



PGLA

Poly [glycolide(90%)-co-lactide(10%)]



Material

Poly [glycolide(90%)-co-lactide(10%)] , Synthetic

Colour

Violet Purple and Undyed

Structure

Braided-Multifilament

Coating

Calcium Stearate, %30 Glycolide, %70 Lactide

Tensile Strength

2nd week ~ %75 wound support

Absorbtion

~ 55 - 70 days

USP - EP Range

USP : 8/0 - 2 EP : 0.4 - 5

Sterilization

EO (Ethylene Oxide)

About of Glikolak Surgical Sutures

Glikolak sutures are synthetic, stripped, absorbable, sterile surgical sutures made from polyglycolide and lactide. Stripped sutures have special coating material. Coating of the sutures were made with Calcium Stearate and Poly (Glycolide Lactide)(30/70) mixture.

Glikolak sutures have violet colour to make surgical operations easier. Natural colouring agents were used in colouring process. Glikolak sutures are manufactured with or without stainless steel needle, at 8/0 range, and with various lengths between 30cm to 150cm.

Main Indication



Gastrointestinal Surgery



Gynaecology



Ophthalmic Surgery



Orthopedics



Urology

































Skin Closure



Ligatures

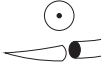
Glikolak

Surgical Suture, Poly[glycolide(90%)-co-lactide(10%)](PGLA)
Absorbable, Synthetic, Braided

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
6 mm							
3/8 Reverse Cutting 150 Micron			GL1165	8/0 0,4	45	12	Violet
3/8 Reverse Cutting 150 Micron			GL1256	7/0 0,5	45	12	Violet
3/8 Spatula 230 Micron			GL1155	8/0 0,4	30	12	Violet
3/8 Spatula 230 Micron			GL1253	7/0 0,5	45	12	Violet
8 mm							
1/2 Spatula 330 Micron			GL1394	6/0 0,7	30	12	Violet
1/4 Spatula 340 Micron			GL1405	6/0 0,7	45	12	Violet
1/4 Spatula 340 Micron			GL1404	6/0 0,7	30	12	Violet
			GL1764	5/0 1,0	45	12	Violet
3/8 Round Body, Taper Point 280 Micron			GL1299	7/0 0,5	45	12	Violet
3/8 Round Body, Taper Point 280 Micron			GL1432	6/0 0,7	75	12	Violet
3/8 Spatula 230 Micron			GL5827	8/0 0,4	45	12	Violet
3/8 Spatula 280 Micron			GL1413	6/0 0,7	45	12	Violet
10 mm							
3/8 Round Body, Taper Point 340 Micron			GL1803	5/0 1,0	45	12	Violet
3/8 Reverse Cutting 330 Micron			GL1496	6/0 0,7	45	12	Violet
3/8 Spatula 280 Micron			GL1450	6/0 0,7	45	12	Violet
3/8 Spatula 330 Micron			GL1790	5/0 1,0	75	12	Violet




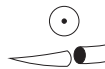








Glikolak

Surgical Suture, Poly[glycolide(90%)-co-lactide(10%)](PGLA)
Absorbable, Synthetic, Braided

Needle Length and description			Product No	USP EP	Length (cm)	Unit Pcs	Color
12 mm							
1/2 Round Body, Taper Point 430 Micron			GL1836	5/0 1,0	45	12	Violet
13 mm							
1/2 Round Body, Taper Point 330 Micron			GL1560	6/0 0,7	45	12	Violet
			GL1564	6/0 0,7	75	12	Violet
1/2 Round Body, Taper Point 430 Micron			GL1894	5/0 1,0	75	12	Violet
			GL1900	5/0 1,0	90	12	Violet
3/8 Round Body, Taper Point 330 Micron			GL1580	6/0 0,7	45	12	Violet
3/8 Round Body, Taper Point 380 Micron			GL1914	5/0 1,0	75	12	Violet
3/8 Round Body, Taper Point 430 Micron			GL2434	4/0 1,5	60	12	Violet
3/8 Reverse Cutting Premium 330 Micron			GL1626	6/0 0,7	45	12	Violet
16 mm							
1/2 Round Body, Taper Point			GL1990	5/0 1,0	75	12	Violet
			GL1994	5/0 1,0	75	12	Violet
1/2 Round Body, Taper Point			GL2504	4/0 1,5	75	12	Violet
			GL3005	3/0 2,0	75	12	Violet
3/8 Reverse Cutting			GL2021	5/0 1,0	75	12	Violet
			GL2540	4/0 1,5	75	12	Violet
			GL3025	3/0 2,0	75	12	Violet
3/8 Inside Cutting			GL2144	5/0 1,0	75	12	Violet








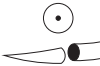



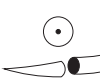
Glikolak

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Absorbable, Synthetic, Braided

