

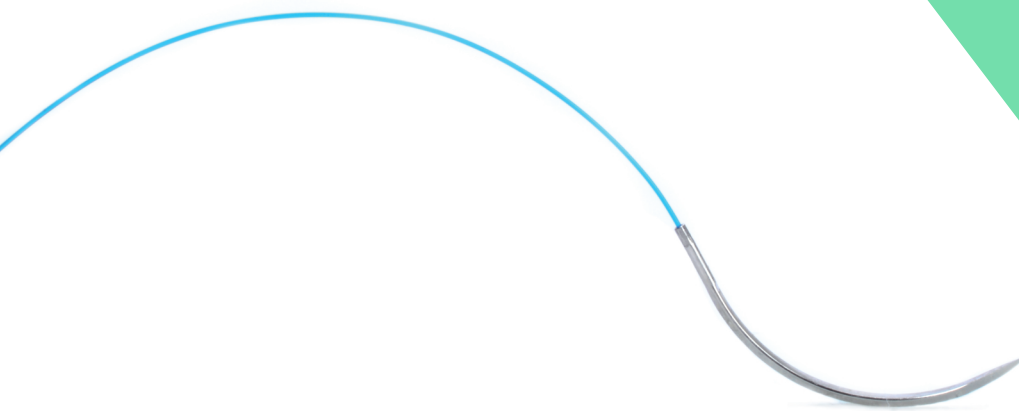
## Surgical Sutures

### Non-Absorbable

# Monamid

Surgical Suture, Monofilament Polyamide (PA)  
Nonabsorbable, Synthetic

Boz®



#### Definition

Synthetic Non-Absorbable

#### Material

Nylon 6 and Nylon 6.6 (PA)

#### Coating

Uncoated

#### Structure

Monofilament

#### Colour

Blue, Black, Undyed

#### Size

EP : 0.2 to 5

USP : 10/0 to 2

#### Tensile Strenght Retention

Moderate Loss

#### Mass Absorption

Permanent

#### Sterilization Method

Ethylene Oxide Gas

#### Main Indication

General Soft tissue approximation or ligation

Cardiovascular

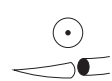
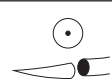
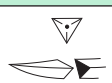
Ophthalmic Surgery

Neurosurgical Surgery

Plastic Surgery

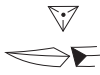
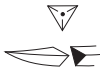
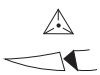
# Monamid

