

Monoprolen

Surgical Suture, Polypropylene (PP)
Nonabsorbable, Synthetic, Monofilament

Boz®



Definition

Synthetic Non-Absorbable

Material

Polypropylene (PP)

Coating

No Coating

Structure

Monofilament

Colour

Blue, Black, Undyed

Size

EP : 0.2 to 5

USP : 10/0 to 2

Tensile Strenght Retention

Permanent

Mass Absorption

Permanent

Sterilization Method

Ethylene Oxide Gas

Main Indication

Microsugery

Skin closure

Cosmetic Surgery

Cardiac Surgery

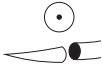
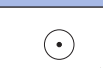
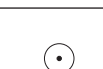
Vascular Surgery

Ophthalmic procedures

Neurosurgical procedures

Monoprolen

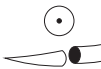
Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

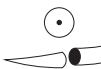
Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
5 mm							
3/8 Round Body, Taper Point 130 Micron			ML1047	10/0 0,2	13	12	Black
5.1 mm							
3/8 Round Body, Taper Point 100 Micron			ML1110	9/0 0,3	13	12	Blue
6 mm							
3/8 Round Body, Taper Point 130 Micron			ML1161	8/0 0,4	60	12	Blue
3/8 Round Body, Taper Point 220 Micron			ML1255	7/0 0,5	75	12	Blue
3/8 Round Body, Taper Point 150 Micron			ML1387	6/0 0,7	45	12	Blue
6.5 mm							
3/8 Spatula 130 Micron			ML1172	8/0 0,4	45	12	Blue
8 mm							
3/8 Round Body, Taper Point 220 Micron			ML1292	7/0 0,5	60	12	Blue
3/8 Round Body, Taper Point 220 Micron Black Needle			ML1422	6/0 0,7	60	12	Blue
3/8 Round Body, Taper Point 220 Micron Black Needle			ML1293	7/0 0,5	60	12	Blue
3/8 Round Body, Taper Point 230 Micron			ML1212	8/0 0,4	60	12	Blue
			ML1213	8/0 0,4	75	12	Blue
3/8 Round Body, Taper Point 230 Micron Black Needle			ML1211	8/0 0,4	60	12	Blue
3/8 Round Body, Taper Point 280 Micron			ML1300	7/0 0,5	45	12	Blue
			ML1305	7/0 0,5	60	12	Blue

Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
8 mm					
3/8 Round Body, Taper Point 280 Micron  	ML1425	6/0 0,7	45	12	Blue
	ML1430	6/0 0,7	60	12	Blue
3/8 Spatula 220 Micron  	ML1284	7/0 0,5	75	12	Blue

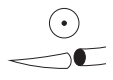
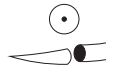
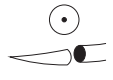
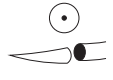
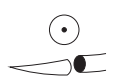
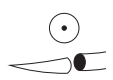
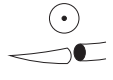
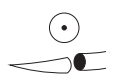
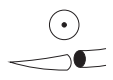
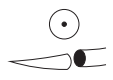
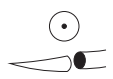
9 mm					
3/8 Round Body, Taper Point 230 Micron  	ML1313	7/0 0,5	75	12	Blue

10 mm					
1/2 Round Body, Taper Point 280 Micron  	ML1463	6/0 0,7	75	12	Blue
3/8 Round Body, Taper Point 220 Micron  	ML1326	7/0 0,5	60	12	Blue
3/8 Round Body, Taper Point 230 Micron Black Needle  	ML1324	7/0 0,5	75	12	Blue
3/8 Round Body, Taper Point 280 Micron  	ML1477	6/0 0,7	60	12	Blue
	ML1483	6/0 0,7	75	12	Blue
3/8 Round Body, Taper Point 280 Micron Black Needle  	ML1476	6/0 0,7	60	12	Blue
3/8 Round Body, Taper Point 330 Micron  	ML1801	5/0 1,0	60	12	Blue
	ML1802	5/0 1,0	75	12	Blue
3/8 Reverse Cutting 340 Micron  	ML1497	6/0 0,7	45	12	Blue

