

Silk

Surgical Suture, Silk, Silicone Coated
Nonabsorbable, Noncapillary

Surgical Sutures Non-Absorbable

Boz®



Definition

Natural Non-absorbable

Material

Natural Silk

Coating

Silicon Coated, Paraffin Wax, Uncoated

Structure

Braided, Twisted

Colour

Black, Ivory, methylene blue

Size

EP : 0.2 to 7

USP : 10/0 to 5

Tensile Strenght Retention

Moderate Loss

Mass Absorption

Permanent

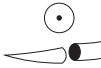
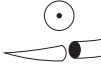
Sterilization Method

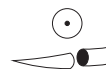
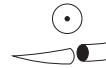
Ethylene Oxide Gas

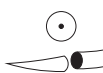
Main Indication

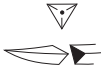
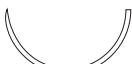
Ligatures
Skin Closure
Oral Surgery
Neurosurgery
Cardiovascular procedures
Ophthalmic procedures

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
6 mm							
3/8 Spatula 200 Micron			SB1120	9/0 0,3	30	12	Black
3/8 Spatula 220 Micron			SB1153	8/0 0,4	45	12	Black
6,55 mm							
3/8 Spatula 220 Micron			SB1174	8/0 0,4	45	12	Black
7,6 mm							
1/2 Reverse Cutting 330 Micron			SB5522	6/0 0,7	75	12	Black
8 mm							
1/2 Spatula 230 Micron			SB1197	8/0 0,4	45	12	Black
1/4 Spatula 330 Micron			SB1399	6/0 0,7	45	12	Black
			SB1761	5/0 1,0	45	12	Black
3/8 Round Body, Taper Point 230 Micron			SB1297	7/0 0,5	45	12	Black
3/8 Round Body, Taper Point 230 Micron			SB1209	8/0 0,4	45	12	Black
3/8 Reverse Cutting 280 Micron			SB1308	7/0 0,5	45	12	Black
3/8 Spatula 230 Micron			SB1201	8/0 0,4	45	12	Black
			SB1282	7/0 0,5	45	12	Black
3/8 Spatula 280 Micron			SB1414	6/0 0,7	45	12	Black
10 mm							
3/8 Round Body, Taper Point 330 Micron			SB1810	5/0 1,0	75	12	Black
3/8 Reverse Cutting 330 Micron			SB1495	6/0 0,7	45	12	Black

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
13 mm					
3/8 Round Body, Taper Point 330 Micron  	SB1581	6/0 0,7	45	12	Black
	SB1591	6/0 0,7	75	12	Black
3/8 Round Body, Taper Point 380 Micron  	SB1913	5/0 1,0	75	12	Black
3/8 Round Body, Taper Point 430 Micron  	SB2437	4/0 1,5	75	12	Black
3/8 Reverse Cutting 330 Micron  	SB1613	6/0 0,7	45	12	Black
3/8 Reverse Cutting 330 Micron  	SB1617	6/0 0,7	45	12	Black
3/8 Reverse Cutting 430 Micron  	SB1931	5/0 1,0	45	12	Black
	SB2446	4/0 1,5	45	12	Black
16 mm					
1/2 Round Body, Taper Point  	SB1653	6/0 0,7	45	12	Black
	SB1993	5/0 1,0	75	12	Black
	SB2505	4/0 1,5	75	12	Black
	SB3006	3/0 2,0	75	12	Black
1/2 Reverse Cutting  	SB3019	3/0 2,0	75	12	Black
3/8 Reverse Cutting  	SB1667	6/0 0,7	45	12	Black
	SB1671	6/0 0,7	75	12	Black
	SB2015	5/0 1,0	45	12	Black

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
16 mm							
3/8 Reverse Cutting			SB2023	5/0 1,0	75	12	Black
			SB2542	4/0 1,5	75	12	Black
3/8 Inside Cutting			SB1683	6/0 0,7	75	12	Black
			SB2145	5/0 1,0	75	12	Ivory
			SB2146	5/0 1,0	75	12	Black
			SB2558	4/0 1,5	75	12	Black
			SB3041	3/0 2,0	75	12	Black
18 mm							
1/2 Round Body, Taper Point			SB2176	5/0 1,0	75	12	Black
			SB2614	4/0 1,5	75	12	Black
			SB3082	3/0 2,0	75	12	Black
3/8 Round Body, Taper Point			SB4164	0 3,5	75	12	Black
3/8 Inside Cutting			SB2192	5/0 1,0	75	12	Black
			SB3094	3/0 2,0	75	12	Black
19 mm							
3/8 Reverse Cutting			SB5418	5/0 1,0	75	12	Black
			SB2641	4/0 1,5	75	12	Black
3/8 Inside Cutting			SB2662	4/0 1,5	75	12	Black