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
16 mm					
3/8 Inside Cutting  	GL2557	4/0 1,5	75	12	Undyed
	GL2553	4/0 1,5	45	12	Violet
	GL3039	3/0 2,0	75	12	Violet
17 mm					
1/2 Round Body, Taper Point  	GL2165	5/0 1,0	75	12	Violet
18 mm					
1/2 Round Body, Taper Point  	GL2613	4/0 1,5	75	12	Violet
19 mm					
3/8 Reverse Cutting  	GL1706	6/0 0,7	75	12	Violet
	GL2206	5/0 1,0	75	12	Violet
	GL2640	4/0 1,5	75	12	Violet
	GL3109	3/0 2,0	75	12	Violet
20 mm					
1/2 Round Body, Taper Point  	GL2229	5/0 1,0	75	12	Violet
	GL2685	4/0 1,5	75	12	Violet
	GL2690	4/0 1,5	90	12	Violet
	GL3142	3/0 2,0	75	12	Violet
3/8 Reverse Cutting  	GL2716	4/0 1,5	45	12	Undyed
	GL3164	3/0 2,0	45	12	Violet
	GL3663	2/0 3,0	75	12	Violet


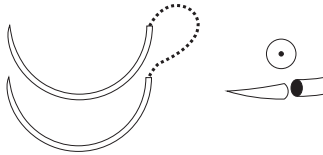



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Absorbable, Synthetic, Braided

Needle Length and description		Product No	USP EP	Length (cm)	Unit Pcs	Color	
25 mm							
1/2 Round Body, Taper Point			GL2788	4/0 1,5	75	12	Violet
			GL3252	3/0 2,0	75	12	Violet
			GL3746	2/0 3,0	100	12	Violet
			GL3724	2/0 3,0	75	12	Violet
25 mm							
3/8 Reverse Cutting			GL2804	4/0 1,5	75	12	Violet
3/8 Inside Cutting			GL2812	4/0 1,5	45	12	Violet
			GL3284	3/0 2,0	45	12	Violet
			GL3763	2/0 3,0	75	12	Violet
26 mm							
1/2 Round Body, Taper Point			GL3313	3/0 2,0	75	12	Violet
			GL4220	0 3,5	90	12	Violet
3/8 Reverse Cutting			GL2852	4/0 1,5	75	12	Violet
			GL3346	3/0 2,0	75	12	Violet
			GL3822	2/0 3,0	75	12	Violet
30 mm							
1/2 Round Body, Taper Point			GL3369	3/0 2,0	75	12	Violet
			GL3858	2/0 3,0	75	12	Violet
			GL3865	2/0 3,0	90	12	Violet

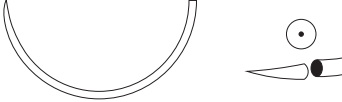





Glikolak

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Absorbable, Synthetic, Braided

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
30 mm					
1/2 Round Body, Taper Point 	GL4244	0 3,5	75	12	Violet
	GL4250	0 3,5	90	12	Violet
	GL4608	1 4,0	75	12	Violet
	GL4614	1 4,0	90	12	Violet
1/2 Round Body, Taper Point 	GL3854	2/0 3,0	75	12	Violet
3/8 Reverse Cutting 	GL3397	3/0 2,0	75	12	Violet
	GL3891	2/0 3,0	75	12	Violet
	GL3895	2/0 3,0	90	12	Violet
	GL4273	0 3,5	75	12	Violet
35 mm					
1/2 Round Body, Taper Point 	GL3916	2/0 3,0	75	12	Violet
	GL4300	0 3,5	75	12	Violet
	GL4644	1 4,0	75	12	Violet
	GL4649	1 4,0	90	12	Violet
3/8 Reverse Cutting 	GL3423	3/0 2,0	75	12	Violet
	GL3933	2/0 3,0	75	12	Violet
	GL5881	1 4,0	75	12	Violet

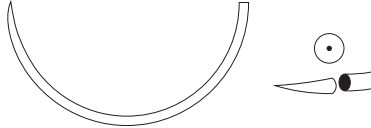
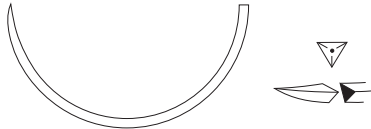



Glikolak

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Absorbable, Synthetic, Braided

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
40 mm					
1/2 Round Body, Taper Point 	GL3982	2/0 3,0	75	12	Violet
	GL4368	0 3,5	75	12	Violet
	GL4375	0 3,5	90	12	Violet
	GL4713	1 4,0	75	12	Violet
	GL4719	1 4,0	90	12	Violet
	GL5003	2 5,0	75	12	Violet
1/2 Reverse Cutting 	GL4399	0 3,5	90	12	Violet
	GL4749	1 4,0	90	12	Violet
	GL5019	2 5,0	75	12	Violet
3/8 Reverse Cutting 	GL4408	0 3,5	75	12	Violet
45 mm					
1/2 Round Body, Taper Point 	GL4772	1 4,0	75	12	Violet
	GL4775	1 4,0	90	12	Violet
	GL5035	2 5,0	75	12	Violet
3/8 Reverse Cutting 	GL4022	2/0 3,0	75	12	Violet
	GL4432	0 3,5	75	12	Violet
	GL4787	1 4,0	75	12	Violet
Straight Reverse Cutting 	GL2909	4/0 1,5	45	12	Violet

Glikolak

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Absorbable, Synthetic, Braided