12 mm					
3/8 Round Body, Taper Point 280 Micron  	ML1346	7/0 0,5	75	12	Blue

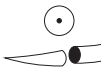
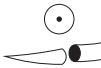
Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
13 mm							
1/2 Round Body, Taper Point 320 Micron			ML1882	5/0 1,0	75	12	Blue
1/2 Round Body, Taper Point 330 Micron			ML1565	6/0 0,7	75	12	Blue
1/2 Round Body, Taper Point 330 Micron			ML1566	6/0 0,7	75	12	Blue
			ML1569	6/0 0,7	90	12	Blue
1/2 Round Body, Taper Point 380 Micron			ML1884	5/0 1,0	75	12	Blue
1/2 Round Body, Taper Point 430 Micron			ML2427	4/0 1,5	75	12	Blue
1/2 Round Body, Taper Point 430 Micron			ML1898	5/0 1,0	75	12	Blue
			ML2428	4/0 1,5	75	12	Blue
3/8 Round Body, Taper Point 230 Micron			ML1363	7/0 0,5	60	12	Blue
3/8 Round Body, Taper Point 280 Micron			ML1571	6/0 0,7	60	12	Blue
3/8 Round Body, Taper Point 280 Micron Black Needle			ML1365	7/0 0,5	75	12	Blue
			ML1572	6/0 0,7	60	12	Blue
3/8 Round Body, Taper Point 330 Micron			ML1582	6/0 0,7	45	12	Blue
			ML1592	6/0 0,7	75	12	Blue
3/8 Round Body, Taper Point 330 Micron			ML1584	6/0 0,7	60	12	Blue
			ML1588	6/0 0,7	75	12	Blue
3/8 Round Body, Taper Point 330 Micron Black Needle			ML1593	6/0 0,7	90	12	Blue

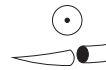
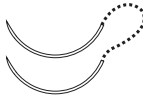
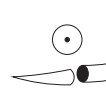
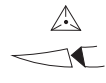
Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
13 mm							
3/8 Round Body, Taper Point 380 Micron			ML1910	5/0 1,0	60	12	Blue
3/8 Round Body, Taper Point 380 Micron			ML1917	5/0 1,0	75	12	Blue
3/8 Reverse Cutting 330 Micron			ML1612	6/0 0,7	45	12	Blue
3/8 Reverse Cutting 330 Micron			ML1621	6/0 0,7	75	12	Blue
3/8 Reverse Cutting 380 Micron			ML1927	5/0 1,0	45	12	Blue
3/8 Reverse Cutting 560 Micron			ML2454	4/0 1,5	45	12	Blue
3/8 Spatula 280 Micron			ML1606	6/0 0,7	75	12	Blue
16 mm							
1/2 Round Body, Taper Point			ML1987	5/0 1,0	45	12	Blue
			ML2506	4/0 1,5	75	12	Blue
			ML3007	3/0 2,0	75	12	Blue
1/2 Round Body, Taper Point			ML1658	6/0 0,7	90	12	Blue
			ML1998	5/0 1,0	90	12	Blue
			ML2514	4/0 1,5	90	12	Blue
			ML3010	3/0 2,0	90	12	Blue
1/2 Round Body, Taper Point Black Needle			ML1997	5/0 1,0	90	12	Blue
			ML2499	4/0 1,5	45	12	Blue

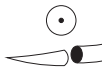
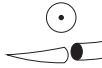
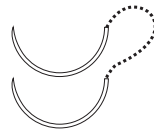
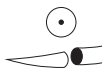
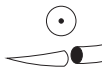
Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
16 mm							
3/8 Round Body, Taper Point			ML2007	5/0 1,0	75	12	Blue
3/8 Round Body, Taper Point			ML2009	5/0 1,0	90	12	Blue
			ML2524	4/0 1,5	90	12	Blue
3/8 Reverse Cutting			ML1669	6/0 0,7	45	12	Blue
			ML1672	6/0 0,7	75	12	Blue
			ML2017	5/0 1,0	45	12	Blue
			ML2126	5/0 1,0	90	12	Blue
			ML2536	4/0 1,5	45	12	Blue
			ML2541	4/0 1,5	75	12	Blue
			ML3027	3/0 2,0	75	12	Blue
3/8 Inside Cutting			ML1681	6/0 0,7	45	12	Blue
			ML2141	5/0 1,0	45	12	Blue
			ML2556	4/0 1,5	45	12	Blue
			ML3041	3/0 2,0	75	12	Blue
17 mm							
1/2 Round Body, Taper Point			ML1690	6/0 0,7	75	12	Blue
			ML2164	5/0 1,0	75	12	Blue
			ML3060	3/0 2,0	75	12	Blue

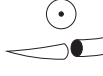
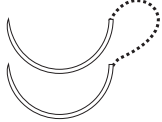
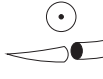
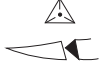
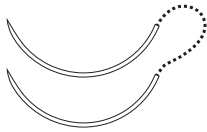
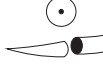
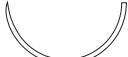
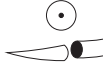
Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
17 mm							
3/8 Round Body, Taper Point			ML2169	5/0 1,0	90	12	Blue
			ML2595	4/0 1,5	90	12	Blue
18 mm							
1/2 Round Body, Taper Point			ML2615	4/0 1,5	75	12	Blue
19 mm							
3/8 Reverse Cutting			ML2207	5/0 1,0	75	12	Blue
			ML2642	4/0 1,5	75	12	Blue
20 mm							
1/2 Round Body, Taper Point			ML2230	5/0 1,0	75	12	Blue
			ML2684	4/0 1,5	75	12	Blue
			ML3143	3/0 2,0	75	12	Blue
			ML3647	2/0 3,0	75	12	Blue
1/2 Round Body, Taper Point			ML2234	5/0 1,0	90	12	Blue
			ML2696	4/0 1,5	90	12	Blue
			ML3155	3/0 2,0	90	12	Blue
1/2 Round Body, Taper Point Black Needle			ML2697	4/0 1,5	90	12	Blue
3/8 Reverse Cutting			ML2249	5/0 1,0	45	12	Blue
			ML2715	4/0 1,5	45	12	Blue