Surgical Suture, Monofilament Polyamide (PA) Nonabsorbable, Synthetic

| Needle Length and description                             |                                                                                     |                                                                                     | Product No    | USP EP             | Length (cm) | Unit Pcs | Color |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------|--------------------|-------------|----------|-------|
| 4 mm                                                      |                                                                                     |                                                                                     |               |                    |             |          |       |
| <b>3/8</b><br>Round Body,Taper Point<br><b>70 Micron</b>  |    |    | <b>MA1001</b> | <b>11/0</b><br>0,1 | 10          | 12       | Black |
| <b>3/8</b><br>Round Body,Taper Point<br><b>100 Micron</b> |    |    | <b>MA1023</b> | <b>10/0</b><br>0,2 | 15          | 12       | Black |
| <b>3/8</b><br>Round Body,Taper Point<br><b>150 Micron</b> |    |    | <b>MA1099</b> | <b>9/0</b><br>0,3  | 30          | 12       | Black |
|                                                           |                                                                                     |                                                                                     | <b>MA1129</b> | <b>8/0</b><br>0,4  | 13          | 12       | Black |
| 5 mm                                                      |                                                                                     |                                                                                     |               |                    |             |          |       |
| <b>3/8</b><br>Round Body,Taper Point<br><b>100 Micron</b> |    |    | <b>MA1045</b> | <b>10/0</b><br>0,2 | 13          | 12       | Black |
|                                                           |                                                                                     |                                                                                     | <b>MA1107</b> | <b>9/0</b><br>0,3  | 13          | 12       | Black |
| <b>3/8</b><br>Round Body,Taper Point<br><b>130 Micron</b> |    |    | <b>MA1133</b> | <b>8/0</b><br>0,4  | 13          | 12       | Black |
| 6 mm                                                      |                                                                                     |                                                                                     |               |                    |             |          |       |
| <b>3/8</b><br>Round Body,Taper Point<br><b>140 Micron</b> |  |  | <b>MA1162</b> | <b>8/0</b><br>0,4  | 15          | 12       | Black |
| <b>3/8</b><br>Spatula<br><b>150 Micron Micropoint</b>     |  |  | <b>MA1065</b> | <b>10/0</b><br>0,2 | 30          | 12       | Black |
| <b>3/8</b><br>Spatula<br><b>150 Micron</b>                |  |  | <b>MA1066</b> | <b>10/0</b><br>0,2 | 30          | 12       | Black |
|                                                           |                                                                                     |                                                                                     | <b>MA1068</b> | <b>10/0</b><br>0,2 | 45          | 12       | Black |
|                                                           |                                                                                     |                                                                                     | <b>MA1118</b> | <b>9/0</b><br>0,3  | 30          | 12       | Black |
| 6,6 mm                                                    |                                                                                     |                                                                                     |               |                    |             |          |       |
| <b>1/2</b><br>Cobra<br><b>150 Micron</b>                  |  |  | <b>MA5520</b> | <b>10/0</b><br>0,2 | 60          | 12       | Blue  |
|                                                           |                                                                                     |                                                                                     | <b>MA5521</b> | <b>9/0</b><br>0,3  | 60          | 12       | Blue  |
| 10 mm                                                     |                                                                                     |                                                                                     |               |                    |             |          |       |
| <b>1/2</b><br>Reverse Cutting<br><b>330 Micron</b>        |  |  | <b>MA1488</b> | <b>6/0</b><br>0,7  | 45          | 12       | Black |
| <b>3/8</b><br>Reverse Cutting<br><b>330 Micron</b>        |  |  | <b>MA1495</b> | <b>6/0</b><br>0,7  | 45          | 12       | Black |

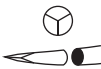
# Monamid

Surgical Suture, Monofilament Polyamide (PA) Nonabsorbable, Synthetic

| Needle Length and description        |                                                                                                                                                                         | Product No | USP EP     | Length (cm) | Unit Pcs | Color |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|-------------|----------|-------|
| 13 mm                                |                                                                                                                                                                         |            |            |             |          |       |
| 3/8<br>Reverse Cutting<br>330 Micron |       | MA1612     | 6/0<br>0,7 | 45          | 12       | Blue  |
|                                      |                                                                                                                                                                         | MA1619     | 6/0<br>0,7 | 75          | 12       | Blue  |
| 16 mm                                |                                                                                                                                                                         |            |            |             |          |       |
| 1/2<br>Reverse Cutting               |       | MA2012     | 5/0<br>1,0 | 75          | 12       | Blue  |
| 3/8<br>Reverse Cutting               |   | MA1672     | 6/0<br>0,7 | 75          | 12       | Blue  |
|                                      |                                                                                                                                                                         | MA1667     | 6/0<br>0,7 | 45          | 12       | Black |
|                                      |                                                                                                                                                                         | MA2017     | 5/0<br>1,0 | 45          | 12       | Blue  |
|                                      |                                                                                                                                                                         | MA2536     | 4/0<br>1,5 | 45          | 12       | Blue  |
|                                      |                                                                                                                                                                         | MA2542     | 4/0<br>1,5 | 75          | 12       | Black |
|                                      |                                                                                                                                                                         | MA3021     | 3/0<br>2,0 | 45          | 12       | Black |
|                                      |                                                                                                                                                                         | MA3027     | 3/0<br>2,0 | 75          | 12       | Blue  |
| 19 mm                                |                                                                                                                                                                         |            |            |             |          |       |
| 3/8<br>Reverse Cutting               |   | MA2201     | 5/0<br>1,0 | 45          | 12       | Blue  |
|                                      |                                                                                                                                                                         | MA2207     | 5/0<br>1,0 | 75          | 12       | Blue  |
|                                      |                                                                                                                                                                         | MA2638     | 4/0<br>1,5 | 45          | 12       | Blue  |
|                                      |                                                                                                                                                                         | MA2642     | 4/0<br>1,5 | 75          | 12       | Blue  |
| 3/8<br>Inside Cutting                |   | MA3120     | 3/0<br>2,0 | 45          | 12       | Blue  |
|                                      |                                                                                                                                                                         | MA3121     | 3/0<br>2,0 | 45          | 12       | Black |