Needle Length and description	Product No	USP EP	Length (cm)	Unit Pcs	Color
50 mm					
1/2 Round Body, Taper Point 	GL4454	0 3,5	75	12	Violet
	GL4459	0 3,5	90	12	Violet
	GL4812	1 4,0	75	12	Violet
	GL4818	1 4,0	90	12	Violet
	GL5066	2 5,0	75	12	Violet
	GL5070	2 5,0	90	12	Violet
1/2 Reverse Cutting 	GL5078	2 5,0	75	12	Violet
60 mm					
Straight Reverse Cutting 	GL2923	4/0 1,5	75	12	Violet
	GL3492	3/0 2,0	75	12	Violet
	GL4074	2/0 3,0	75	12	Violet
63 mm					
3/8 Blunt 	GL4858	1 4,0	75	12	Violet
64 mm					
3/8 Blunt 	GL4861	1 4,0	90	12	Violet

Glikolak

Surgical Suture, Poly[glycolide(90%)-co-lactide(10%)](PGLA)
Absorbable, Synthetic, Braided

Non-Needle Suture	Product No	USP EP	Length (cm)	Unit Pcs	Color
6x45 cm					
GLIKOLAK Non-Needle Suture	GL2950	3/0 2,0	6x45	12	Violet
	GL4137	0 3,5	6x45	12	Violet
	GL4563	1 4,0	6x45	12	Violet

12x45 cm					
GLIKOLAK Non-Needle Suture	GL2344	4/0 1,5	12x45	12	Violet
	GL2958	3/0 2,0	12x45	12	Violet
	GL3552	2/0 3,0	12x45	12	Violet
	GL4145	0 3,5	12x45	12	Violet
	GL4554	1 4,0	12x45	12	Violet

17x45 cm					
GLIKOLAK Non-Needle Suture	GL2966	3/0 2,0	17x45	12	Violet
	GL4559	1 4,0	17x45	12	Violet

10x50 cm					
GLIKOLAK Non-Needle Suture	GL4140	0 3,5	10x50	12	Violet
	GL2955	3/0 2,0	10x75	12	Violet

10x75 cm					
GLIKOLAK Non-Needle Suture	GL4550	1 4,0	10x75	12	Violet

Glikolak

Surgical Suture, Poly[glycolide(90%)-co-lactide(10%)](PGLA)
Absorbable, Synthetic, Braided

Non-Needle Suture	Product No	USP EP	Length (cm)	Unit Pcs	Color
150 cm					
GLIKOLAK Non-Needle Suture	GL1737	5/0 1,0	150	12	Violet
	GL2326	4/0 1,5	150	12	Violet
	GL2935	3/0 2,0	150	12	Violet
	GL3511	2/0 3,0	150	12	Violet
	GL4114	0 3,5	150	12	Violet
	GL4532	1 4,0	150	12	Violet

Prospektüs

Prospectus

GLIKOLAK

Emilebilir Cerrahi Ameliyat İpliği

Absorbable Surgical Sutures

Lütfen dilinizi seçiniz
Please select your language



GLIKOLİK

Cerrahi, Poliglaktid(90%)ko-laktid(10%)
Emilabilir PGLA Sütür
Sentezik, Multifilaman, Örgülü, Vücut/Undyed

Kullanma Talimatı**TANIM**

GLIKOLİK suture, %90 glükolik ve %10 L-laktid'ten (glükolik ve laktid asit türevi) sentezlenen bir kopolimerden oluşmuş, esnek yapıda, sentetik, emilabilir, sterili cerrahi ipliktir. Kopolimerin ampirik formülü $(C_4H_6O_4)_m(C_3H_4O_2)_n$ şeklindedir. Multifilaman suture, fiberlerin örülerek birleştirilmesi ile meydana gelmektedir.

GLIKOLİK suturen kaplama malzemesi eşit miktarda karıştırılan kalsiyum sitrat ($C_{12}H_{10}O_{14}$) ve %30 glükolik ile %70 laktid ($(C_4H_6O_4)_m(C_3H_4O_2)_n$ formülünde $m:n=3:7$ den hazırlanmaktadır. GLIKOLİK suture, canlı organizmada kullanıldığında emilabilir ve ayrı tahrişe neden olmaz. Kopolimer ve kaplama maddesi kalsiyum suturen, nonantjenik, nonporojenik ve emilme sırasında sadece hafif doku reaksiyona yolu açarlar.

GLIKOLİK cerrahi iplik USP 8/0 ve 2 (metrik 0.4-5.4) arasında, değişik boylarda, iğnesiz veya çipeli tip ve boyda paslanmaz çelik iğnelerle takvili olarak mevcuttur. GLIKOLİK suture, derinin altına girilmeden (D&C Violet No. 2 C.I. 8.02, FDA Part 74.3602 / Solvent Violet 13) rengine boyanmıştır. Bununla birlikte renksiz olarak da mevcuttur (doga, bey).

GLIKOLİK Suture Amerikan Farmakopisinde (U.S.P.) tanımlanmış olan "Emilabilir Cerrahi Sutureler Monografi" gereklilikleri ve Avrupa Farmakopisinde (E.P.) tanımlanan "Steril Sentezik Emililen Örgülü Sutureler Monografi: 01/2008:0667 gerekliliklerini, bazı kaplarda az miktarda büyük ölçekli harici olmak üzere sağlamaktadır.

KULLANILAN ALANI

GLIKOLİK suture oftalmik uygulamalarla da dahil olduğu geniş yumuşak doku kapaması veya bağa bağlanmasında kullanılır. Kalp-damar ve sinirsel dokularda kullanılmaz.