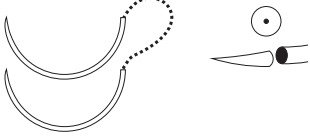
Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
20 mm							
3/8 Reverse Cutting			ML2721	4/0 1,5	75	12	Blue
			ML3166	3/0 2,0	45	12	Blue
			ML3169	3/0 2,0	75	12	Blue
3/8 Inside Cutting			ML2253	5/0 1,0	45	12	Blue
			ML2726	4/0 1,5	45	12	Blue
			ML3178	3/0 2,0	45	12	Blue
			ML3182	3/0 2,0	75	12	Blue
22 mm							
1/2 Round Body, Taper Point			ML2267	5/0 1,0	75	12	Blue
1/2 Round Body, Taper Point			ML2753	4/0 1,5	90	12	Blue
1/2 Inside Cutting			ML3218	3/0 2,0	45	12	Blue
3/8 Round Body, Taper Point			ML2270	5/0 1,0	90	12	Blue
			ML2758	4/0 1,5	90	12	Blue
25 mm							
1/2 Round Body, Taper Point			ML2785	4/0 1,5	45	12	Blue
			ML3253	3/0 2,0	75	12	Blue
			ML3725	2/0 3,0	75	12	Blue
			ML4194	0 3,5	100	12	Blue

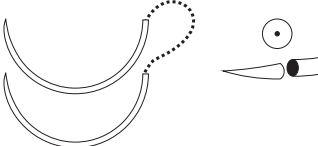
Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
25 mm					
1/2 Round Body, Taper Point 	ML2796	4/0 1,5	90	12	Blue
	ML3261	3/0 2,0	90	12	Blue
	ML3735	2/0 3,0	75	12	Blue
	ML3744	2/0 3,0	90	12	Blue
1/2 Round Body, Taper Point Black Needle 	ML2795	4/0 1,5	90	12	Blue
	ML3260	3/0 2,0	90	12	Blue
3/8 Reverse Cutting 	ML2806	4/0 1,5	75	12	Blue
	ML3272	3/0 2,0	45	12	Blue
3/8 Inside Cutting 	ML2811	4/0 1,5	45	12	Blue
	ML3283	3/0 2,0	45	12	Blue
	ML3761	2/0 3,0	45	12	Blue
26 mm					
1/2 Round Body, Taper Point 	ML2830	4/0 1,5	75	12	Blue
	ML3787	2/0 3,0	75	12	Blue
	ML4216	0 3,5	75	12	Blue
	ML4591	1 4,0	75	12	Blue
3/8 Reverse Cutting 	ML2853	4/0 1,5	75	12	Blue
	ML3348	3/0 2,0	75	12	Blue
	ML3823	2/0 3,0	75	12	Blue

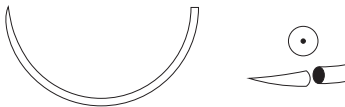
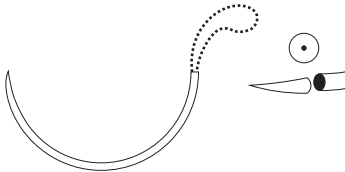
Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
30 mm					
1/2 Round Body, Taper Point 	ML2875	4/0 1,5	75	12	Blue
	ML3372	3/0 2,0	75	12	Blue
	ML3861	2/0 3,0	75	12	Blue
	ML4246	0 3,5	75	12	Blue
	ML4615	1 4,0	100	12	Blue
	ML4610	1 4,0	75	12	Blue
1/2 Round Body, Taper Point 	ML3378	3/0 2,0	90	12	Blue
	ML3867	2/0 3,0	90	12	Blue
1/2 Reverse Cutting 	ML3390	3/0 2,0	75	12	Blue
	ML3884	2/0 3,0	75	12	Blue
3/8 Reverse Cutting 	ML3398	3/0 2,0	75	12	Blue
	ML3894	2/0 3,0	75	12	Blue
	ML4276	0 3,5	75	12	Blue
	ML4631	1 4,0	75	12	Blue
35 mm					
1/2 Round Body, Taper Point 	ML3413	3/0 2,0	75	12	Blue
	ML3919	2/0 3,0	75	12	Blue

