
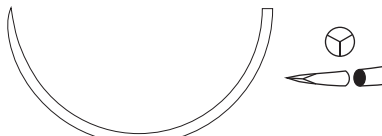
Polisil

Surgical Suture, Braided Polyester, Silicone Coated (PET) Nonabsorbable, Synthetic

Needle Length and description		Product No	USP EP	Length (cm)	Unit Pcs	Color
30 mm						
1/2 Round Body, Taper Point		PS3370	3/0 2,0	75	12	Green
		PS3860	2/0 3,0	75	12	Green
		PS4247	0 3,5	75	12	Green
		PS4611	1 4,0	75	12	Green
1/2 Reverse Cutting		PS4268	0 3,5	75	12	Green
		PS4623	1 4,0	75	12	Green
3/8 Reverse Cutting		PS3400	3/0 2,0	75	12	Green
		PS3892	2/0 3,0	75	12	Green
35 mm						
3/8 Reverse Cutting		PS3935	2/0 3,0	75	12	Green
36 mm						
1/2 Round Body, Taper Point		PS5515	1 4,0	75	12	Green
1/2 Reverse Cutting		PS5514	0 3,5	75	12	Green
40 mm						
1/2 Round Body, Taper Point		PS4369	0 3,5	75	12	Green
		PS4714	1 4,0	75	12	Green
		PS5007	2 5,0	90	12	Green
45 mm						
1/2 Round Body, Taper Point		PS5036	2 5,0	75	12	Green

Polisil

Surgical Suture, Braided Polyester, Silicone Coated (PET) Nonabsorbable, Synthetic

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
50 mm					
1/2 Round Body, Taper Point 	PS4814	1 4,0	75	12	Green
	PS5067	2 5,0	75	12	Green
Straight Reverse Cutting 	PS4049	2/0 3,0	75	12	Green
55 mm					
1/2 Round Body, Taper Point 	PS5181	5 7,0	75	12	Green
1/2 Taper cutting 	PS5173	5 7,0	75	12	Green

Polisil

Surgical Suture, Braided Polyester, Silicone Coated (PET) Nonabsorbable, Synthetic

Non-Needle Suture	Product No	USP EP	Length (cm)	Unit Pcs	Color
17x45 cm					
POLISIL Non-Needle Suture	PS2965	3/0 2,0	17x45	12	Green
	PS3559	2/0 3,0	17x45	12	Green
	PS4150	0 3,5	17x45	12	Green
	PS4560	1 4,0	17x45	12	Green
13x60 cm					
POLISIL Non-Needle Suture	PS2962	3/0 2,0	13x60	12	Green
	PS3554	2/0 3,0	13x60	12	Green
250 cm					
POLISIL Non-Needle Suture	PS4543	1 4,0	250	12	Green

Prospektüs

Prospectus

POLISIL

Emilemeyen Cerrahi Ameliyat İpliği

Non-Absorbable Surgical Sutures

Lütfen dilinizi seçiniz
Please select your language



TR

Kullanma Talimatı

POLISIL® POLIESTER İPLİK

EMİLEMİYEN, CERRAHİ İPLİK U.S.P/ Eur.Ph./ TS-5503

TANIM

POLISIL Poly(etilen tereftalat) tan oluşan, poliester, emilemeyen, örgülü yapıda, steril cerrahi iplikler. Yüksek moleküler ağırlığa sahip, uzun zincirli, lineer poliesterlerden elde edilir.

POLISIL cerrahi iplik düzgün bir şekilde silikon elastomer kaplıdır veya kaplanmasızdır. Yüksek tutunma gücüne sahip kaplama maddesi reaktif değildir. Emilemeyen özellikteki kaplama bileşimi kayganlaştırıcı görev görür; dokudan kolay geçiş ve kullanımı kolaylığı sağlayarak kaplanmamış örgülü ipli fiziksel özelliklerini iyileştirir.

POLISIL ipli kullanıma en uygun şekilde üretilmiş ve görünürlüğü arttırmak için yeşile boyanmıştır. Boyar madde D&C Yeşil #6'dır.

POLISIL ipli Amerikan Farmakopisi (USP) ve Avrupa Farmakopisindeki emilemeyen cerrahi ipler için kabul edilmiş olan tüm gereklilikleri karşılar.

KULLANIM ALANI

POLISIL iplik kalp-damar, oftalmik ve sinir cerrahisi uygulamaları dahil, genel yumuşak doku kapanmasında ve/veya bağlanması kullanılır. Cerrahi Multicron iplik tek kullanımlıdır.

ETKİLERİ

Cerrahi POLISIL iplik dokuda hafif bir şekilde akut yangılaşma cevabı gösterebilir, bu tepkiyi ipli çevresinde deneysel canlı dokü fibroz bağ doku oluşumu takip eder. Iplik materyalinin ve silikon kaplamanın farmakolojik olarak bir etkisi yoktur.

KULLANILMAMASI GEREKEN YERLER

Bilinen yoktur.

UYARILAR

Yararın açılma riski, uygulama bölgesi ve kullanılan malzemeye göre değişebildiği için kullanılan POLISIL ipli kullanımdan önce emilebilir olmayan cerrahi iplerin kullanımına ilişkin cerrahi yöntem ve tekniklere aşina olmalıdır.

Tekrar steril etmeyiniz. Açılmış poşetleri ve kullanılmayan ipleri imha ediniz. İpliklerin kordon, safra ya da üriner sistemdeki gibi mevcut olan tuz çözeltileri ile uzun süreli teması tortu oluşumuna sebebiyet verebilir. Enfekte ve kontamine olmuş yaralarda kabul edilebilir cerrahi uygulamalar takip edilmelidir.