ETKİLERİ

GLIKOLİK suture, dokuda hafif aktif reaksiyonu ve fibröz bağ dokusuna neden olabilir. Hidrolik kademe edilmiş gereksiz ve zamanla gerilime mukavemetine azalma meydana gelir. Hidroliğin sonra karbondioksit ve su şeklinde vücuttan atılır. Emilin, gerilme kuvvetinin azalması ile bağlar ve buni kütle kaybı takip eder. Hayvan ve in-vitro hidrolik çalışmalar GLIKOLİK suturen implantasyondan 2 hafta sonra orijinal gerilme kuvvetinin %75'ini muhafaza ettiğini göstermiştir. En az 21-28 gün doku desteği sağlayan bu sutureler 55-70 gün içerisinde tamamen emilmektedir.

İmplantasyon Günü	Orjinal Mukavemetin Yaklaşık Kalan Yüzdesi
GLIKOLİK	
7 Gün	9.90
14 Gün	9.75
21 Gün (6-8 hafta kalın)	9.50
21 Gün (7-8 hafta kalın)	9.40
28 Gün (8-9 hafta kalın)	9.25

KULLANILMAMASI GEREKEN YERLER

Emilabilir iplik olmasından dolayı uzun süreli doku kapaması gereken yerlerde kullanılmamalıdır.

UYARILAR

Yararın aşırına riski, uygulama bölgesi ve kullanılmı malzemeye göre değişebildiği için kullanıcılara doku kapaması için suture kullanmadan önce emilabilir cerrahi ipliklerin kullanıldığında cerrahi yöntem ve tekniklere aşırı olmalıdır. Doktorlar hastalarla kullanıcılara suture seçimi yaparken in-vivo performans ("ETKİLERİ" bölümünde) göz önünde bulundurulmalıdır.

Bu suturen kullanımı geçiren dögmiş, bünseyi zayıf veya/ya da iyileşme cevabı yetersiz olan yapı hastalarla uygun olmayabilir.

İpliklerin saflığı ya da ümrin sisteminde bulunan tuz çözeltisi ile uzun süreli teması taş doku yarana neden olabilir.

GLIKOLİK emilabilir bir suture olduğundan; yayılımı, gerilimi, şişmesi ya da ilave destek istenen yaralı bölgenin kapamasında ek olarak emilmeyen sutureler ile kullanılmının gerekebileceği cerrah tarafından göz önünde bulundurulmalıdır.

Tekrar sterili etmeyiniz. Açılmış poşetleri ve kullanılmayan ipleri imha ediniz. Enfeksiye ve kontamine olmuş yaralarda kabul edilebilir cerrahi uygulamalar takip edilmelidir.

ÖNEMLER

Çilite 7 gündün fazla kalan dikiyler lokal tahrişe neden olabilir ve bu durumda dikiyler kesilmesi ya da çıkarılması gerekir. Bazı koşullarda özellikle ortopedi prosedürlerinde, cerrahin tahrihe bağlı olarak bağları, tendonları, diğer destekli hareketli bölge getirilmesi sağlanabilir.

Zayıf kan dolaşımının olduğu dokularda dikili atma ve geç emilim ösilebileceğinden, emilabilir ipliklerin kullanılması bu durumlarda dikkate alınmalıdır.

GLIKOLİK veya diğer sutureların kullanılması iğle ve iğneye zarar vermekten kaçınılmalıdır. Forseps veya iğne tutucu gibi cerrahi aletlerin kullanılması bağli ezme veya çarpma hatalarından kaçınılmalıdır.

İğne uçlarını ve bağları bölgesinin hasar görmemesi için, bağları su ve iğne su arasında dikili mesafenin üçte biri (1/3) ile yansı (1/2) arasındaki kısmattan tutun. İğneleri yeniden şekillendirmek, güçlerini kaybetmelerine ve bükülmeye ve kırılmalara karşı dikkatli kullanılması neden olabilir. İstem dışı iğne batmalarından kaçınmak için kullanıcıların cerrahi iğne kullanırken dikkatli olmaları gerekir.

GLIKOLİK iplikler, kullanan karakteristiktir atırmak için kabul görmüş düz ve kare düğüm teknikleri ile cerrahi duruma ve cerrahin atırmak istediği bağli doku içine düğüm teknikleri gerekliliklerdir.

Yüksek sıcaklıklara uzun süre maruz bırakılmamalıdır.

Kontamine ve kullanılmamış ürünleri bölgeye ve tesis gereksinimlerini uygun olarak imha ediniz.

Kullanılan iğneleri "kesici alet" kaplarına atınız.

YAN ETKİLERİ

Bu cihazın kullanılması bağli yan etkileri; yara bölgesinde gecici tahriş, akut doku yangı reaksiyonu, kızamık ve deri altı dikiylerin emilimi sırasında sertleşme şeklindedir. GLIKOLİK, bütün yabancı maddeler gibi, mevcut bir enfeksiyosunu artırabilir.

PİYASAYA SUNULUŞ ŞEKLİ

GLIKOLİK sutureleri, örgülü, boyanmış (mor) ve boyanmamış (beyaz), U.S.P. 8/0 ve 2 (metrik 0.4-5.4) arasında, değişik boylarda, çipeli tip ve ebatlarda paslanmaz çelik iğne veya iğnesiz olarak mevcuttur.