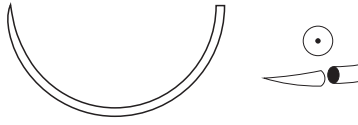
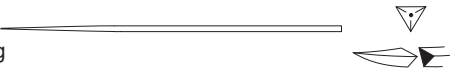
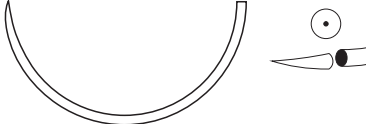
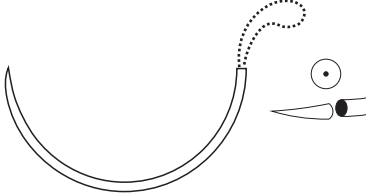
Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
35 mm					
1/2 Round Body, Taper Point 	ML4302	0 3,5	75	12	Blue
	ML4652	1 4,0	100	12	Blue
3/8 Reverse Cutting 	ML3426	3/0 2,0	75	12	Blue
	ML3936	2/0 3,0	75	12	Blue
	ML4321	0 3,5	75	12	Blue
	ML4662	1 4,0	75	12	Blue
40 mm					
1/2 Round Body, Taper Point 	ML3990	2/0 3,0	100	12	Blue
	ML4377	0 3,5	100	12	Blue
	ML4371	0 3,5	75	12	Blue
	ML4726	1 4,0	100	12	Blue
	ML4715	1 4,0	75	12	Blue
	ML5011	2 5,0	100	12	Blue
	ML5002	2 5,0	75	12	Blue
1/2 Round Body, Taper Point LOOP 	ML4387	0 3,5	150	12	Blue
	ML4737	1 4,0	150	12	Blue
1/2 Round Body, Taper Point Heavy 	ML4733	1 4,0	100	12	Blue

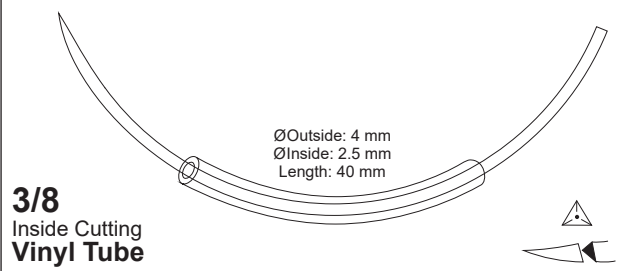
Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
40 mm					
1/2 Reverse Cutting 	ML4402	0 3,5	100	12	Blue
	ML4751	1 4,0	100	12	Blue
3/8 Reverse Cutting 	ML4009	2/0 3,0	100	12	Blue
	ML4413	0 3,5	100	12	Blue
	ML4760	1 4,0	100	12	Blue
45 mm					
1/2 Round Body, Taper Point LOOP 	ML4781	1 4,0	150	12	Blue
Straight Reverse Cutting 	ML4028	2/0 3,0	75	12	Blue
50 mm					
1/2 Round Body, Taper Point 	ML4820	1 4,0	100	12	Blue
	ML5071	2 5,0	100	12	Blue
1/2 Round Body, Taper Point LOOP 	ML4465	0 3,5	150	12	Blue
	ML4829	1 4,0	150	12	Blue
1/2 Reverse Cutting 	ML4837	1 4,0	100	12	Blue
60 mm					
Straight Reverse Cutting 	ML3495	3/0 2,0	75	12	Blue
	ML4077	2/0 3,0	75	12	Blue

Monoprolen

Surgical Suture, Polypropylene (PP) Nonabsorbable, Synthetic, Monofilament

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
90 mm					
 ØOutside: 4 mm ØInside: 2.5 mm Length: 40 mm 3/8 Inside Cutting Vinyl Tube	ML4887	1 4,0	2 X 50	12	Blue

Prospektüs

Prospectus

MONOPROLEN

Emilemeyen Cerrahi Ameliyat İpliği

Non-Absorbable Surgical Sutures

Lütfen dilinizi seçiniz
Please select your language



TR

Kullanma Talimatı

MONOPROLEN® POLİPROPİLEN İPLİK

EMİLEMİYEN CERRAHI İPLİK, U.S.P/ Eur.Ph./TSEK

TANIM

Monofilaman (renksiz ya da renklendirilmiş), emilemeyen, steril cerrahi iplik olan MONOPROLEN, polipropilenin izotaktik kristallerin stereozoomerinden oluşan, sentetik bir lineer poliolefinidir. Görünüşü ve dayanıklılığı artırarak için mayavi (C.I. #61568 veya C.I. #74160) ve siyah (C.I. #77266) boyanmıştır.