Needle Length and description		Product No	USP EP	Length (cm)	Unit Pcs	Color	
20 mm							
1/2 Round Body, Taper Point			SB2231	5/0 1,0	75	12	Black
			SB2687	4/0 1,5	75	12	Black
			SB3145	3/0 2,0	75	12	Black
			SB3649	2/0 3,0	75	12	Black
1/2 Reverse Cutting			SB2711	4/0 1,5	75	12	Black
			SB3163	3/0 2,0	75	12	Black
1/2 Inside Cutting			SB2725	4/0 1,5	75	12	Black
3/8 Reverse Cutting			SB2251	5/0 1,0	75	12	Black
			SB2720	4/0 1,5	75	12	Black
			SB3171	3/0 2,0	75	12	Black
			SB3664	2/0 3,0	75	12	Black
3/8 Inside Cutting			SB2257	5/0 1,0	75	12	Black
			SB2732	4/0 1,5	75	12	Black
			SB3183	3/0 2,0	75	12	Black
22 mm							
1/2 Round Body, Taper Point			SB2749	4/0 1,5	75	12	Black
1/2 Inside Cutting			SB3221	3/0 2,0	75	12	Black
			SB3687	2/0 3,0	75	12	Black

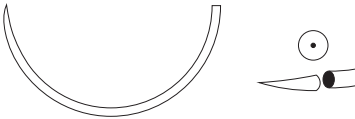
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25 mm						
3/8 Reverse Cutting  		SB2807	4/0 1,5	75	12	Black
		SB2279	5/0 1,0	45	12	Black
		SB2282	5/0 1,0	75	12	Black
		SB2813	4/0 1,5	45	12	Black
		SB3286	3/0 2,0	75	12	Black
3/8 Inside Cutting  		SB3764	2/0 3,0	75	12	Black
26 mm						
1/2 Round Body, Taper Point  		SB2831	4/0 1,5	75	12	Black
		SB3315	3/0 2,0	75	12	Black
		SB3789	2/0 3,0	75	12	Black
		SB4218	0 3,5	75	12	Black
1/2 Reverse Cutting  		SB3337	3/0 2,0	75	12	Black
		SB4231	0 3,5	75	12	Black
3/8 Reverse Cutting  		SB2854	4/0 1,5	75	12	Black
		SB3347	3/0 2,0	75	12	Black
		SB3825	2/0 3,0	75	12	Black
		SB4238	0 3,5	75	12	Black

Silk

Surgical Suture, Silk, Silicone Coated Nonabsorbable, Noncapillary

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
30 mm					
1/2 Round Body, Taper Point 	SB3371	3/0 2,0	75	12	Black
	SB3859	2/0 3,0	75	12	Black
	SB4245	0 3,5	75	12	Black
	SB4609	1 4,0	75	12	Black
1/2 Reverse Cutting 	SB3883	2/0 3,0	75	12	Black
	SB4267	0 3,5	75	12	Black
	SB4624	1 4,0	75	12	Black
3/8 Reverse Cutting 	SB2886	4/0 1,5	75	12	Black
	SB3399	3/0 2,0	75	12	Black
30 mm					
3/8 Reverse Cutting 	SB3893	2/0 3,0	75	12	Black
	SB4274	0 3,5	75	12	Black
	SB4630	1 4,0	75	12	Black
35 mm					
1/2 Round Body, Taper Point 	SB3917	2/0 3,0	75	12	Black
	SB4301	0 3,5	75	12	Black
	SB4646	1 4,0	75	12	Black

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
35 mm					
3/8 Reverse Cutting 	SB3425	3/0 2,0	75	12	Black
	SB3934	2/0 3,0	75	12	Black
	SB4663	1 4,0	75	12	Black
37 mm					
1/2 Round Body, Taper Point 	SB4339	0 3,5	75	12	Black
	SB4683	1 4,0	75	12	Black
1/2 Reverse Cutting 	SB4353	0 3,5	75	12	Black
	SB4695	1 4,0	75	12	Black
40 mm					
1/2 Round Body, Taper Point 	SB3983	2/0 3,0	75	12	Black
	SB4370	0 3,5	75	12	Black
	SB4716	1 4,0	75	12	Black
	SB5004	2 5,0	75	12	Black
1/2 Reverse Cutting 	SB4746	1 4,0	75	12	Black
	SB5020	2 5,0	75	12	Black
3/8 Reverse Cutting 	SB4409	0 3,5	75	12	Black
	SB4757	1 4,0	75	12	Black
	SB4759	1 4,0	90	12	Black