ÖNLEMLER

POLISIL ipliğin ve diğer tüm cerrahi iplerin kullanımında ipliğe ve iğneye zarar vermekten kaçınılmalıdır. Forseps veya iğne tutucu gibi cerrahi aletlerin kullanımına bağlı ezme, veya çarpma hatalarından kaçınılmalıdır. POLISIL suture, kullanımı karakteristiğini arttırmak için kabul görmüş düz ve kare düğüm teknikleri ile cerrahi dorum ve cerrahin deneyimine bağlı olarak ilave düğüm teknikleri gerektirmektedir.

İğne uçlarının ve bağlantı bölgesinin hasar görmemesi için, bağlantı ucu ve iğne ucu arasındaki mesafenin üçte biri (1/3) ile yarısı (1/2) arasındadır.

kısımdan tutun. İğneleri yeniden şekillendirmek, güçlerini kaybetmelerine ve bükülmeye ve kırılmalara karşı dirençlerinin azalmasına neden olabilir. İstem dışı iğne batmalarından kaçınmak için kullanıcıların cerrahi iğne kullanırken dikkatli olmaları gerekir.

Kontamine ve kullanılmamış ürünleri bölgesel ve tesis gereksinimlerine uygun olarak imha ediniz.

Kullanılan iğneleri "kesici alet" kaplarına atınız.

YAN ETKİLER

Bu cihazın kullanımına bağlı yan etkiler; yara açılması, uzun süreli tuz çözeltileri ile temasta ürün sisteminde tortu oluşumu, enfeksiyon, akut doku yangı reaksiyonu, yara çevresinde geçici bölgesel tahriş şeklindedir.

PİYASAAARZ-SUNUŞ ŞEKLİ

POLISIL cerrahi iplikler steril, örgülü yapıda, yeşil ve boyasız olarak (beyaz), USP 7/0 ve 5 (metrik 0,5 ile 7) arasında, değişik boyarda iğneli ve iğnesiz olarak bulunur.

POLISIL iplikler boyasız ve yeşil renkte, Politetraflorotilen (PTFE) plejitlere takılı biçimde de bulunur.

POLISIL iplikler yarım, bir, iki veya üç düzinelik kutularda bulunmaktadır.

Cerrahi POLISIL iplik tek kullanımlıdır.

DEPOLAMA

25°C'nin altında ve güneş ışığından uzakta depolayınız.

Nemden koruyunuz.

Son kullanma tarihinden sonra kullanmayınız.

ETİKETLEMEDE KULLANILAN İŞRETLER

	Tek kullanımlık		REF	Katalog numarası
	Tekrar steril etmeyiniz			25°C'nin altında muhafaza ediniz
	Paket zarar görmüşse kullanmayınız			Güneşten uzak tutunuz
	Üretici			Nemden koruyunuz
	YYYYYY Üretim tarihi, Yıl			Geri dönüştürülmüş paket
	YYMMYY-MM Son kullanma tarihi, Yıl-Ay			Dikkat, Kullanma kılavuzuna bakınız
	STERILE EO Steril Ed: Etilenoksit			
	LOT Seri No			
	Boyalı, Emilemez, Örgülü, K aplanmış			

İTÜ-PS-REV-03-05-05-2017

İssue date: 11.09.2012

"EASSİ (Avrupa Cerrahi Suture Sanayi Birliği) çeşitli suture ürün karakteristیکlerini sevgisel ve resmîsel olarak tanımlamak için tasarlanmış bir sistem geliştirmiştir. Sembol kullanımına Tıbbi Cihaz Direktifi (Medical Device Directive) (MDD 93/42/EEC) izin vermektedir ve çözümlü doku cerrahisine gerek kalmadan üreticilerin kullanıcılarına bilgi sağlamaına imkan tanımaktadır."



BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.
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Boz

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Instructions for Use

POLISIL® POLYESTER SUTURE

NONABSORBABLE, SURGICAL SUTURE, U.S.P./Eur.Ph./TS-5503

DESCRIPTION

POLISIL polyester suture is a nonabsorbable, braided, sterile, surgical suture composed of Poly (ethylene terephthalate). It is prepared from fibers of high molecular weight, long-chain, linear polyester. POLISIL suture is uniformly coated with silicone elastomer or uncoated. The highly adherent coating is a relatively nonreactive. Coating compound which is nonabsorbable, acts as a lubricant and mechanically improves the physical properties of the braided uncoated suture by improving easy passage through tissues and overall handling qualities. POLISIL suture is braided for optimal handling properties and dyed green to increase visibility. The dye is D&C Green #6. POLISIL suture meets all requirements for nonabsorbable surgical sutures established by the United States Pharmacopoeia (U.S.P) and European Pharmacopoeia (E.P.).

INDICATIONS

POLISIL suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgical procedures.

ACTIONS

POLISIL suture elicits a minimal acute inflammatory reaction in tissue, followed by gradual encapsulation of the suture by fibrous connective tissue. Both polyester fiber suture material and the silicone coating are pharmacologically inactive.

CONTRAINDICATIONS

Not known.

WARNINGS

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing POLISIL suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Do not re-sterilize. Discard open and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Acceptable surgical practices must be followed for the management of contaminated or infected wounds.

PRECAUTIONS

In handling POLISIL or any other suture material, care should be taken to avoid damage to needle and suture. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Multicron sutures, which are treated to enhance handling characteristics requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstances and the experience of the surgeon.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks.