KULLANILAN ALANI

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

ETKİLERİ

Cerrahi MONOPROLEN iplik dokuda hafif bir şekilde akut yangınlama reaksiyonu gösterebilir, bu tepkiyi ipliğin çevresinde dereceli olarak fibröz bağ doku oluşumunu takip eder. MONOPROLEN iplik emilemez ve doku enzimleriyle zayıflamaz ve parçalanmaz. Monofilament olan MONOPROLEN enfeksiyona dirençli ve sonradan oluşabilecek sinüs formasyonu ve ipliğin atılımının en aza indirmek veya ortadan kaldırmak için enfekte veya kontamine olmuş yaralarda başarılı bir şekilde kullanılmaktadır. Dokulara yapışmaması MONOPROLEN ipliğin çıkarılıp, alınmasını kolaylaştırır.

KULLANILMAMASI GEREKEN YERLER

Bilinen yoktur.

UYARILAR

Yararın açılma riski, uygulama bölgesi ve kullanılan malzemeye göre değişebildiği için kullanılan MONOPROLEN ipliği kullanmadan önce emilebilir olmayan cerrahi iplerin kullanımına ilişkin iplik cerrahi yöntem ve tekniklere aşina olmalıdır.

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

ÖNEMLER

MONOPROLEN ipliğin kullanımında ipliğe ve iğneye zarar vermekten kaçınılmalıdır. Forseps veya iğne tutucu gibi cerrahi aletlerin kullanımına bağlı ezme veya çarpma hatalarından kaçınılmalıdır. Yeterli düğüm emniyeti için, tek ipliğin düz, kare düğümlenmesi şeklindeki kabul görmüş cerrahi teknik gereklidir. Polipropilen cerrahi iplik ile düğüm atarken ilave düğümlerin kullanımı özellikle uygun olur.

İğne uçlarının ve bağlantı bölgesinin hasar görmemesi için, bağlantı ucu ve iğne ucu arasındaki mesafenin üçte biri (1/3) ile yarısı (1/2) arasındaki kısmıdan tutun. İğneleri yeniden şekillendirmek, güçlerini kaybetmelerine ve büküme 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.

YANETKİLER

MONOPROLEN ipliğin kullanımına bağlı yan etkiler uzun süre tuz çözeltileri ile temasta üriner sistemde tortu oluşumunu, enfeksiyonu, minimal akut doku yangınlama reaksiyonu, yara bölgesinde geçici tahriş içermektedir.

PIYASAYARZ-SUNUŞ SEKİLİ

Boyanmış veya renksiz MONOPROLEN iplikler U.S.P. 10/0 ve 2 (metrik 0.2-5.0) arasında steril olarak mevcuttur.

MONOLENE iplikler değişik boyalarda, iğneli olarak arz ediliyor. MONOPROLEN iplikler boyanmış ve renksiz şekilde, polietetrafloroetilen (PTFE) tamponlarla (pledget) takılı biçimde de mevcuttur.

MONOPROLEN iplikler bir, iki veya üç düzinelik kutularda bulunmaktadır. MONOPROLEN iplik tek kullanımlıktır.

DEPOLAMA

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

Nemden koruyunuz.

Son kullanma tarihinden sonra kullanmayınız.

ETİKETLEMEDE KULLANILAN İŞRETLER

IFU-ML-rev-04-05-05-2017

Issue date: 11.09.2012

"EASSI (Avrupa Cerrahi Sütür Sanayi Birliği) çeşitli suture ürün karakteristیکlerini seçmiş ve resimsel olarak tanımlamak için tasarlanmış bir sistem geliştirmiştir. Sembol kullanımları Tıbbi Cihaz Direktifi (Directive) (MDD 93/42/EEC) için vermektedir ve çoklu dil tercümesine gerek kalmadan üreticilerin kullanıcılarına bilgi sağlamasına imkan tanımaktadır."



BOZ TIBBİ MALZEME SANAYİ VE TİCARİET A.Ş.

Sağlık Sokak No:33/5 Şişliye/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

MONOPROLEN® POLYPROPYLENE SUTURE
 NONABSORBABLE SURGICAL SUTURE, U.S.P./Eur.Ph./TSEK
DESCRIPTION

MONOPROLEN polypropylene suture (clear or pigmented) is a monofilament, non-absorbable, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The suture is pigmented blue (C.I. #61568 or C.I. #74160) and black (C.I. #77266) to enhance visibility.

INDICATIONS

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

ACTIONS

MONOPROLEN suture elicits a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. MONOPROLEN suture is not absorbed and it is not degraded or weakened by the action of tissue enzymes. As a monofilament, MONOPROLEN suture, resists involvement in infection and has been successfully employed in contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion. The lack of adherence to tissues has facilitated removing of MONOPROLEN suture.

CONTRAINDICATIONS

Not known.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing MONOPROLEN suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Do not sterilize. Discard opened packages 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 practice must be followed for the management of infected or contaminated wounds.