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
45 mm					
1/2 Round Body, Taper Point 	SB5037	2 5,0	75	12	Black
3/8 Reverse Cutting 	SB4788	1 4,0	75	12	Black
Straight Reverse Cutting 	SB3463	3/0 2,0	75	12	Black

50 mm					
Straight Reverse Cutting 	SB4048	2/0 3,0	75	12	Black

60 mm					
Straight Reverse Cutting 	SB3493	3/0 2,0	75	12	Black
	SB4076	2/0 3,0	75	12	Black

Non-Needle Suture	Product No	USP EP	Length (cm)	Unit Pcs	Color
10x75 cm					
SILK Non-Needle Suture	SB2340	4/0 1,5	10x75	12	Black
	SB2956	3/0 2,0	10x75	12	Black
	SB3549	2/0 3,0	10x75	12	Black
	SB4142	0 3,5	10x75	12	Black
	SB4552	1 4,0	10x75	12	Black
	SB4929	2 5,0	10x75	12	Black

12x45 cm					
SILK Non-Needle Suture	SB5840	0 3,5	12x45	12	Black
	SB5839	1 4,0	12x45	12	Black

13x60 cm					
SILK Non-Needle Suture	SB2348	4/0 1,5	13x60	12	Black
	SB2963	3/0 2,0	13x60	12	Black
	SB3555	2/0 3,0	13x60	12	Black
	SB4148	0 3,5	13x60	12	Black
	SB4558	1 4,0	13x60	12	Black

Non-Needle Suture	Product No	USP EP	Length (cm)	Unit Pcs	Color
17x45 cm					
SILK Non-Needle Suture	SB1740	5/0 1,0	17x45	12	Black
	SB2351	4/0 1,5	17x45	12	Black
	SB2964	3/0 2,0	17x45	12	Black
	SB3560	2/0 3,0	17x45	12	Black
	SB4151	0 3,5	17x45	12	Black
	SB4938	2 5,0	17x45	12	Black
	SB4561	1 4,0	17x45	12	Black

150 cm					
SILK Non-Needle Suture	SB2936	3/0 2,0	150	12	Black

180 cm					
SILK Non-Needle Suture	SB2940	3/0 2,0	180	12	Black
	SB3516	2/0 3,0	180	12	Black
	SB4119	0 3,5	180	12	Black
	SB4539	1 4,0	180	12	Black
	SB4914	2 5,0	180	12	Black
	SB5107	3 6,0	180	12	Black
	SB5133	4 6,0	180	12	Black

Prospektüs

Prospectus

İPEK - SILK

Emilemeyen Cerrahi Ameliyat İpliği

Non-Absorbable Surgical Sutures

Lütfen dilinizi seçiniz
Please select your language



TR

Kullanma Talimatı

İPEK

EMİLEMEYEN, CERRAHI İPEK İPLİK, USP/ EP/TS5505

TANIM

Cerrahi İpek iplik, fibroin adı verilen organik polimerden oluşan emilmeyen, steril, cerrahi ipliklerdir. Bu protein Bombisida familyasının evcilleştirilmiş Bombis mori (B.mori) türünden elde edilmiştir. Tabii ipek ipliğinin doğasında olan mum ve zamkalar işleme tabii tutularak uzaklaştırılmıştır. USP 7/0 yukarıda örgülü yapıya sahiptir. USP 7/0 ve 8/0 bükülü veya örgülü olarak mevcuttur. Cerrahi İpek iplik, siyah boyanmış ve parafin mumu (vaks) veya silikon ile kaplanmıştır. Siyah boyar madde Hematen HCK dir (C.I.-renk indeks no. 75290) İpek iplik kendi doğal renginde de (ivori-tiftiği) mevcuttur. Ham (virgin) ipek, serisin zamkı uzaklaştırılmış ve lifleri bir arada tutar şekilde de arz edilmektedir. Ham ipek metilen mavimsi (C.I. renk indeks no 52015) ile mavimsi veya hematini ile siyaha boyanmıştır.

Cerrahi İpek iplikler, Amerika Birleşik Devletleri Farmakopisi (U.S.P.) Emilebilir Olmayan Cerrahi Dikiş İplikleri Monografi ve Avrupa Farmakopisi (E.P.) Steril Örgülü İpek İplik Monografi şartlarına uygundur.

KULLANIMALANI

Cerrahi İpek iplik kalp-damar, oftalmik ve sinir cerrahisi uygulamaları dahil, genel yumuşak doku kapanmasında ve/veya bağlanmasında kullanılır.