Dispose of contaminated and unused products are in accordance with local and facility requirements. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transitory local irritation at the wound site.

HOW SUPPLIED

POLISIL sutures are available as sterile, braided, green, and undyed (white) strands in U.S.P. sizes 7/0 to 5 (metric sizes 0.5 - 7) in a variety of lengths, with and without permanently attached needles. POLISIL sutures, green and undyed, are also available attached to Polytetrafluoroethylene (PTFE) pledget. POLISIL sutures are available in half, one, two, and three dozen boxes. POLISIL suture is for single use only.


















STORAGE

Store below 25 °C. and keep away from sunlight.

Protect from humidity.

Do not use after expiry date.

SYMBOLS USED ON LABELLING

	Do not reuse!		Catalogue Number
	Do not re-sterilize		Store below 25°C
	Do not use if pack age is damaged		Keep away from sunlight
	Manufacturer		Protect from humidity
	YYYY MM Date of Manufacture/Year		Recyclable pack
	YYYY-MM Expiry Date, Year-Month		Attention, See instruction for use
	STERILE EO Sterile EO: Ethylene oxide		
	LOT Batch Number		1014
	Dyed, Non-absorbable, Braided, Coated		

ITU-PS-rev-03-05-05-2017

Issue date: 11.09.2012

"EASSI (The European Association of Surgical Suture Industry) has developed a system of symbols which is designed to describe various suture product characteristics in an intuitive, pictorial manner. The use of symbols is mandated by the Medical Device Directive (MDD 93/42/EEC) and enables companies to provide information to the customer without having to provide multilingual translations."



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Mode d'emploi

POLISIL* FIL POLYESTERE**FIL CHIRURGICAL NON RESORBABLE, U.S.P./ Eur.Ph./ TS-5503****DESCRIPTION**

POLISIL est un fil chirurgical stérile, tressé, polyester, non résorbable constitué de Poly (éthylène téréphthalate). Ils sont obtenus de polyester linéaire à longue chaîne de haute masse moléculaire. Le fil chirurgical POLISIL est revêtu avec l'élastomère de silicone ou non revêtu.

La matière de revêtement de haute force d'implantation n'est pas réactive. La composition de revêtement non résorbable agit comme lubrifiant, facilite le passage par le tissu et améliore les particularités physiques du fil tressé non revêtu.

Les fils POLISIL sont tressés de façon adéquate pour l'utilisation et colorés en vert pour augmenter la visibilité. Le colorant est D&C vert #6. Les fils POLISIL sont conformes aux exigences valables pour les fils de suture non résorbables de la Pharmacopée Européenne (E.P.) et la Pharmacopée Américaine (U.S.P.).

INDICATIONS

Le fil chirurgical POLISIL est utilisé pour la fermeture ou le raccordement des tissus mou en général y compris les applications cardiovasculaire, ophtalmiques et nerveux. Le fil chirurgical POLISIL est pour utilisation unique.

EFFICACITE

Le fil chirurgical POLISIL peut manifester une faible réaction inflammatoire aiguë dans le tissu, cette réaction est suivie d'une formation d'une tissue collagène fibreuse. Le matériel du fil et le revêtement en silicone n'ont pas d'effets pharmacologiques.

CONTRE-INDICATIONS

Aucun reconnu

AVIS

Le risque d'ouverture de plaie pouvant varier selon la zone d'application et le matériel employé, les utilisateurs doivent être familiers aux méthodes et techniques chirurgicales concernant les fils chirurgicaux de suture non

résorbables avant l'utilisation du POLISIL.
Ne pas stériliser. Détruire les sachets ouverts et les fils non utilisables. Le contact des fils avec les solutions de sel présents dans le cordon, la bile ou le système urinaire peut donner lieu à la formation de calcul. Poursuivre les applications chirurgicales acceptables pour le traitement des plaies infectées et contaminées.

PRECAUTIONS

Veiller à ne pas endommager le fil et l'aiguille lors de l'utilisation du fil POLISIL et tous les fils chirurgicaux. Eviter les erreurs comme le broyage et le frappé résultant de l'utilisation des outils chirurgicaux comme le forceps ou le porte-aiguille.

Selon la situation chirurgicale et l'expérience du chirurgien, POLISIL suture nécessite des techniques de nœuds supplémentaires avec des techniques de nœuds droits et carrés afin d'améliorer la caractéristique. Afin de ne pas endommager les pointes d'aiguille et la zone de connexion, maintenez-le entre le troisième (1/3) et le demi (1/2) de la distance entre

l'attache et l'axe de l'aiguille. Remodeler les aiguilles, il peut perdre leur force et réduire leur résistance à la flexion et à la rupture. Les utilisateurs doivent faire attention lorsque vous utilisez des aiguilles chirurgicales pour éviter les baguettes à aiguilles involontaires.

Éliminez les produits contaminés et inutilisés selon les exigences régionales et de l'usine.

Mettez les aiguilles usées dans les boîtes "outils de coupe".

EFFETS SECONDAIRES

Les effets secondaires liés à l'utilisation de cet appareil sont l'ouverture des plaies, la sédimentation dans le système urinaire par le contact prolongé avec les solutions de sel, l'infection, la réaction minimal d'inflammation aiguë et l'irritation provisoire dans la zone de plaie.

COMMERCIALISATION

Les (ils chirurgicaux POLISIL existent dans différentes tailles entre U.S.P. 7/0 et 5 (métrique 0,5 - 7), sont stériles, tressés, en couleur verte et sans couleur (blanc), avec ou sans aiguille.