PRECAUTIONS

In handling this suture material, care should be taken to avoid damage to needle and suture from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Adequate knot security requires the accepted surgical technique of flat, square ties of single suture strands. The use of additional throws is particularly appropriate when knotting polypropylene sutures.

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 as are in accordance with local and facility requirements. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of MONOPROLEN suture 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

MONOPROLEN sutures pigmented or clear, are available as sterile strands in USP sizes 10/0 to 2 (metric sizes 0.2 to 5). MONOPROLEN sutures are available in a variety of lengths, with permanently attached needles. MONOPROLEN sutures, pigmented and clear, are also available attached to Polytetrafluoroethylene (PTFE) pledgets. MONOPROLEN sutures are available in one, two, and three dozen boxes. MONOPROLEN 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		Undyed, Non-absorbable, Monofilament
	Do not sterilize		Catalogue Number
	Do not use if pack age is damaged		Store below 25°C
	Manufacturer		Keep away from sunlight
YYYY 	Date of Manufacture, Year		Protect from humidity
YYMM 	Expiry Date, Year- Month		Recyclable pack
	Sterile EO: Ethylene oxide		Attention, See instruction for use
	Batch Number		1014
	Dyed, Non-absorbable, Monofilament		

IFU-ML-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."

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

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

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

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

FR

Mode d'emploi

MONOPROLEN® FIL POLYPROPYLENE **FIL CHIRURGICAL NON RESORBABLE, U.S.P./ Eur.Ph./TSEK**

DESCRIPTION

La suture MONOPROLEN polypropylène (claire ou pigmentée) est un monofilament, non-absorbable, élastique et chirurgical composée d'une cristalline isotactique stéréoisomère du polypropylène, au polyoléfine linéaire synthétique. La suture est pigmentée en bleu (C.I. #61568 or C.I. #74160) and black (C.I. #77266) pour augmenter la visibilité.

INDICATIONS

La suture MONOPROLEN est indiquée pour l'approximation et/ou ligature des tissus mous en général y inclus les applications cardiovasculaires, ophtalmiques et nerveuses.

EFFICACITE

La suture MONOPROLEN manifeste une faible réaction inflammatoire aigue dans le tissu, suivi d'une formation de tissu collagène fibreux. La suture MONOPROLEN n'est pas absorbée et n'est pas dégradée ou affaiblie par l'action des enzymes du tissu. Comme un mono-filament, la suture MONOPROLEN, résiste contre l'infection et elle est utilisée avec succès pour la formation de sinus susceptible de se présenter postérieurement et minimaliser ou supprimer le rejet du fil dans les plaies infectées ou contaminées. Le manque d'adhérence aux tissus a facilité le retrait de la suture MONOPROLEN.

CONTRE-INDICATIONS

Aucunes reconnues.

AVERTISSEMENTS

Les utilisateurs doivent être familiers aux procédures et techniques chirurgicales concernant les sutures non absorbable savant d'employer la suture MONOPROLEN pour la fermeture des plaies, car le risque de déhiscence de plaie peut varier avec la zone d'application et le matériel de suture utilisé. Ne pas restériliser. Détruire les sachets ouverts et les sutures non utilisées. Comen avec tout corps étranger, le contact prolongé de toute suture avec les solutions de sel, telles que celles trouvées dans les voies urinaires ou biliaires peuvent résulter à la formation de calcul. Une pratique chirurgicale acceptable doit être poursuivie pour la gestion des plaies contaminées ou infectées.

PRECAUTIONS

En manipulant ce matériel de suture, on doit être attentif à éviter d'endommager la suture et l'aiguille. Eviter des endommagements comme le broyage et le serrage résultant de l'application des outils chirurgicaux comme le forceps ou le porte-aiguille.

La sécurité de noue demande une technique chirurgicale acceptée don't lefil est noué en carré ou aplati est nécessaire. Il convient notamment utilise des noeuds supplémentaires en faisant des noeuds avec le fil chirurgical en polypropylène.

Pour éviter d'endommager les points de l'aiguille et les zones de d'étampe, agrippez l'aiguille dans une zone tierce (1/3) à une-demi (1/2) de la distance de l'extrémité foncée à la pointe.

Le remodelage des aiguilles peut leur causer une perte de force et les rendre moins résistantes à la flexion et à la rupture. Les utilisateurs doivent faire attention à la manipulation des aiguilles chirurgicales pour éviter les piqûres d'aiguilles accidentales.

La disposition des produits contaminés et non utilisés est en conformité avec les exigences locales et d'installation. Jeter les aiguilles utilisées dans des conteneurs pour "objets pointus".