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| Needle Length and description                                                                                                                                                                         | Product No    | USP EP            | Length (cm) | Unit Pcs | Color |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|-------|
| <b>19 mm</b>                                                                                                                                                                                          |               |                   |             |          |       |
| <b>3/8</b><br>Inside Cutting        | <b>MA3125</b> | <b>3/0</b><br>2,0 | 75          | 12       | Blue  |
|                                                                                                                                                                                                       | <b>MA2659</b> | <b>4/0</b><br>1,5 | 45          | 12       | Blue  |
|                                                                                                                                                                                                       | <b>MA2663</b> | <b>4/0</b><br>1,5 | 75          | 12       | Blue  |
| <b>20 mm</b>                                                                                                                                                                                          |               |                   |             |          |       |
| <b>1/2</b><br>Reverse Cutting       | <b>MA3162</b> | <b>3/0</b><br>2,0 | 75          | 12       | Blue  |
| <b>3/8</b><br>Reverse Cutting       | <b>MA3165</b> | <b>3/0</b><br>2,0 | 45          | 12       | Black |
| <b>24 mm</b>                                                                                                                                                                                          |               |                   |             |          |       |
| <b>3/8</b><br>Inside Cutting    | <b>MA3235</b> | <b>3/0</b><br>2,0 | 45          | 12       | Blue  |
| <b>25 mm</b>                                                                                                                                                                                          |               |                   |             |          |       |
| <b>1/2</b><br>Tapercutting      | <b>MA5513</b> | <b>3/0</b><br>2,0 | 45          | 12       | Blue  |
| <b>3/8</b><br>Reverse Cutting   | <b>MA2802</b> | <b>4/0</b><br>1,5 | 45          | 12       | Blue  |
|                                                                                                                                                                                                       | <b>MA3758</b> | <b>2/0</b><br>3,0 | 75          | 12       | Blue  |
| <b>3/8</b><br>Inside Cutting    | <b>MA2811</b> | <b>4/0</b><br>1,5 | 45          | 12       | Blue  |
| <b>26 mm</b>                                                                                                                                                                                          |               |                   |             |          |       |
| <b>1/2</b><br>Reverse Cutting   | <b>MA3812</b> | <b>2/0</b><br>3,0 | 75          | 12       | Blue  |
| <b>3/8</b><br>Reverse Cutting   | <b>MA3344</b> | <b>3/0</b><br>2,0 | 45          | 12       | Blue  |
|                                                                                                                                                                                                       | <b>MA3347</b> | <b>3/0</b><br>2,0 | 75          | 12       | Black |
|                                                                                                                                                                                                       | <b>MA3348</b> | <b>3/0</b><br>2,0 | 75          | 12       | Blue  |

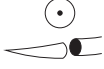
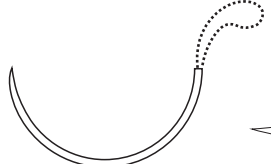
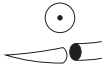
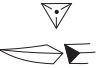
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Surgical Suture, Monofilament Polyamide (PA) Nonabsorbable, Synthetic