Les fils POLISIL existent également en vert et sans couleur attachés sur les plégites polytétrafluoroéthylène (PTFE).

Les fils POLISIL sont commercialisés dans des boîtes à une, deux et trois douzaines.

Le fil chirurgical POLISIL est pour utilisation unique.

















CONSERVATION

Conservé sous température 25°C et loin du rayonnement solaire

Protéger de l'humidité.

Ne pas utiliser après la date limite de consommation.

SIGNES UTILISES POUR L'ETIQUETAGE

	Pour utilisation unique		REF Numéro de catalogue
	Ne pas stériliser à nouveau		25°C Conservé sous 25°C
	Ne pas utiliser si l'emballage est endommagé		Protéger du soleil
	Fabricant		Conservé dans un lieu sec
YYYY 	Date de production, Année		Emballage recyclable
YYMM 	YYYY-MM Date d'expiration, Année - mois		Attention, Voir les instructions d'utilisation
	STERILE EQ Stérile EO: oxyde d'éthylène		1014
	LOT No de série		
	Avec peinture, non absorbable, tressé, revêtu		

IfU-PS-rev-03-05-05-2017

Issue date: 11.09.2012

*EASSI (Association d'Industrie de la Suture Européenne de Chirurgie) a développé un système conçu pour identifier comme intuitive et imagée les caractéristiques des différents produits de suture. Le Directif sur les Dispositifs Médicaux (Medical Device Directive) (MDD 93/42/EEC) permis à utiliser le symbole et il permet les informations aux utilisateurs des fabricants sans obligé à traduire en plusieurs langues.



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تعليمات الاستعمال

AR

مولتيكوزن POLISIL خطوط بوليمتر

خطوط جراحية غير قابلة للامتصاص 5503 - TS U.S.P/ Eur. Ph/

التعريف :

تتكون خطوط مولتيكوزن POLISIL من بولي (تركيبات أثيرات)، بوليستر. غير قابل للامتصاص، ذو تركيب نسجي مضفر، خطوط ممطعة للجراحة، ذو كثافة نوية عالية، سلسلة طويلة، ينتج من مادة البوليمر الخشبي. خطوط مولتيكوزن POLISIL ممطعة بمادة البوليكون المرونة بشكل منتظم أو تكون غير ممطعة مادة التغليف غير معاملة ذات تماسك عالي. التغليف غير القابل للامتصاص يكسبه خاصية ذات لزاوية. عمل هي تحسين الخواص الميكانيكية للخطوط المضفرة. غير الممطعة وتلك في تسهيل الاستعمال والسرور من خلال الاستجابة الحيوية. أن خطوط مولتيكوزن POLISIL ذات جودة نوعية مضفرة بأفضل شكل حيث تم صبغها باللون الأخضر لتتميزها من اللون الأبيض الحيوي بسهولة. اللون الأصفر المستخدم دي و سي أخضر 6B. خطوط مولتيكوزن POLISIL تحمل كافة المواصفات التي تتطابق مع المواصفات الأمريكية والأوروبية المتعلقة بالخطوط غير القابلة للامتصاص.

مجالات الاستعمال

تستعمل خطوط مولتيكوزن POLISIL الجراحية في عمليات القلب والأوعية الدموية الجراحية، وجراحة الأوعية الدموية، وفي عمليات خلق جروح الاستجابة الخاصة (الوخز) بشكل عام أو في عملية ربطها. خطوط مولتيكوزن POLISIL للاستعمال مرة واحدة فقط.

التحذيرات

يمكن أن تؤثر خطوط مولتيكوزن POLISIL على الاستجابة بعمل تقابل معها على شكل التهاب أو تيج خفيف، هذا التأثير سيؤثر تدريجيا وبشكل منتظم على طرفه في النسيج الحيوي. ويتبعه لطف في المنطقة ليس للمادة التي يتكون من الخيط ومادة التغليف أي تأثير من الناحية الباثية.

الأسان التي لا يجوز فيها استعماله

لا توجد.

التحذيرات

ي يجب أن يحذروا حدوث اقتلاع بالجروح (فوق) تختلف من منطقة إلى أخرى وتختلف أيضا حسب المواد المستخدمة، فانه يجب على مستخدمين خطوط مولتيكوزن POLISIL أن يكون لهم اطلاع على الطرق الجراحية والتدابير الملائمة المتبعة باستخدام الخطوط الجراحية غير القابلة للامتصاص قبل استخدام خطوط مولتيكوزن POLISIL. لا يجوز إعادة تعقيم. نظر اكياس التغليف المعالجة حتى لو كانت خطوط غير مستعملة من الممكن أن تسبب عند الخيطوط تكوين الحمضي في غدة الصفراء أو الحالب والمجاري البولية إذا طالت فترة تماسها مع المحتال المحيطة الموجودة في تلك الأجهزة الحيوية يجب اتباع الطرق الجراحية المعقولة في الجروح المفتوحة أو المصاصة والمكثفة.