EFFETS SECONDAIRES

Les effets secondaires liés à l'utilisation du fil MONOPROLEN sont la sédimentation dans le système urinaire par le contact prolongé avec les solutions de sel, la formation du calcul dans les voies urinaires et biliaires lorsqu'un contact prolongé est nécessaire avec les solutions salées comme l'urine et la bile, l'infection, la réaction minimale d'inflammation aigue et l'irritation provisoire locale dans la zone de plaie.

COMMERCIALISATION

Les sutures de MONOPROLEN pigmentées ou claires sont disponibles stériles en tresses et dimensions USP 10/0 to 2 (dimensions métriques 0.2 à5). Les sutures de MONOPROLEN sont disponibles dans une variété de longueurs avec des aiguilles attachées en permanence. Les sutures MONOPROLEN, pigmentées ou claires sont aussi disponibles attachées aux tampons d'ouate et Poly(tétrafluoroéthylène) (PTFE). Les suture MONOPROLEN sont disponibles dans des boîtes à un, deux et trois douzaines. La suture MONOPROLEN est pour utilisation unique.

CONSERVATION

Conserver sous la température de 25 °C et garder loin des rayons solaires. Protéger de l'humidité.

Ne pas utiliser après la date limite de consommation.

SIGNES UTILISES POUR L'ETIQUETAGE

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

ITU-ML-rev-04-05-05-2017

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 image les caractéristiques des différents produits de suture. Le langage sur les Dispositifs 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.

Sağlık Sokak No:33/5 Şişhiiye/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

مونوبلن MONOPROLEN* خيوط بوليبيروبيلان خيوط جراحية غير قابلة للامتصاص TSEK Ph// Eur. S.P.

التعريف :

تتكون خيوط مونوبلن MONOPROLEN مونيولامن (مونة أو غير مونة) من بوليبيروبيلاتات ستيريل وأيزوميرين كريسفال الأيزوتيك ، من بولي إيثيلين الخطي الصناعي ، كما تم تلويحه بمادة زرقاء مميزة عن الجراحية الحيوية (C.I. #61568 or C.I. #74160) والأسود (#77266) (C.I.).

الاستعمال

تستعمل خيوط مونوبلن MONOPROLEN الجراحية في عمليات القلب والأوعية الدموية الجراحية ، وجراحة لأعصاب والإفراطية ، وفي مجالات خيطة وعلاق جروح الأنسجة الناعمة بشكل عام و/أو في عملية الربط خيوط مونوبلن للاستعمال مرة واحدة فقط.

التحذيرات

يمكن أن تؤثر خيوط مونوبلن MONOPROLEN على الأنسجة بعملها تقابل معها على شكل التهاب أو تهيج خفيف ، هذا التأثير سيؤثر تدريجياً وبشكل منتشر على أطرافه في السنج الحيوي. خيوط مونوبلن MONOPROLEN غير قابلة للامتصاص ، لا يمكن لأثريمات الأنسجة الحيوية أن تضعفه أو تلتقه أو تقطعه. خيوط مونوبلن MONOPROLEN المتكونة من مونيولامنت مقاومة للأحماض والجراثيم. يستخدم بشكل ناجح وفعال في معالجة الجروح وتقليل أو منع أضرارها وتلويها بعد نزح الخيوط منها أو تقليل أو منع تكوين الجيوب التي يمكن أن تحدث بعد ذلك. من السهولة إزالة وزرع خيوط مونوبلن MONOPROLEN بجوانب التي يمكن أن تصدق مكان الجرح.

الاحتياطات التي لا يجوز فيها استعماله

لا توجد.

التحذيرات

بسبب أن خطورة حدوث الفتح بالجروح تختلف من منطقة إلى أخرى وتختلف أيضاً حسب المواد المستخدمة، فإنه يجب على مستخدمين خيوط مونوبلن MONOPROLEN الجراحية أن يكون لهم اطلاع على الطرق الجراحية والتقنيات المألوفة باستخدام الخيوط الجراحية غير القابلة للامتصاص قبل استخدامها. لا يجوز إعادة تعليم. التلوث الكيماوي للتغليف المعقود حتى أو كانت الخيوط غير مستعملة. من الممكن أن تسبب هذه الخيوط تكوين الحصى في الغدة الصفراء أو الحالب أو الكبد عند طائعات فترة زمنية مع المجالس المحلية الموجودة في تلك الأجهزة الحيوية. يجب اتباع الطرق الجراحية المعقولة في الجروح المتأثرة أو المصابة.

التعليمات

لتجنب الحق الضرر بالأداة أو خيوط مونوبلن MONOPROLEN عند الاستخدام تجنب الرفع أو إجهاد عملية سحب أو ضغط أو شد أو التواء الخيوط خلال استخدام الأدوات لجراحة مثل الملقاط أو المسحات وغيرها من الأدوات.