| Needle Length and description                                                                                           | Product No    | USP EP            | Length (cm) | Unit Pcs | Color |
|-------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|-------|
| <b>26 mm</b>                                                                                                            |               |                   |             |          |       |
| <b>3/8</b><br>Reverse Cutting          | <b>MA3820</b> | <b>2/0</b><br>3,0 | 45          | 12       | Blue  |
|                                                                                                                         | <b>MA3823</b> | <b>2/0</b><br>3,0 | 75          | 12       | Blue  |
| <b>3/8</b><br>Inside Cutting           | <b>MA3358</b> | <b>3/0</b><br>2,0 | 45          | 12       | Blue  |
| <b>30 mm</b>                                                                                                            |               |                   |             |          |       |
| <b>1/2</b><br>Round Body, Taper Point  | <b>MA4254</b> | <b>0</b><br>3,5   | 100         | 12       | Blue  |
|                                                                                                                         | <b>MA4255</b> | <b>0</b><br>3,5   | 100         | 12       | Black |
|                                                                                                                         | <b>MA4615</b> | <b>1</b><br>4,0   | 100         | 12       | Blue  |
|                                                                                                                         | <b>MA4610</b> | <b>1</b><br>4,0   | 75          | 12       | Blue  |
| <b>1/2</b><br>Reverse Cutting        | <b>MA3392</b> | <b>3/0</b><br>2,0 | 90          | 12       | Blue  |
|                                                                                                                         | <b>MA3884</b> | <b>2/0</b><br>3,0 | 75          | 12       | Blue  |
| <b>3/8</b><br>Reverse Cutting        | <b>MA3398</b> | <b>3/0</b><br>2,0 | 75          | 12       | Blue  |
|                                                                                                                         | <b>MA3399</b> | <b>3/0</b><br>2,0 | 75          | 12       | Black |
|                                                                                                                         | <b>MA3893</b> | <b>2/0</b><br>3,0 | 75          | 12       | Black |
|                                                                                                                         | <b>MA3894</b> | <b>2/0</b><br>3,0 | 75          | 12       | Blue  |
|                                                                                                                         | <b>MA4276</b> | <b>0</b><br>3,5   | 75          | 12       | Blue  |
|                                                                                                                         | <b>MA4631</b> | <b>1</b><br>4,0   | 75          | 12       | Blue  |
| <b>3/8</b><br>Inside Cutting         | <b>MA3902</b> | <b>2/0</b><br>3,0 | 75          | 12       | Blue  |

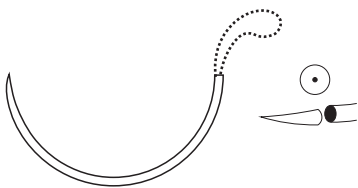
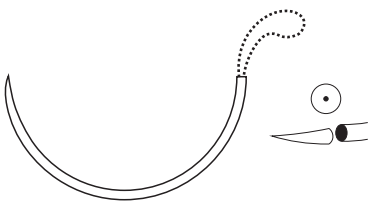
# Monamid

Surgical Suture, Monofilament Polyamide (PA) Nonabsorbable, Synthetic

| Needle Length and description                                                                                                                                                                                                | Product No    | USP EP            | Length (cm) | Unit Pcs | Color |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|-------|
| <b>35 mm</b>                                                                                                                                                                                                                 |               |                   |             |          |       |
| <b>1/2</b><br>Round Body, Taper Point                      | <b>MA4309</b> | <b>0</b><br>3,5   | 100         | 12       | Black |
|                                                                                                                                                                                                                              | <b>MA4298</b> | <b>0</b><br>3,5   | 45          | 12       | Blue  |
|                                                                                                                                                                                                                              | <b>MA4652</b> | <b>1</b><br>4,0   | 100         | 12       | Black |
| <b>1/2</b><br>Reverse Cutting                              | <b>MA4317</b> | <b>0</b><br>3,5   | 75          | 12       | Black |
| <b>3/8</b><br>Reverse Cutting                              | <b>MA3936</b> | <b>2/0</b><br>3,0 | 75          | 12       | Blue  |
|                                                                                                                                                                                                                              | <b>MA4664</b> | <b>1</b><br>4,0   | 100         | 12       | Blue  |
| <b>38 mm</b>                                                                                                                                                                                                                 |               |                   |             |          |       |
| <b>1/2</b><br>Reverse Cutting                          | <b>MA5512</b> | <b>2/0</b><br>3,0 | 75          | 12       | Black |
|                                                                                                                                                                                                                              | <b>MA5510</b> | <b>0</b><br>3,5   | 75          | 12       | Black |
| <b>40 mm</b>                                                                                                                                                                                                                 |               |                   |             |          |       |
| <b>1/2</b><br>Round Body, Taper Point                  | <b>MA4377</b> | <b>0</b><br>3,5   | 100         | 12       | Blue  |
|                                                                                                                                                                                                                              | <b>MA4370</b> | <b>0</b><br>3,5   | 75          | 12       | Black |
|                                                                                                                                                                                                                              | <b>MA4725</b> | <b>1</b><br>4,0   | 100         | 12       | Black |
|                                                                                                                                                                                                                              | <b>MA4726</b> | <b>1</b><br>4,0   | 100         | 12       | Blue  |
| <b>1/2</b><br>Round Body, Taper Point<br><b>LOOP</b>   | <b>MA4387</b> | <b>0</b><br>3,5   | 150         | 12       | Blue  |
| <b>1/2</b><br>Reverse Cutting                          | <b>MA4401</b> | <b>0</b><br>3,5   | 100         | 12       | Black |
|                                                                                                                                                                                                                              | <b>MA4402</b> | <b>0</b><br>3,5   | 100         | 12       | Blue  |