İplikler bir, iki veya üç düğümekli dokularda bulunmaktadır.

GLIKOLİK sutureler tek kullanımlıdır.

DEPOLAMA

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

Nemden korununuz.

Son kullanma tarihinden sonra kullanmayınız.

ETİKETLEMEDE KULLANILAN İŞRETLER

Tek kullanımlık



Boyasız, Emilabilir, Örgülü, Kaplamalı



Tokrar sterili etmeyiniz



Katalog numarası



Paket zarar görmüşse kullanmayınız



25°C'nin altında muhafaza ediniz



Üretici



Günepten uzak tutunuz



Üretim tarihi, Yıl



Nemden korununuz



YYYY-MM Son kullanma tarihi, Yıl/ay



Geri dönüştürümlü paket



STERILE EO Steril Eto: Etilenoksit



Dikkat, Kullanma Kılavuzuna bakınız



Seri No



Boyalı, Emilabilir, Örgülü, Kaplamalı



2292

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"EASSİ (Avrupa Cerrahi Suture Sanayi Birliği) çipeli suture ürün karakteristیکlerini seçtiği ve resimsel olarak tanımladığı için tasarlama bir sistem geliştirmiştir. Sembol kullanılması Tıbbi Cihaz Direktifi (Medical Device Directive) (MDG 93/42/EEC) için vermektedir ve çipeli di türlerine gerek kalmadan ürünlerin kullanıcılarına bilgi sağlanmasına imkan tanımaktadır."



BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.

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GLIKOLAK**Instruction for Use**

Surgical, Poly(glycolide(90%-co-lactide)(10%))
Absorbable PGLA Suture
Synthetic, Multifilament, Braided, Violet/Undyed

DESCRIPTION

GLIKOLAK suture is synthetic absorbable sterile surgical suture which is flexible strand composed of a copolymer synthesized from 90% glycolide and 10 % L-lactide (derived from glycolic and lactic acids). The empirical formula of the copolymer is $(C_4H_6O_4)_m(C_3H_4O_3)_n$. Multifilament suture is consisting of elementary fibres which are assembled by braiding.

GLIKOLAK suture is prepared by coating suture material with a mixture composed of equal parts calcium stearate ($C_{18}H_{35}O_2$) and 30% glycolide and 70% lactide ($C_3H_4O_3$) where $m+n=3.7$. When GLIKOLAK suture is introduced into a living organism it is absorbed by that organism cause no undue tissue irritation. Copolymer and the coating with calcium stearate have been found to be nonantigenic, nonpyrogenic and elicit only a mild tissue reaction during absorption.

GLIKOLAK suture has been presented in USP 80 to 2 (metric sizes 0.4 and 5) gauge sizes in a variety of lengths, as non-needled or attached to stainless steel needles of varying types and sizes. The suture is colored with violet (D&C Violet No. 2 C.I. # 60725, FDA Part 74.3602 / Solvent Violet 13) to enhance visibility in tissue. The suture is also available in the undyed (natural beige) form.

GLIKOLAK sutures meet United States Pharmacopoeia (U.S.P.) requirements as described in the U.S.P. "Monograph for Absorbable Surgical Sutures" and European Pharmacopoeia (E.P.) requirements as described in the E.P. "Monograph for Sutures. Sterile Synthetic Absorbable Braided; 012008.0667" with the exception of an occasional slight oversize in some gauges.

INDICATIONS

GLIKOLAK suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures but not for use in cardiovascular and neurological tissues.

ACTIONS

GLIKOLAK suture elicits a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of suture occurs by means of hydrolysis gradually and decrease the strength in the body. After hydrolysis it is excreted from the body as carbon dioxide and water. Absorption begins as a loss of tensile strength followed by a loss of mass.

Animal and in-vitro hydrolysis studies indicate that GLIKOLAK suture retains approximately 75% of the original tensile strength (Break Strength Retention-BSR) after two weeks post implantation. This suture provides tissue supporting during 21-28 days and suture absorption is essentially complete between 55 and 70 days.

Days Implantation	Approximate % Original Strength Remaining (%Break Strength Retention-BSR)
	GLIKOLAK
7 Days	90%
14 Days	87%
21 Days (B-S and larger)	80%
21 Days (L-S and larger)	84%
28 Days (B-S and larger)	92%

CONTRAINDICATIONS

This suture, being absorbable, should not be used where extended approximation of tissues is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) when selecting a suture for use in patients. The use of this suture may be inappropriate in elderly malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.

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

As GLIKOLAK is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching, or distension, or which may require additional support. Do not re-sterilize. Discard open packages and unused sutures.

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

PRECAUTIONS

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed. Under some circumstances, notably orthopedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply, as suture extrusion and delayed absorption may occur.

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

To avoid damaging needle points and suture areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the suture 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.

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

Avoid prolonged exposure to elevated temperatures.

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

ADVERSE REACTIONS

Adverse reactions associates with the use of GLIKOLAK suture include transitory local irritation at the wound site, acute inflammatory tissue reaction, erythema and induration during the absorption process of subcuticular sutures. Like all foreign bodies GLIKOLAK may potentiate an existing infection.