التعليمات

تجنب التعرض المباشر للبالوعة أو خطوط مولتيكوزن POLISIL عند الاستخدام تجنب الوقوع في أخطاء عملية يسبق أو اصطدام الخيطوط خلال استخدام الأدوات الجراحية مثل الملاط أو المناشير وغيرها من الأدوات. من أجل زيادة قدرات خطوط مولتيكوزن POLISIL تكون تقنيات العدة المستوية والمرونة ستكون عند كفاءتها مع ظروف عند إصغافها بالإضافة إلى ضمانات تجربة وخبرات الجراحين وشروط ومواصفات الجراحة. خطوط مولتيكوزن مناسبة للأغراض من إجراء عمل فيها. لتجنب الإصابة والتلف والاضطراب الجرح بالتعرض للأشعة، يجب أن يتم توجيه الإبرة في ثلث المساحة (3/1) إلى النصف (2/1) من مسافة وجب من نهاية الإبرة إلى هذه النقطة. إعادة تشكيل الإبر قد تسبب القوة وتكون أقل مقاومة للثني والتمزق. يجب على المستخدمين توخي الحذر عند التعامل مع الإبر الجراحية لتجنب وخز الإبر غير المقصود.

التخلص من المنتجات الملوثة وغير المستخدمة يجب أن يكون وفقًا للممارسات المحلية والمرافق ذات الصلة. يجب إلقاء الإبر المستخدمة في حاويات التغليف "الأدوات الحادة".

التحذيرات الجراحية

الكثيرات الجراحية لهذه المادة فتح في الجروح والتلصق الخيطوط من الممكن أن تحدث ترسبات. عند تماس خطوط مولتيكوزن POLISIL لفترة طويلة مع المحتال المحيطة الموجودة في الجهاز البولي. تهيجات في الاستجابة عند مناطق التماس، تخثر في المنطقة وأطرافها.

اشكال عرضه في الأسواق

يتم عرضه في الأسواق على شكل خطوط مولتيكوزن POLISIL معاملة ذات التركيب المضفر وبدون لون (بيضا) أو باللون الأخضر بطول تتراوح ما بين (0.5 - 7 متر) U.S.P 0/7 و 5. خطوط مولتيكوزن POLISIL مضفرة باللون الأخضر أو عديم اللون كما تتوفر بشكل مقفلة فيها البليجات البولي ثاثير والبولين. خطوط مولتيكوزن POLISIL مضفرة على غلب تحتوي على زينة احادية أو ثنائية أو ثلاثية خطوط مولتيكوزن POLISIL تستخدم لمرة واحدة فقط.

التخزين

يجب أن يتم عملية التخزين في درجات حرارة أقل من 25 درجة مئوية وبعيدة عن أشعة الشمس وأشعة فوق البنفسجية. لا تستخدموا الخيطوط الباقية للاستعمال.

الرموز المستخدمة في البطاقة

REF	رقم الكatalog
2	لاستعمال مرة واحد
لا	لا يتم إعادة التعقيم مرة أخرى
لا	لا تستخدم إذا كانت العدة التالفة
الصنع	
YYYY	تاريخ الإنتاج / السنة
YYYY-MM	تاريخ انتهاء الصلاحية / السنة / الشهر
STERILE EO	مطعم بالاعتماد
LOT	رقم الدفعة
CE 1014	ملون، خيوط قابل للامتصاص، مثليات، مصلع

Issue date: 11.09.2012

IU-PS-RV-03-05-2017

"قامت الرابطة الأوروبية للصناعة المعجلات الجراحية (EASSI) بتطوير نظام مصمم لتعريف مختلف خصائص منتجات المعجلات الجراحية بشكل مرئي ويهيئ كما أن إدارة الأجهزة الطبية (Medical Device Directive) (MDR 93/42/EEC) فتاحت إمكانية استخدام الرموز وتوضيل المعلومات من المصنعين إلى المستخدمين مباشرة دون الحاجة إلى الترجمة لعدة لغات"

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Declaration of Conformity

Manufacturer	BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.
Address	Sağlık Mah. Sağlık 1 Sk. No:33/5 Çankaya / ANKARA / TÜRKİYE
Product Name	POLISIL Surgical, Polyester (PET) Suture
Properties	Synthetic, Sterile, Non-Absorbable, Multifilament, Braided, Silicon coated, Green or White colored Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, Single Use
Dye	Green coloring material (D&C Blue#6 C.I.61565) White (Undyed)
Insulation/Coating	Silicon coated
Product Models	For product models see page 2
Lot No	2101001..... 2112099
GMDN No	13906
Classification	Class III , Rule 8
<i>We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards.All supporting documentations are retained under the premises of the manufacturer and the notified body. It conforms to Conformity Assesment Route Annex 2, and Route Annex 2 article 4 of the 93/42/EEC directive.</i>	
DIRECTIVES General applicable directives: -Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 Included Amendment 2007/47/EC concerning medical devices (MDD 93/42/EEC).	
Standards: -For Applicable Standards List see page 3 and 4	
Notified Body	UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-Çankaya ANKARA TÜRKİYE
Notified Body No	CE 2292
European Authorised Representative	EMERGO Prinsessegracht 20 2514 AP The Hague The Netherlands Phone +31.70.345.8570 - Fax +31.70.346.7299 – EmergoEurope@ul.com

Certificate	Certificate No	Certificate Date	Date of Validity
EC Design Examination Certificate	M.2020.106.13692-1	29.06.2020	27.05.2024
EC Certificate full quality assurance system	M.2020.106.13692	29.06.2020	27.05.2024

Place, Date

Ankara, 14.06.2021

Signature
Name
Position

Aysel KOSE
Management Representative

Document Code : YT-DC-PS	Effective Date: 11.09.2012	Revision No: 08	Revision Date: 14.06.2021	Number of Pages: 1 / 4
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Surgical, Polyester (PET) Suture Product Models

Synthetic, Sterile, Non-Absorbable, Multifilament, Braided, Silicon coated, Green or White colored Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:

USP:	7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5
EP:	0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7
Suture Lengths :	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 5 mm to 110 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