ETKİLERİ

Cerrahi İpek iplik dokuda hafif bir şekilde akut yangı reaksiyonu oluşturabilir. Bu reaksiyonu iplik çevresinde doreceli olarak fibröz bağ doku oluşumunu takip eder. İpek iplik emilmeyen ip olmakla birlikte protein yapısındaki ipek liflerin organizma içinde zamanla parçalanması, iplik kopma mukavemetinde kademesi bir azalmaya neden olabilir.

KULLANILMAMASI GEREKEN YERLER

İpeğe karşı hassasiyeti veya alerjisi olduğu bilinen hastalarda kullanılmamalıdır. Ürün sürede organizma içerisinde meydana gelebilecek mukavemet kaybına bağlı olarak, kopma dayanımı direncinin kalıcı olması istendiği yerlerde ipek iplik kullanılmamalıdır.

UYARILAR

Yara ayrılması riski, uygulanan bölgeye ve kullanılan suture malzemesine göre değişikliğinden kullanıcının yara kapanması için SILK suture kullanmadan önce emilebilir olmayan sutureların kullanıldığı cerrahi prosedürler ve tekniklere aşina olması gerekir.

Tüm cerrahi işlemlerde olduğu gibi, uzun süreli tuz çözültüleri ile temasta, ürün sisteminde olduğu gibi, tortu oluşumu meydana gelebilir.

Tekrar steril etmeyiniz. Açılmış poşetleri ile kullanılmayan iplikler imha ediniz.

Enfekte veya kontamine yaraların tedavisinde kabul edilir cerrahi uygulamalar kabul edilmelidir.

Yedi günden fazla zaman deni dikisiyle bölgesel deri üstü tahrişe neden olabilir ve dışarda kalan kısım geç yedi gün arasında ayrılabilir.

ÖNEMLER

İpek ipliğin ve diğer tüm cerrahi iplerin kullanılmada ipliğe ve iğneye zarar vermekten kaçınılmalıdır. Forseps veya iğne tutucu gibi cerrahi aletlerin kullanılması bağlı ezme veya çarpma hatalarından kaçınılmalıdır.

Silik iplikler, uygulama özelliklerini artırmak için, cerrahi durum ve cerrahin deneyimine bağlı olarak yeterli düğüm güvenliği için silk dikişlerle birlikte kabul görmüş düğümler ve kare cerrahi düğüm teknikleri gereklidir.

İğne uçlarının ve bağlantı bölgesinin hasar görmemesi için, bağlantı ucu ve iğne ucu arasındaki mesafenin üçte biri (1/3) ile yansı (1/2) arasındaki kısımdan tutun. İğnelere yeniden şekillendirme, güçlerini kaybetmelerine ve bükülme ve kırılmaları karşı direncinin 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 kullanılması bağlı yan etkiler hastada alerjik reaksiyon olarak bilinen ipeğe duyarlılık, akut doku yangı reaksiyonu, yara çevresinde geçici bölgesel tahşiş/çermektir.

PİYASAYA ARZ-SUNUŞ ŞEKLİ

Cerrahi İpek iplikler U.S.P. 10/0 ve 5 (metrik 0.2-7.0) arasında, değişik boylarda, iğneli veya iğnesiz olarak mevcuttur. İğneli iplikler bir, iki veya üç düzlenlik kutularında bulunmaktadırlar. İpek iplikleri steril olarak arz edilir. Cerrahi ipek iplik tek kullanımlıktır.

DEPOLAMA

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

Nemden koruyunuz.

Son kullanma tarihinden sonra kullanmayınız.

ETİKETLEMEDE KULLANILAN İŞARETLER

	Tek kullanımlık		Boyasız, Emilemez, Bükümlü, Kaplanmalı
	Tekrar steril etmeyiniz		Boyalı, Emilemez, Bükümlü, Kaplanmalı
	Paket zarar görmüşse kullanmayınız		Katalog numarası
	Üretili		25°C'nin altında muhafaza ediniz
	Üretim tarihi, Yıl		Güneşten uzak tutunuz
	Son kullanma tarihi, Yıl-Ay		Nemden koruyunuz
	Steril EO: Etilenoksit		Ger döngümlü paket
	Seri No		Dikkat, Kullanma kılavuzuna bakınız
	Boyalı, Emilemez, Örgülü, Kaplanmalı		
	Boyasız, Emilemez, Örgülü, Kaplanmalı		

İU-SB-rev-04-05-05-2017

Issue date: 11.09.2012

"EASSI (Avrupa Cerrahi Suture Sanayi Birliği) çeşitli suture ürün karakteristیکlerini seçmiş ve resmî olarak tanımlamak için tasarımların bir sistem geliştirmiştir. Sembol kullanımları Tibbi Cihaz Direktifi (Medical Device Directive) (MDD 93/42/EEC) için vermektedir ve çoklu dil tercümesine gerek kalmadan üreticilerin kullanıcılarına bilgi sağlanmasına imkan tanımaktadır."



BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.

Sağlık Sokak No:33/5 Sıhhiye/ANKARA/TÜRKİYE

Tel:+90 (312) 435 50 80-81 Faks:+90 (312) 435 41 26

web: www.boztibbi.com e-mail: boz@boztibbi.com

Boz

GB

Instructions for Use

SILK

NONABSORBABLE, SURGICAL SILK SUTURE, USP/ EP/TS5505

DESCRIPTION

Silk suture is a nonabsorbable, sterile, surgical suture composed of an organic protein called fibrin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. Silk sutures are processed to remove the natural waxes and gums. Above USP 7/0 it is braided, USP 7/0 and 8/0 available braided or twisted. Silk suture is dyed black and coated with paraffin wax or silicone. Black dye is Hematein HCK (C.I. color index no. 75290). Silk suture is also available in its natural color, ivory. Virgin silk suture is available in which the sericin gum is not removed and serves to hold the filaments together. Virgin silk coloured blue by Methylene Blue (C.I. 52015) or black by Hematein.

Silk suture meets requirements established by the United States Pharmacopoeia (U.S.P.) for Nonabsorbable Surgical Suture Monogram and the requirements of Braided Silk Suture Monogram established by European Pharmacopoeia (E.P.).

INDICATIONS

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

ACTIONS

Silk suture elicits an acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. While silk sutures are not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of all of the suture's tensile strength over time.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to silk. Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, silk should not be used where permanent retention of tensile strength is required.

WARNINGS

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

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.

Do not re-sterilize. Discard opened packages and unused sutures.

Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

Skin sutures which remain in place for periods of longer than seven days may cause localized topical irritation and the extended portion of suture may be snipped off after five to seven days.

PRECAUTIONS

In handling this 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.

Silk 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 circumstance 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 Silk suture include, allergic response in patients that are known to be sensitive to silk, initial inflammatory tissue reaction and transitory local irritation at the wound site and infection.

HOW SUPPLIED

Silk sutures are available in U.S.P sizes 10/0 to 5 (metric sizes 0.2 - 7.0) in a variety of lengths and affixed to needles or non-needled. Silk sutures are available in one, two, and three dozen boxes. Silk suture is supplied sterile. Silk 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



Do not resterilize



Do not use if package is damaged



Manufacturer



YYYY-MM Date of Manufacture, Year



YYYY-MM Expiry Date, Year-Month



STERILE EO Sterile EO: Ethylene oxide



LOT Batch Number



Dyed, Non-absorbable, Braided, Coated



Undyed, Non-absorbable, Braided, Coated



Undyed, Non-absorbable, Twisted, Coated



Dyed, Non-absorbable, Twisted, Coated



REF Catalogue Number



Store below 25°C



Keep away from sunlight



Protect from humidity



Recyclable pack



Attention, See instruction for use



Attention, See instruction for use



Attention, See instruction for use



Attention, See instruction for use



Attention, See instruction for use



Attention, See instruction for use



Attention, See instruction for use



Attention, See instruction for use



Attention, See instruction for use

IFU-SB-rev-04-05-05-2017

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 permitted 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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Saglık Sokak No:33/5 Sıhhiye/ANKARA/TÜRKİYE

Tel:+90 (312) 435 50 80-81 Faks:+90 (312) 435 41 26

web: www.boztibbi.com e-mail: boz@boztibbi.com

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Mode d'emploi

SILK**FIL DE SOIE CHIRURGICAL NON RESORBABLE, USP/ EP/T55505****DEFINITION**

Le fil soyeux chirurgical est un fil chirurgical stéril, non absorbable, composé par des polymères organiques nommés fibroïnes. Cette protéine est obtenue de l'espèce de Bombyx mori (B. mori) domestiquée de la famille de Bombyxidae. La cre et les coites se trouvant dans la nature du fil soyeux naturel ont été éliminées par traitement. Il a une structure tissée au-dessus de USP 7/0. Il existe en USP 7/0 et 8/0 courbé ou tissé. Le fil soyeux chirurgical est teinté en noir est revêtu par la cre de paraffine (cire) ou la silicone. La substance noire de teinture est l'hémateine HCK (C.I.-nr. de l'index de couleur: 75290) Le fil soyeux existe dans sa couleur naturelle (ivoire). La série de soie vierge (virgin) est offert sans l'élimination de bleu et tenant les fibres toutes ensemble. La soie vierge est teintée en blanc avec le bleu de méthylène (C.I. nr. d'index de couleur 52015) ou en noir avec hémateine.