HOW SUPPLIED

GLIKOLAK suture is available sterile, as braided dyed (violet) and undyed (natural) strands in sizes 8/0 to 2 (metric sizes 0.4 - 5) in a variety of lengths, as non-needled or attached to stainless steel needles of varying types and sizes. Suture is available one, two and three dozen in boxes. GLIKOLAK suture is for single use only.

STORAGE

Store below 25 °C and keep away from sunlight. Protect from humidity. Do not use after expiry date.

SYMBOLS USED ON LABELLING

Do not reuse



Do not re-sterilize



Do not use if package is damaged



Manufacturer



Date of Manufacture, Year



YYYY-MM Expiry Date, Year-Month



STERILE EO Sterile EO: Ethylene oxide



Lot Batch Number



Dyed/Absorbable, Braided, Coated



Undyed/Absorbable, Braided, Coated



REF Catalogue Number



Store below 25°C



Keep away from sunlight



Protect from humidity



Recyclable pack



Attention, See instruction for use



CE 2292

IFU-GL-rev-06-15-01-2018

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

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GLIKOLAK**Mode d'emploi**

Chirurgie, Poly(Glycolique(90%)-colactide(10%))
 PGLA absorbable Suture
 Synthétique, Multifilament, Tressé, Violet/Non coloré

DESCRIPTION

La suture de GLIKOLAK est une suture synthétique absorbable stérile chirurgicale. Étant une tresse flexible composée par un copolymère synthétisé de 90% de glycolide et 10 % L-lactide (dérivé de l'acide glycolique et les acides lactiques). La formule empilée du copolymère est $(C_4H_6O_4)_m(C_3H_4O_2)_n$. La suture de multi-filament consiste aux fibres élémentaires qui sont assemblées par tressage.

La suture GLIKOLAK est préparée en revêtant le matériel de suture avec un mélange composé des parts égales de calcium stéarate $(C_{18}H_{35}O_2Ca)$ et 30% de glycolide et 10 % de lactide $(C_4H_6O_4)_m(C_3H_4O_2)_n$ ou $n:m=3:7$). Lorsque la suture de GLIKOLAK est introduite dans un organisme vivant il est absorbé par cet organisme causant une légère irritation de tissu. Le Copolymère et le revêtement avec le calcium stéarate ont été trouvés être non antitoxiques, non pyrogéniques et activent seulement une faible réaction de tissu lors de l'absorption.

La suture de GLIKOLAK est présentée en USP 8/0 à 2 (métrique) (4 ou 5) dimensions de jauge dans une variété de longueurs, comme sans aiguilles ou attachées aux aiguilles d'acier inoxydable en types et dimensions variées. La suture est colorée en violet (D&C Violet No. 2, I, II 60725, FDA Part 74.3625 / Solvent Violet 13) pour permettre la visibilité dans le tissu. La suture est aussi disponible en forme non peinte (naturel beige).

La suture de GLIKOLAK couvre les exigences de la Pharmacopée des États-Unis (U.S.P) comme décrites dans le "U.S.P. Monographie pour Sutures Chirurgicales, Absorbables" et les exigences de la Pharmacopée Européenne (E.P) comme décrites dans le "P. Monographie pour Sutures, Stériles Synthétiques Absorbables Tressées ; 01/2006:0667" avec l'exception rare d'une sur dimension faible dans certaines jagues.

INDICATIONS

La suture GLIKOLAK est indiquée dans l'usage en général de l'approximation et/ou ligature du tissu mou ; y inclus l'utilisation dans les procédures ophtalmiques mais non pour l'usage dans les tissus cardiovasculaires et neurologiques.

EFFICACITÉ

La suture GLIKOLAK peut donner lieu à une faible réaction d'inflammation dans le tissu et un tissu connecté peut se produire dans le tissu. La résistance de la suture PGDL diminue par l'hydrolyse et son absorption se réalise. Après l'hydrolyse il est rejeté du corps comme carbone dioxyde et eau. L'Absorption commence comme une perte de force de détachement poursuivi par une perte de masse.

Les études d'hydrolyse sur les animaux et in-vitro montrent que la suture GLIKOLAK retient environ 75% de sa force de tension originale dans deux semaines après l'implantation. La suture supporte le tissu pendant 21/28 jours et l'absorption de la suture est essentiellement complète entre 55 et 70 jours.

Le jour d'implantation	Le pourcentage approximatif restant de la résistance originale	GLIKOLAK
7 jours	90%	95%
14 jours	80%	85%
21 jours (8-0 et 6-0)	70%	75%
21 jours (5-0 et 4-0)	60%	65%
28 jours (3-0 et 2-0 et 1-0)	50%	55%

CONTRE-INDICATIONS

Cette suture, étant absorbable, ne doit pas être utilisée où une approximation étendue du tissu est demandée.

AVERTISSEMENTS

Les utilisateurs doivent être familiers avec les procédures et techniques chirurgicales couvrant les sutures absorbables avant l'emploi pour la fermeture de plaie, car le risque de déhiscence de la plaie peut varier avec la zone d'application et le matériel de suture utilisé. Les physiologistes doivent considérer la performance in vivo (sous la section EFFICACITÉ) en choisissant la suture pour l'utilisation chez les malades.

L'utilisation de cette suture peut être non appropriée chez les patients âgés mal nourris ou débilisés souffrant des conditions pouvant retarder la guérison de la plaie. Comme 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.