APPLICABLE STANDARDS LIST

Document Number	Title of Document
EP10.0-07/2018:0324	European Pharmacopoeia 10.0-07/ 2018:0324 Sutures, Sterile Non-absorbable Monograph.
USP 43/ NF 38	United States Pharmacopoeia 4191 Suture / Official Monographs- Nonabsorbable Surgical Suture
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14630: 2012	Non-active Surgical Implants- General Requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
EN 556-1: 2001	Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041: 2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
EN ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-1:2017)
EN ISO 11737-1: 2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
EN 1422:2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
EN 868-5: 2018	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5:2009	Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6:2016	Biological evaluation of medical devices- Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
EN ISO 10993-7:2008	Biological evaluation of medical devices part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-11:2017)
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)

KM-FR-85

Document Code : YT-DC-PS	Effective Date: 11.09.2012	Revision No: 08	Revision Date: 14.06.2021	Number of Pages: 3 / 4
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APPLICABLE STANDARDS LIST

Document Number	Title of Document
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019, Corrected version 2020-06)
EN ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
TS 10410/ OCT 1992	Methods For Sterility Control (For Medical Purposes) Part 3- Application Of Medicines, Medical And Surgical Materials To Inoculation Methods
TS 4020/ MAY 2016	Surgical needles
ASTM-F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM-F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1840 - 10(2016)	Standard Terminology for Surgical Suture Needles
ASTM F88 / F88M - 15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D5276 - 19	Standard Test Method for Drop Test of Loaded Containers by Free Fall
MEDDEV 2. 4/1 Rev. 9 June 2010	MEDICAL DEVICES: Guidance document - Classification of medical devices
MEDDEV 2. 2/3 rev.3 June 1998	'Use-by' date for medical devices
MEDDEV 2.7/1 revision 4 June 2016	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12/2 rev2 January 2012	Post-Market Clinical Follow-up Studies
MEDDEV 2.12-1 rev 8 January 2013	Guidelines on a Medical Devices Vigilance System
NB-MED/2.5.1/Rec5-rev4	Technical Documentation
NB-MED/2.5.1/Rec6-rev4	Renewal of EC Design-Examination and Type-Examination Certificates
NB-MED/2.5.2/Rec1-rev4	Subcontracting - QS related
NB-MED/2.12/Rec1-rev11	Post-Marketing Surveillance (PMS) post market/production
NB-MED/2.13/Rec1-rev3	CE-Marking of pre-MDD devices
EC-DIRECTIVES ON MED. DEVICES/ 2007	Guidelines on A Medical Devices Vigilance System

KM-FR-85

Document Code : YT-DC-PS	Effective Date: 11.09.2012	Revision No: 08	Revision Date: 14.06.2021	Number of Pages: 4 / 4
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EC DESIGN EXAMINATION CERTIFICATE

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2018.106.9177 the validity of the certificate
M.2018.106.9177-1 will also end.

Company Name : Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş.

Company Address : Sağlık Mh. Sağlık 1 Sk. No:33/5 Sıhhiye Çankaya ANKARA / TURKEY

Manufacturing and Storage : 29 Ekim Mh. Necip Fazıl Blv. No:71 Yenikent Sincan ANKARA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Section 4)

Product : Single use, Sterile, Synthetic Monofilament/Multifilament, Absorbable
Surgical Sutures - Class III

GMDN : 17471, 13908, 16584, 45814

Product Types are attached.

Certificate Number : M.2018.106.9177-1

Report Number : MD.3532.IB

Initial Assessment Date : 07.11.2017

Registration Date : 15.01.2018

Revision Date /No : 14.01.2021/01

Expiry Date : 14.01.2023


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

The EC design examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.



Address: Muflukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76

E-mail: info@udemltd.com.tr www.udem.com.tr



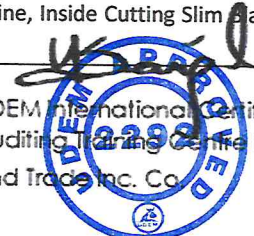
This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9177-1 and with the registration date of 15.01.2018 and with the revision date of 14.01.2021 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Poly[glycolide(90%)-co-lactide(10%)] (PGLA)	GMDN NO:17471
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2	
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5	
Suture Lengths : Variety of lengths, from 10 cm to 500 cm	
Needle Lengths : Variety of lengths, from 3 mm to 150 mm	
Needle Shapes : 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
Poly[glycolide(90%)-co-lactide(10%)] (Rapid Absorbable PGLA)	GMDN NO:17471
Synthetic, Sterile, Rapid Absorbable, Multifilament, Braided, Undyed Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2	
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5	
Suture Lengths : Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
Polyglycolic acid (PGA)	GMDN NO:13908
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6	
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8	
Suture Lengths: Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	



This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9177-1 and with the registration date of 15.01.2018 and with the revision date of 14.01.2021 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Polyglycolic acid (Rapid Absorbable PGA)	GMDN NO:13908
Synthetic, Sterile, Rapid Absorbable, Multifilament, Braided, Undyed Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6	
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8	
Suture Lengths: Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
Polydioxanone (PDO)	GMDN NO:16584
Synthetic, Sterile, Absorbable, Monofilament, Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2	
EP: 0,5 0,7 1 1,5 2 3 3,5 4 5	
Suture Lengths: Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
Poly[glycolide(75%)-co-caprolactone(25%)] (PGCL)	GMDN NO:45814
Synthetic, Sterile, Absorbable, Monofilament, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2	
EP: 0,7 1 1,5 2 3 3,5 4 5	
Suture Lengths: Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	





EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2018.106.9177-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : Boz Tıbbi Malzeme Sanayi ve Ticaret A.Ş.