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| Needle Length and description                                                                                                     | Product No    | USP EP            | Length (cm) | Unit Pcs | Color |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|-------|
| 40 mm                                                                                                                             |               |                   |             |          |       |
| <b>1/2</b><br>Reverse Cutting<br>Heavy           | <b>MA4405</b> | <b>0</b><br>3,5   | 100         | 12       | Black |
| <b>3/8</b> Reverse Cutting                       | <b>MA4758</b> | <b>1</b><br>4,0   | 75          | 12       | Blue  |
| 45 mm                                                                                                                             |               |                   |             |          |       |
| <b>1/2</b><br>Round Body, Taper Point,<br>LOOP   | <b>MA4781</b> | <b>1</b><br>4,0   | 150         | 12       | Blue  |
| <b>3/8</b><br>Reverse Cutting                   | <b>MA4789</b> | <b>1</b><br>4,0   | 75          | 12       | Blue  |
| 50 mm                                                                                                                             |               |                   |             |          |       |
| <b>1/2</b><br>Round Body, Taper Point<br>LOOP  | <b>MA4464</b> | <b>0</b><br>3,5   | 150         | 12       | Black |
|                                                                                                                                   | <b>MA4465</b> | <b>0</b><br>3,5   | 150         | 12       | Blue  |
|                                                                                                                                   | <b>MA4828</b> | <b>1</b><br>4,0   | 150         | 12       | Black |
|                                                                                                                                   | <b>MA4829</b> | <b>1</b><br>4,0   | 150         | 12       | Blue  |
| 60 mm                                                                                                                             |               |                   |             |          |       |
| <b>Straight</b><br>Reverse Cutting             | <b>MA4077</b> | <b>2/0</b><br>3,0 | 75          | 12       | Blue  |
| 61 mm                                                                                                                             |               |                   |             |          |       |
| <b>Straight</b><br>Reverse Cutting             | <b>MA4083</b> | <b>2/0</b><br>3,0 | 100         | 12       | Blue  |

# Prospektüs

## Prospectus

# MONAMID

## Emilemeyen Cerrahi Ameliyat İpliği

Non-Absorbable Surgical Sutures

Lütfen dilinizi seçiniz  
Please select your language



TR

## Kullanma Talimatı MONAMID® NAYLON İPLİK

EMİLEMİYEN CERRAHI İPLİK, U.S.P./ Eur.Ph./ITS5504

### TANIM

MONAMID Nylon 6 veya Nylon 6,6 olarak anılan uzun zincirli alifatik polimerler zincirlerinden oluşan, emilemeyen, steril, monofilaman cerrahi iplerdir. MONAMID cerrahi iplikler dokudaki görünürlüğü arttırmak amacı ile mavî (C.I. renk index no: 74 160) ya da siyaha (C.I.-renk indeks no. 77260) boyanmıştır.

MONAMID ipler boyasız olarak da arz edilebilir.