La suture GLIKOLAK étant une suture absorbable matériel de suture absorbable, l'usage des sutures non absorbables supplémentaires doit être considéré par le chirurgien dans la fermeture des zones montrant une dilatation, un étirement ou distension ou qui peut demander un support adjuvant.

Ne pas re-stériliser. Détruire les sachets ouverts et les fils non utilisés.

Des pratiques chirurgicales acceptables doivent être suivies pour la gestion des plaies contaminées et infectées.

PRÉCAUTIONS

Les suture de la peau qui doivent rester en place plus de 7 jours peuvent causer une irritation et doivent être découpées ou enlevées comme indiqué. Sous certaines circonstances, notamment des procédures orthopédiques, l'immobilisation des joints par un support externe peut être employé à la discrétion du chirurgien.

Considération doit se faire dans l'usage des sutures absorbables dans les tissus avec fourniture facile de sang car l'extrusion de la suture et une absorption retardée peuvent se produire.

Lors de la manipulation du GLIKOLAK ou d'autres matériaux de suture, on doit être attentif à éviter d'endommager la suture et l'aiguille. Éviter les endommagements comme le broyage et le serrage résultant de l'application des outils chirurgicaux comme le forceps ou le porte-aiguille. Pour éviter d'endommager les points de l'aiguille et les zones d'étampage, agrippez l'aiguille dans une zone tierce (1/3) à une-demi (1/2) de la distance de l'extrémité forcée à la pointe. Le remède/déplacement des aiguilles peut leur causer une perte de force et les rendre moins résistants à la flexion et à la rupture. Les utilisateurs doivent faire attention à la manipulation des aiguilles chirurgicales pour éviter les piqûres d'aiguilles accidentelles.

Les suture GLIKOLAK qui sont traitées pour augmenter les caractéristiques de manipulation demandant la technique chirurgicale acceptées des nœuds droits et carrés avec des jets supplémentaires comme garantissant les circonstances chirurgicales et les expériences du chirurgien.

Eviter l'exposition prolongée aux températures élevées.

Disposer les produits contaminés et les produits non utilisés en conformité aux exigences locales. Détruire les aiguilles utilisées dans des conteneurs "pointus".

EFFETS SECONDAIRES

Les effets secondaires associés avec l'utilisation des suture de GLIKOLAK couvrent une irritation transitoire locale sur la zone de la plaie, la réaction inflammatoire aigüe du tissu, l'erythème et l'induration lors du processus d'absorption des sutures sous-cuticulaires. Comme tous les corps étrangers, GLIKOLAK peut potentialiser une infection existante.

COMMERCIALISATION

La suture de GLIKOLAK est disponible stérile, en tresse peinte (violet) et non peinte (naturel) dans les dimensions de 8/0 à 2 (métrique) (4-5) en une variété de longueurs, comme sans aiguilles et attachées aux aiguilles en acier inoxydable dans des types et dimensions variées. La suture est disponible dans des boîtes de une, deux, trois douzaines. La suture de GLIKOLAK 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



Ne pas stériliser à nouveau



Ne pas utiliser si l'emballage est endommagé



Fabricant



YYYY-MM Date de production, Année



YYYY-MM Date d'expiration, Année - mois



STERILE EO Stérile EO: Traçage d'éthylène



LOT No de série



Avec peinture, absorbable, tressé, revêtu



Sans peinture, absorbable, tressé, revêtu



REF Numéro de catalogue



Conserver sous 25°C



Protéger du soleil



Conserver dans un lieu sec



Emballage recyclable



Attention, Voir les instructions d'utilisation



CE 2292

EU-GL-REV-06-15-01-2018

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



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Declaration of Conformity

Manufacturer	BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.
Address	Sağlık Mah. Sağlık 1 Sk. No:33/5 Çankaya / ANKARA / TÜRKİYE
Product Name	GLIKOLAK Surgical, Poly[glycolide (90%)-co-lactide (10%)] (PGLA) Suture
Properties	Sterile, Synthetic, Absorbable, Braided, Multifilament, Undyed or Violet colored, Coated, With or Without Needles, Single Use
Dye	Violet coloring material D&C Violet no.2- C.I. 60725 Undyed (natural, beige)
Insulation/Coating	Poly(glycolide-co-lactide)(30/70) + Calcium stearate
Product Models	For product models see page 2
Lot No	2101001..... 2112099
GMDN No	17471
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 of 93/42/EEC</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 see page 3, 4, 5 and 6	
Notified Body	UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. Mutlukent Mahallesi 2073 Sokak No:10 Umitköy-Çankaya ANKARA TÜRKİYE
Notified Body No	CE 2292

European Authorised Representative	EMERGO Prinsessegracht 20 2514 AP The Hague The Netherlands Phone +31.70.345.8570 - Fax +31.70.346.7299 – EmergoEurope@ul.com
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Certificate	Certificate No	Certificate Date	Date of Validity
EC Design Examination Certificate	M.2018.106.9177-1	15.01.2018	14.01.2023
Full Quality Assurance System	M.2018.106.9177	15.01.2018	14.01.2023

Place, Date Ankara, 10.11.2021

Signature
Name 
Position Adil BOZ
 General Manager

Surgical, Poly[glycolide (90%)-co-lactide (10%)] (PGLA) Suture Product Models

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.