Company Address : Sağlık Mh. Sağlık 1 Sk. No:33/5 Sıhhiye Çankaya ANKARA / TURKEY

Manufacturing and Storage : 29 Ekim Mh. Necip Fazıl Blv. No:71 Yenikent Sincan ANKARA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : Single use, Sterile, Synthetic Monofilament/Multifilament, Absorbable Surgical Sutures - Class III

GMDN : 17471, 13908, 16584, 45814

Product Types are attached.

Certificate Number : M.2018.106.9177

Report Number : MD.3532.IB

Initial Assessment Date : 07.11.2017

Registration Date : 15.01.2018

Revision Date /No : 14.01.2021/01

Expiry Date : 14.01.2023


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned



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E-mail: info@udemltd.com.tr www.udem.com.tr



This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9177 and with the registration date of 15.01.2018 and with the revision date of 14.01.2021 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Poly[glycolide(90%)-co-lactide(10%)] (PGLA)	GMDN NO:17471
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2	
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5	
Suture Lengths : Variety of lengths, from 10 cm to 500 cm	
Needle Lengths : Variety of lengths, from 3 mm to 150 mm	
Needle Shapes : 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
Poly[glycolide(90%)-co-lactide(10%)] (Rapid Absorbable PGLA)	GMDN NO:17471
Synthetic, Sterile, Rapid Absorbable, Multifilament, Braided, Undyed Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2	
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5	
Suture Lengths : Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
Polyglycolic acid (PGA)	GMDN NO:13908
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6	
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8	
Suture Lengths: Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	



This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9177 and with the registration date of 15.01.2018 and with the revision date of 14.01.2021 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Polyglycolic acid (Rapid Absorbable PGA)	GMDN NO:13908
Synthetic, Sterile, Rapid Absorbable, Multifilament, Braided, Undyed Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6	
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8	
Suture Lengths: Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
Polydioxanone (PDO)	GMDN NO:16584
Synthetic, Sterile, Absorbable, Monofilament, Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2	
EP: 0,5 0,7 1 1,5 2 3 3,5 4 5	
Suture Lengths: Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
Poly[glycolide(75%)-co-caprolactone(25%)] (PGCL)	GMDN NO:45814
Synthetic, Sterile, Absorbable, Monofilament, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP: 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2	
EP: 0,7 1 1,5 2 3 3,5 4 5	
Suture Lengths: Variety of lengths, from 10 cm to 500 cm	
Needle Lengths: Variety of lengths, from 3 mm to 150 mm	
Needle Shapes: 1/2, 3/8, 1/4, 5/8, Straight, J, SKI	
Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	



C E R T I F I C A T E

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2020.106.13692-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : Boz Tıbbi Malzeme Sanayi ve Ticaret A.Ş.

Company Address : Sağlık Mahallesi Sağlık 1 Sk. No:33/5 Çankaya ANKARA / TURKEY

Manufacturing and Storage : 29 Ekim Mahallesi Necip Fazıl Bulv. No:71 Yenikent Sincan
ANKARA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : Single use, Sterile Nonabsorbable Surgical Sutures - Class III and Class IIb
Single use, Sterile Nonabsorbable Teflon Pledget - Class III

GMDN : 13910, 38000, 13909, 13909, 13906, 31744, 13909, 15971

Product Types are attached.

Certificate Number : M.2020.106.13692
Report Number : MD.3532.IB
Initial Assessment Date : 08.11.2019
Registration Date : 29.06.2020
Revision Date /No : -
Expiry Date : 27.05.2024


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design-examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.



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This document containing 3 (three) pages is the Annex of the Certificate with the number M.2020.106. 13692 and with the registration date of 29.06.2020 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

Surgical Silk Suture Product Models GMDN No: 13910 Class III

Natural, Sterile, Nonabsorbable, Multifilament, Braided, Black or Undyed colored, Silicon Coated, Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4
EP:	0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6
Thread Lengths :	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point

Surgical Polypropylene (PP) Suture Product Models GMDN No: 13909 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Blue colored, Uncoated, Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Thread Lengths :	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Poly(vinylidene difluoride) (PVDF) Suture Product Models GMDN No: 13909 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Blue colored, Uncoated, Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties	
USP:	10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm

Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Polyamide 6-6,6 (PA) Suture Product Models GMDN No: 38000 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Blue or Black colored, Uncoated Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Polyester (PET) Suture Product Models GMDN No: 13906 Class III

Synthetic, Sterile, Nonabsorbable, Multifilament, Braided, Silicon coated, Green or White colored Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5
EP:	0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 5 mm to 110 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Polytetrafluoroethylene (PTFE) Suture Product Models GMDN No: 13909 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Uncoated, White (Undyed) colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	6/0, 5/0, 4/0, 3/0, 2/0
EP:	0,7 1 1,5 2 3
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 5 mm to 110 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Stainless Steel Wire Product Models GMDN No: 15971 Sınıf IIb

Sterile, Nonabsorbable, Monofilament, Uncoated, Natural Metallic Colour Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7
EP:	1 1,5 2 3 3,5 4 5 6 6 7 8 9
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 10 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical, Polytetrafluoroethylene (PTFE) Pledget Product Models GMDN No: 31744 Sınıf III

Sterile, Nonabsorbable, Non-woven, White colored and in the following dimension ranges:	
Width	= 3 mm 150 mm
Length	= 3 mm150 mm
Height	= 1 mm 2 mm



C E R T I F I C A T E

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2020.106.13692-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş.