Les fils soyeux chirurgicaux sont conformes aux conditions à la Monographie des Fils de Suture Chirurgicaux non absorbables des Etats-Unis d'Amérique et à la Monographie des Fils Soyeux Tressés Stériles de la Pharmacopée Européenne (E.P.).

CHAMP D'UTILISATION

Le fil soyeux chirurgical est utilisé en général dans la fermeture et/ou la ligation des tissus mous, y incluses les applications des chirurgies cardiovasculaires, ophtalmiques et nerveuses.

EFFETS

Le fil soyeux chirurgical peut former une réaction légère acoute sur le tissu. Cette réaction est poursuivie par la formation graduelle du tissu conjonctif fibreux autour du fil. Malgré que le fil soyeux soit un fil non absorbable, la rupture des fibres soyeux de la structure de protéine dans l'organisme avec le temps peut causer une diminution graduelle dans la résistance de la rupture du fil.

CAUTION DE NON UTILISATION

On ne doit pas utiliser chez les patients ayant une sensibilité ou une allergie au soie. Dépendant de la perte de résistance pouvant survenir dans l'organisme dans un long délai, on ne doit pas utiliser le fil soyeux où l'on désire que la résistance de l'endurance de rupture soit permanente.

AVERTISSEMENTS

Comme le risque de séparation de plaie change selon la région appliquée et le matériel de suture utilisé, l'utilisateur, avant d'utiliser la suture de SOIE pour la fermeture de la plaie, doit être familiarisé aux procédures et techniques chirurgicales dans lesquelles on utilise les suture non absorbables.

Comme chez tous les fils chirurgicaux, dans le long contact avec les solutions salines, une formation de résidu peut se former comme chez le système urinaire. Ne pas restériliser. Détruire les sacs ouverts et les fils non utilisés.

On doit poursuivre les applications chirurgicales acceptables dans le traitement des plaies infectées ou contaminées.

Les suture cutanées restant plus de sept jours peuvent causer l'irritation de la peau et la partie restant à l'extérieur peut se séparer dans cinq sept jours.

MESURES

On doit éviter d'endommager le fil et l'aiguille lors de l'utilisation du fil soyeux et de tous les autres fils chirurgicaux. Évitez les erreurs comme l'écrasement ou le heurt venant de l'utilisation des appareils chirurgicaux comme les forceps ou le porte-aiguille.

Chez les fils soyeux, on nécessite les techniques de noeud carré ou plat chirurgical acceptées ensemble avec les sutures complémentaires pour la sécurité suffisante de noeud dépendant de la situation chirurgicale et l'expérience du chirurgien.

Chez les fils soyeux, on nécessite les techniques de noeud carré ou plat chirurgical acceptées ensemble avec les sutures complémentaires pour la sécurité suffisante de noeud dépendant de la situation chirurgicale et l'expérience du chirurgien. Pour que les extrémités de l'aiguille et la portion de connection ne s'endommagent pas, tenez par la partie entre le tiers (1/3) de la distance entre l'extrémité de connection et l'extrémité de l'aiguille et la moitié (1/2). La réformation des aiguilles peut causer la perte de leur force et la diminution de leur résistance contre les flexions et les ruptures. Il faut que les utilisateurs soient attentifs lors de l'usage de l'aiguille chirurgicale pour éviter les piqûres d'aiguille involontaires. Détruire les produits contaminés et non utilisés selon les exigences régionales et de l'installation.

Jeter les aiguilles utilisées dans les récipients "d'outil de coupe".

EFFETS ADVERSES

Les effets adverses vis-à-vis de l'utilisation de cet appareil couvrent la sensibilité au soie connue comme une réaction allergique chez le patient, la réaction d'inflammation acoute de tissu et l'irritation temporaire régionale autour de la plaie.

MODE DE PRESENTATION SUR LE MARCHE

Les fils soyeux chirurgicaux existent en dimensions variées entre U.S.P. 10/0 et 5 (métrique 0.2-7.0) avec ou sans aiguille.

Les fils soyeux se trouvent dans dans boîtes à une, deux et trois douzaines.

Le fil soyeux est présenté de façon stérile. Le fil soyeux chirurgical est pour usage unique.

EMMAGASINAGE

Emmagasiner sous 25°C et loin de la lumière solaire.

Protéger de l'humidité.

Ne pas utiliser après la date de dernière consommation.