APPLICABLE STANDARDS LIST

Document Number	Title of Document
1. Harmonised Standards	
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
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 1422:2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
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 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 ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
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 11138-2:2017)
EN ISO 11737-1: 2018	Sterilization of health care products - 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 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 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

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Document Number	Title of Document
EN ISO 10993-13:2010	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
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)
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 ISO 14630:2012	Non-active surgical implants - General requirements (ISO 14630:2012)
2. Pharmacopeia	
EP 10.0-01/ 2008:0667	European Pharmacopoeia 10.0-01/ 2008:0667 Sutures, Sterile Synthetic Absorbable Braided Monograph
USP 43/ NF 38	United States Pharmacopoeia Official Monographs / Absorbable Surgical Suture
3. Other Standards	
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 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
EN ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
ISO 8601-1:2019	Date and time — Representations for information interchange — Part 1: Basic rules
ISO 13781:2017	Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing
TS 4020/ MAY 2016	Surgical needles
TS 4169/ FEB 1984	The Determination Of Hazardous Residues In Plastics Used For Health Purposes
TS 10410/ OCT 1992	Methods For Sterility Control (For Medical Purposes) Part 3- Application Of Medicines, Medical And Surgical Materials To Inoculation Methods
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)

Document Code : YT-DC-GL	Effective Date: 11.09.2012	Revision No: 07	Revision Date: 10.11.2021	Number of Pages: 4 / 6
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Document Number	Title of Document
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
4. Guidance Documents	
4.1. ASTM Documents	
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
4.2. Guidance MEDDEVs	
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
4.3. NB-MED Documents	
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
4.4. MDCG Documents	
MDCG 2019-5 April 2019	Registration of legacy devices in EUDAMED
MDCG 2019-7 June 2019	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)
MDCG 2020-3 March 2020	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2020-7 April 2020	Guidance on PMCF plan template

Document Code : YT-DC-GL	Effective Date: 11.09.2012	Revision No: 07	Revision Date: 10.11.2021	Number of Pages: 5 / 6
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Document Number	Title of Document
MDGC 2020-8 April 2020	Guidance on PMCF evaluation report template
MDCG 2020-15 August 2020	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
MDCG 2020-18 December 2020	MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers
MDCG 2021-1 Rev.1 May 2021	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
MDCG 2021-09 May 2021	MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers
MDCG 2021-10 June 2021	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices
MDCG 2021-13 Rev.1 July 2021	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR
MDCG 2021-19 July 2021	Guidance note integration of the UDI within an organisation's quality management system
MDCG 2021-25 October 2021	Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
MDCG 2019-7 June 2019	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)
MDCG 2020-3 March 2020	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2020-7 April 2020	Guidance on PMCF plan template
MDGC 2020-8 April 2020	Guidance on PMCF evaluation report template
MDCG 2020-15 August 2020	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
MDCG 2020-18 December 2020	MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers
MDCG 2021-1 Rev.1 May 2021	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
MDCG 2021-09 May 2021	MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers
MDCG 2021-10 June 2021	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices
MDCG 2021-13 Rev.1 July 2021	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR
4.5. Directive	
EC-DIRECTIVES ON MED. DEVICES/ 2007	Guidelines on A Medical Devices Vigilance System

KM-FR-85

Document Code : YT-DC-GL	Effective Date: 11.09.2012	Revision No: 07	Revision Date: 10.11.2021	Number of Pages: 6 / 6
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EC DESIGN EXAMINATION CERTIFICATE

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

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

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

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

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

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

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

GMDN : 17471, 13908, 16584, 45814

Product Types are attached.

Certificate Number : M.2018.106.9177-1

Report Number : MD.3532.IB

Initial Assessment Date : 07.11.2017

Registration Date : 15.01.2018

Revision Date /No : 14.01.2021/01

Expiry Date : 14.01.2023


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

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



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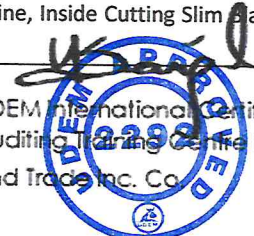
E-mail: info@udemltd.com.tr www.udem.com.tr

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



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

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





EC CERTIFICATE

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

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

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

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

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

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

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

GMDN : 17471, 13908, 16584, 45814

Product Types are attached.

Certificate Number : M.2018.106.9177

Report Number : MD.3532.IB

Initial Assessment Date : 07.11.2017

Registration Date : 15.01.2018

Revision Date /No : 14.01.2021/01

Expiry Date : 14.01.2023


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

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



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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.



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

Surgical Silk Suture Product Models GMDN No: 13910 Class III

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



C E R T I F I C A T E

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

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

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

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

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

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

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

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

Product Types are attached.

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


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

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



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Surgical Silk Suture Product Models GMDN No: 13910 Class III

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



C E R T I F I C A T E

EC Design-Examination Certificate

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

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

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

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

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

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

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

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

Product Types are attached.

Certificate Number : M.2020.106.13692-1

Report Number : MD.3532.IB

Initial Assessment Date : 08.11.2019

Registration Date : 29.06.2020

Revision Date /No : -

Expiry Date : 27.05.2024



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

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

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Surgical Silk Suture Product Models GMDN No: 13910 Class III

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

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

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

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

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

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

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

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

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

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

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

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

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

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