Company Address : Sağlık Mahallesi Sağlık 1 Sk. No:33/5 Çankaya ANKARA / TURKEY

Manufacturing and Storage : 29 Ekim Mahallesi Necip Fazıl Bulv. No:71 Yenikent Sincan
ANKARA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : Single use, Sterile Nonabsorbable Surgical Sutures - Class III and Class IIb
Single use, Sterile Nonabsorbable Teflon Pledget - Class III

GMDN : 13910, 38000, 13909, 13909, 13906, 31744, 13909, 15971

Product Types are attached.

Certificate Number : M.2020.106.13692
Report Number : MD.3532.IB
Initial Assessment Date : 08.11.2019
Registration Date : 29.06.2020
Revision Date /No : -
Expiry Date : 27.05.2024


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 on EC design-examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.



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Surgical Silk Suture Product Models GMDN No: 13910 Class III

Natural, Sterile, Nonabsorbable, Multifilament, Braided, Black or Undyed colored, Silicon Coated, Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4
EP:	0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6
Thread Lengths :	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point

Surgical Polypropylene (PP) Suture Product Models GMDN No: 13909 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Blue colored, Uncoated, Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Thread Lengths :	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Poly(vinylidene difluoride) (PVDF) Suture Product Models GMDN No: 13909 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Blue colored, Uncoated, Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties	
USP:	10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm

Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Polyamide 6-6,6 (PA) Suture Product Models GMDN No: 38000 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Blue or Black colored, Uncoated Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Polyester (PET) Suture Product Models GMDN No: 13906 Class III

Synthetic, Sterile, Nonabsorbable, Multifilament, Braided, Silicon coated, Green or White colored Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5
EP:	0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 5 mm to 110 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Polytetrafluoroethylene (PTFE) Suture Product Models GMDN No: 13909 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Uncoated, White (Undyed) colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	6/0, 5/0, 4/0, 3/0, 2/0
EP:	0,7 1 1,5 2 3
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 5 mm to 110 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Stainless Steel Wire Product Models GMDN No: 15971 Sınıf IIb

Sterile, Nonabsorbable, Monofilament, Uncoated, Natural Metallic Colour Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7
EP:	1 1,5 2 3 3,5 4 5 6 6 7 8 9
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 10 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical, Polytetrafluoroethylene (PTFE) Pledget Product Models GMDN No: 31744 Sınıf III

Sterile, Nonabsorbable, Non-woven, White colored and in the following dimension ranges:	
Width	= 3 mm 150 mm
Length	= 3 mm150 mm
Height	= 1 mm 2 mm



C E R T I F I C A T E

EC Design-Examination Certificate

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2020.106.13692 the validity of the certificate M.2020.106.13692-1 will also end.

Company Name : Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş.

Company Address : Sağlık Mahallesi Sağlık 1 Sk. No:33/5 Çankaya ANKARA / TURKEY

Manufacturing and Storage : 29 Ekim Mahallesi Necip Fazıl Bulv. No:71 Yenikent Sincan ANKARA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive – Annex II (Section 4)

Product : Single use, Sterile Nonabsorbable Surgical Sutures - Class III
Single use, Sterile Nonabsorbable Teflon Pledget - Class III

GMDN : 13910, 38000, 13909, 13909, 13906, 31744, 13909, 15971

Product Types are attached.

Certificate Number : M.2020.106.13692-1

Report Number : MD.3532.IB

Initial Assessment Date : 08.11.2019

Registration Date : 29.06.2020

Revision Date /No : -

Expiry Date : 27.05.2024



UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

The EC design examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

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Surgical Silk Suture Product Models GMDN No: 13910 Class III

Natural, Sterile, Nonabsorbable, Multifilament, Braided, Black or Undyed colored, Silicon Coated, Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4
EP:	0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6
Thread Lengths :	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point

Surgical Polypropylene (PP) Suture Product Models GMDN No: 13909 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Blue colored, Uncoated, Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Thread Lengths :	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Poly(vinylidene difluoride) (PVDF) Suture Product Models GMDN No: 13909 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Blue colored, Uncoated, Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties	
USP:	10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm

Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Polyamide 6-6,6 (PA) Suture Product Models GMDN No: 38000 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Blue or Black colored, Uncoated Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 3 mm to 150 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Polyester (PET) Suture Product Models GMDN No: 13906 Class III

Synthetic, Sterile, Nonabsorbable, Multifilament, Braided, Silicon coated, Green or White colored Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5
EP:	0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 5 mm to 110 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical Polytetrafluoroethylene (PTFE) Suture Product Models GMDN No: 13909 Class III

Synthetic, Sterile, Nonabsorbable, Monofilament, Uncoated, White (Undyed) colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Thread Length, Needle Length, Needle Shape and Needle properties:	
USP:	6/0, 5/0, 4/0, 3/0, 2/0
EP:	0,7 1 1,5 2 3
Thread Lengths:	Variety of lengths, from 10 cm to 500 cm
Needle Lengths :	Variety of lengths, from 5 mm to 110 mm
Needle Shapes :	1/2, 3/8, 1/4, 5/8, Straight, J, SKI
Needle Properties:	Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Surgical, Polytetrafluoroethylene (PTFE) Pledget Product Models GMDN No: 31744 Sınıf III

Sterile, Nonabsorbable, Non-woven, White colored and in the following dimension ranges:	
Width	= 3 mm 150 mm
Length	= 3 mm150 mm
Height	= 1 mm 2 mm