SIGNES UTILISES POUR L'ETIQUETAGE

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

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

**BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.**

Saklı Sokak, No:3/50 Etiler/Beşiktaş/İSTANBUL

Tel:+90 (312) 435 50 80-81 Faks:+90 (312) 435 41 26

web: www.boztibbi.com e-mail: boz@boztibbi.com

قد بالتخلص من المنتجات الملوثة وغير المستخدمة بما يتناسب مع المتطلبات المحلية والصنعية.
قم بإلقاء الإبر المستخدمة في حاوية "A" لألوات الحادة

التأثيرات الجانبية

تتضمن التأثيرات الجانبية لاستخدام هذا الجهاز رد فعل تحسسي عند المرضى المعروف بحدوث حساسية تجاه الحبر لديهم، تقابل التهابي حاد في النسيج، وتخثر موضعي عابر في محيط الجرح.

التقديم في السوق

خيط جراحة حرة حرجة USP 10/0 بين 5 و 7.0 -0.2 (متر) بطول مختلفة، مع إبرة أو بدون إبرة.

توفر الخيوط الحرة حرجة في علم ذرية واحد، اثنان أو ثلاثة.

تقدم الخيوط الحرة حرجة بشكل معلم. الخيوط الحرة حرجة معدة لاستعمال لمرة واحدة.

التخزين

تُخزن في درجات حرارة أقل من 25 درجة مئوية وبعيدا عن أشعة الشمس.

التعليمات

لا تستخدم بعد انقضاء تاريخ انتهاء الصلاحية.

تعليمات الاستخدام

الخيوط الحرة حرجة غير قابلة للاستخدام U.S.P/ EP/TS5505

AR

تعريف

خيط الحبر الحرجة هو خيط جراحي معلم غير قابل للاستخدام مزك من بوليستر عضوي يسمى بوليستر بولي إيثيلين. يتم تصنيعه على هذا الموزن من ثلاثة دودة تقري (بوليستر بولي إيثيلين) من مادة القز. يتألف من ثلاثة أضع ونصف المصنع الموجود في خيط الحبر الحرجة عن طريق المعالجة. يتم بنية مجرولة USP أكثر من 7/0 و هم موجود كخيط مجرول أو من 7/0 USP و 8/0. تم مصابة خيط الحرجة الحرجة باللون الأسود وعلته يتم البياض (الشمع) أو السيلكون. إن مادة الصبغة السوداء هي الهيماتين HCK (رقم مؤشر المنصب اللون: 75290) وكذلك يوجد خيط الحبر الحرجة بولونه الطبيعي (اللون الأبيض). يوجد أيضا خيط الحرجة الذي يتجمع فيه الألياف ولم يتم تلوينه. لا تصنع السبريسين منه. تم مصابة خيط الحرجة بالآلوان مع أزرق الميثيلين (رقم مؤشر المنصب اللون: 52015) أو الهيماتين مع الأسود.

خيط الحبر الحرجة تتبع لمتطلبات الأدوية الأمريكية ودراسات خيط الحبر الحرجة الحرة حرجة القابلة للاستخدام ودراسات الأدوية الأوروبية ودراسات خيط الحبر الحرجة المجرولة المعطاة.

مجالات الاستخدام

تستخدم خيوط الحبر الحرجة في إغراق و/ أو وصل الأنسجة الناعمة العامة بما في ذلك التفتتات الحرة على القلب والأوعية الدموية، والعنق والأصابع.

التأثيرات

يمكن أن تسبب الخيوط الحرة حرجة في النسيج تقابل التهابي حاد بشكل خفيف. يتبع هذا التفاعل بشكل تسريع بعد إبرة في محيط الخيط. مع كون الخيط الحرجة غير قابل للاستخدام الحرجة فإن تسريع التهاب الحبر الحرجة الموجودة في بنية البروتين ضمن الكائن الحي مع مرور الزمن قد يسبب التفتتات تدرجي في قوة شد الخيط.

الأمكانات التي ينبغي تجنبها

ينبغي عدم استخدام الخيط عند المرضى المعروف بأن لديهم حساسية أو تحسّن تجاه الحبر. ينبغي عدم استخدام الخيط الحرة حرجة في الأماكن التي تتصلب قوة شد ناعمة.

تحذيرات

بما أن مخاطر اتصال الجرح تختلف تبعاً للمنطقة المغطى عليها والخيطات والمواد المستخدمة في خيطات الخيط، يتوجب على المستخدم قبل استخدام الخيط الحرجة إطلاع الجرح أن يكون على ذرية بالتفتتات والأجزاء الحرة حرجة التي تستخدم في الخيط غير قابل للاستخدام. كما هو الحال في جميع الخيوط الحرجة، يمكن أن يسبب تشكّل رواسب عند التماس مع محيط ملحية لفترة طويلة كما في الجهاز البولي.

لا يتم تعليمه مرة أخرى. تخلف من الجرح المفتوحة والخيوط غير المستخدمة.