تتأثر بجري في عملية الخيطة باستخدام الخيوط الجراحية في كافة أنواع الجراحة، فإنه يجب استخدام تعليمات البعثة والمستوية والرمعة التي تعبر من الطرق المصنوعة والمرتبطة بفترة وتسمية الجراح وشروط الجراحة ، وذلك من أجل زيادة قابليته على الاستعمال المطلوب. خيوط مونوبلن الجراحية مناسبة للمزيد من أراء العدة في العمليات الجراحية.

لتجنب فطائر إبرة والمناطق الأرجح المعرض للضرر ، يجب أن يتم توجيه الإبرة في ثلث المساحة (3/1) في الصف (2/1) من مسافة واحدة من نهاية الإبرة إلى هذه النقطة إعادة تشكيل الإبرة قد تسبب دفع الفلور وتكون أقل مقاومة للثقب والكسر. يجب على المستخدمين توخي الحذر عند التعامل مع الجراحية لتجنب وخز الإبر غير المقصود.

لتفحص من المنتجات المتأثرة وغير المستخدمة يجب أن يكون وفقاً للمعطيات المحلية والمراقب ذات الصلة تجاهل الإبر المستخدمة في حواشي الفلوات "المادة".

التأثيرات الجانبية

من الممكن أن تحدث تهيجات مؤقتة في مناطق الجروح أو تورسات أو إصابات أو التهابات أو تفاعلات التهابية عند تماس خيوط مونوبلن MONOPROLEN لفترة طويلة مع المجالس المحلية الموجودة في الجهاز البولي كما يمكن حدوث العدوى، والحد الأدنى الحد من رد فعل الأنسجة المتأثرة، وتهيج موضعي مؤقت في موقع الجرح.

اشكال عرضه في الأسواق

يتم عرضه في الأسواق على شكل خيوط مونوبلن MONOPROLEN بألوان أو عديمة الألوان (شفاف) معقمة بأطول اقتران ما بين ١٠ / ٠ 2 (0.2 - 5.0 متر) خيوط مونوبلن MONOPROLEN موفرة بأطول مختلفة مع الإبرة و بدونها. تعتبر خيوط أحادية السطح، مسطحة بشكل واضح، وتوفر مرونة مع نتر فلوروفلورين (PTFE) أيضاً مونوبلن MONOPROLEN موفرة في طب تحتوي على زينة أحادية أو ثنائية أو ثلاثية. خيوط مونوبلن MONOPROLEN تستخدم لمرة واحدة فقط.

التخزين

يجب أن يتم عملية التخزين في درجة حرارة أقل من 25 درجة مئوية بعيدة عن أشعة الشمس والرطوبة. لا تستخدموا الخيوط النفاذة للاستخدام.

الرموز المستخدمة في البطاقة

	لا تستعمل مرة واحد	
	لا يتم إعادة التعقيم مرة أخرى	
	لا تستخدم إلا كانت العبوة الفاتكة	
	المصنع	
	تاريخ الإنتاج / السنة	
	YYYY-MM	
	تاريخ انتهاء الصلاحية / السنة / الشهر	
	معلمة بـ	
	رقم الفاتكة	
	مكون غلاف للاستعمال، احادي الفيل	

Issue date: 11.09.2012

ITU-ML-rev-04-05-05-2017

تحتفظ الرابطة الأوروبية للصناعة للمعدات الجراحية (EASSI) بتطوير نظام مصمم لتعريف مختلف خصائص منتجات المعدات الجراحية بشكل مرئي وبديهي كما أن إدارة الأجهزة الطبية "CEC" (Medical Device Directive) (MDD 93/42/EEC) أكدت إمكانية استخدام الرموز وتوصيل المعلومات من المصنعين إلى المستخدمين مباشرة دون الحاجة إلى الترجمة لعدة لغات

BOZ TIBBI MALZEME SANAYI VE TICARET A.Ş.
Sahitlik Sokak No:33/5 Sığırhisye/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



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	MONOPROLEN Surgical, Polypropylene (PP) Suture		
Properties	Synthetic, Sterile, Non-Absorbable, Monofilament, Blue colored, Uncoated, Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, Single Use		
Dye	Blue coloring material (C.I.-color index no 61568)		
Insulation/Coating	Uncoated		
Product Models	For product models see page 2		
Lot No	2101001..... 2112099		
GMDN No	13909		
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 Assessment 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		



Surgical, Polypropylene (PP) Suture Product Models

Synthetic, Sterile, Non-Absorbable, 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, Suture 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
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-ML	Effective Date: 11.09.2012	Revision No: 08	Revision Date: 14.06.2021	Number of Pages: 3 / 4
-----------------------------	-------------------------------	--------------------	------------------------------	---------------------------

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-ML	Effective Date: 11.09.2012	Revision No: 08	Revision Date: 14.06.2021	Number of Pages: 4 / 4
-----------------------------	-------------------------------	--------------------	------------------------------	---------------------------



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



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

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 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 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