ينبغي متابعة العلاجات الحرة حرجة المتزامنة مع معالجة الجروح المشتملة أو الملوثة.

توفر الخيط الحرجة في أكثر من سبعة أماكن يمكن أن تسبب تخثر موضعي في الجرح والقسيم المتبقي من الخيط خارج الجرح يمكن أن يفصل في خمسة إلى عشرة أيام.

الإجراءات الوقائية

ينبغي تجنب أية الخيط والإبرة عند استخدام الخيوط الحرة حرجة وكافة الخيوط الحرة حرجة الأخرى. تجنب أخطاء الملامسة والاحتكاك المرتبطة باستخدام الإبر الحرة حرجة مثل الملامسة وإحمال الإبرة.

من أجل زيادة الخصائص التطبيقية للخيوط الحرجة يتم استخدام التفتتات الحرة حرجة المقولة للحد من المساحة والعمق بالإضافة إلى غرز إضافية لأجل زيادة سلامة الغدة تحت الفك و ذلك يعتمد على الحالة الجراحية وعلى خبرة الجراح.

تجنب أية حواف الإبرة ومنطقة الوصل مع بسك الجزء من الثلث (1/3) والنصف (1/2) من المسافة الموجودة بين نقطة الوصل وحافة الإبرة. إبقاء شكل الإبرة من جديد قد يسبب فقد قوتها وانخفاض مقاومتها تجاه الانحناء والكسر. ينبغي على المستخدم توخي الحذر أثناء استخدام الإبرة الجراحية لتجنب الجرح الإبرة غير المتعمد.

الرموز المستخدمة في البطاقة

	2	لإستعمال مرة واحد
	♻️	عمر، غير قابل للاستخدام، مجرول، مصنع
	⛔	لا يتم بقاءه أو التخلص مرة أخرى
	⛔	ملون، غير قابل للاستخدام، مجرول، مصنع
	REF	رقم الكatalog
	100	تحتفظ لمدة 25 درجة مئوية
	YYYY	تاريخ الإنتاج / السنة
	YYYY-MM	تاريخ انتهاء الصلاحية / السنة / الشهر
	STERILE EO	معلم بالامتلاء
	LOT	رقم التسعير
	⚠️	ملون، غير قابل للاستخدام، مثقب، مصنع
	⚠️	عمر، غير قابل للاستخدام، مثقب، مصنع
	⚠️	قابلة لإعادة التدوير
	⚠️	تحذير: انظر إلى إشارات الاستخدام

CE 1014

Issue date: 11.09.2012

IFU-SB-rev-04-05-05-2017

"تمت" من الرابطة الأوروبية للصناعة المععدات الحرجة (EASST) بتطوير نظام مصمم لتعريف مختلف خصائص منتجات المععدات الحرجة بشكل مرئي ويهدف إلى إدارة الأجهزة الطبية (MDD 93/42/EEC) (Medical Device Directive) أتاح إمكانية استخدام الرموز وتوصيل المعلومات من المصنعين إلى المستخدمين مباشرة دون الحاجة إلى الترجمة لعدة لغات"

BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.
Saglık Sokak No:3/35 Şişli/İSTANBUL/TÜRKİYE
Tel:+90 (312) 435 50 80-81 Faks:+90 (312) 435 41 26
web: www.boztibbi.com.tr e-mail: boz@boztibbi.com

Boz



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	SILK Surgical, Silk Suture
Properties	Natural, Sterile, Non-Absorbable, Multifilament, Braided, Black or Undyed colored, Silicon Coated, Surgical Sutures are loop, single or with double needle or without needle, Single Use
Dye	Black; Hematein HCK (C.I. – colour index no. 75290) Undyed – Natural colour
Insulation/Coating	Silicone Coated
Product Models	For product models see page 2
Lot No	2101001..... 2112099
GMDN No	13910
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
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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-SB	Effective Date: 11.09.2012	Revision No: 08	Revision Date: 14.06.2021	Number of Pages: 1 / 4
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Surgical, Silk Suture Product Models

Natural, Sterile, Non-Absorbable, 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, Suture 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
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.

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-SB	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-SB	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 desing 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



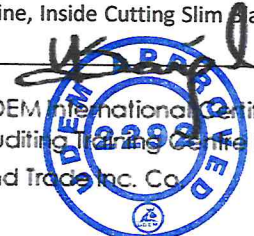
This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9177-1 and with the registration date of 15.01.2018 and with the revision date of 14.01.2021 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme 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



Address: Mutlukent 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 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 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.



Address: Mutlukent 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

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.



Address: Mutlukent 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

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.

Address: Mutlukent 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



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