MONAMID ipler Amerikan Farmakopesi (U.S.P.) ve Avrupa Farmakopesinde (E.P.) emilemeyen cerrahi iplikler için kabul edilmiş olan tüm gereklilikleri sağlar.

### KULLANILMALANI

MONAMID iplik kalbi-damar, oftalmik ve sinir cerrahisi uygulamaları dahil, genel yumuşak doku kapamasında ve/veya bağlanmasında kullanılır. MONAMID iplik tek kullanımlıktır.

### ETKİLERİ

Cerrahi MONAMID iplik dokuda hafif bir şekilde akut yangı reaksiyonu gösterilebilir, bu tepkiyi için çevresinde dereceli olarak fibröz bağ dokusunu takip eder. Nylon iplik emilmeyen ip olsa da, nylonun organizma içinde ilerleyen hidrolizi, zamanla ipin kopma gücünde dereceli bir kayba neden olabilir.

### KULLANILMAMASI GEREKEN YERLER

Uzun sürede organizma içerisinde meydana gelebilecek mukavemet kaybına bağlı olarak, kopma dayanımı direncinin kalıcı olması istendiği yerlerde nylon kullanılmamalıdır.

### UYARILAR

Yararın açılma riski, uygulama bölgesi ve kullanılan malzemeye göre değişebilir için kullanıcılara MONAMID ipliği kullanmadan önce emilebilir olmayan cerrahi iplerin kullanımına ilişkin ilgili cerrahi yöntem ve tekniklere aşina olmalıdır.

İpliklerin kordon, safrı ya da ürün sistemdeki gibi mevcut olan tuz çözümleri ile uzun süreli teması tortu oluşumuna sebebiyet verebilir. Tekrar steril etmeyiniz. Açılmış poşetleri ve kullanılmayan ipleri imha ediniz. Enfekte ve kontamine olmuş yaraları en alınmasında kabul edilebilir cerrahi uygulamalar takip edilmelidir.

### ÖNEMLER

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

MONAMID ipliği kullanımı karakteristiğini arttırmak için, cerrahi şartlara ve cerrahın tecrübesine bağlı olarak garanti altına alınan kabul görmüş düz ve kare düğüm teknikleri ile beraber ilave düğümler gerektirir. Monofilaman iplere düğüm atılmasında ilave düğümlerin kullanımı özellikle uygundur. İğne uçlarının ve bağlantı bölgesinin hasar görmemesi için, bağlantı ucu ve iğne ucu arasındaki mesafenin üçte biri (1/3) ile yarısı (1/2) arasındaki kısmadan tutun.

İğneleri yeniden şekillendirmek, güçlerini kaybetmelerine ve bükülme ve kırılmaları karga dirençlerinin azalmasına neden olabilir. İstem dışı iğne batmalarından kaçınmak için kullanıcıların cerrahi iğne kullanırken dikkatli olmaları gerekir.

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

Kullanılan iğneleri "kesici alet" kaplarına atınız.

### YAN ETKİLER

Bu cihazın kullanımına bağlı yan etkiler; yara açılması, zamana bağlı olarak mukavemet kaybı, uzun süreli tuz çözümleri ile temasta ürün sisteminde tortu (taş), enfeksiyon, minimal akut doku yangı reaksiyonu ve yara bölgesinde geciktirici tahrişler içermektedir.

### PIYASAYA ARZ-SUNUŞ ŞEKLİ

MONAMID iplikler siyah, mavî veya renksiz (şeffaf), steril, monofilaman U.S.P. 10/0 ve 1/0 metrik (sıyah tuz çözümleri ile değişik boylarda, iğneli ve iğnesiz olarak mevcuttur).

MONAMID ipler Politetrafloroetilen (PTFE) plejilere takılı biçimde de bulunur.

MONAMID iplikler bir, iki ve üç düzinelik kutularda bulunmaktadır.

### DEPOLAMA

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

Nemden korununuz.

Son kullanma tarihinden sonra kullanmayınız.

### ETİKETLEMEDE KULLANILAN İŞRETLER



Tek kullanımlık



Boyasız, Emilemez, Monofilaman



Tekrar steril etmeyiniz



REF Katalog numarası



Paket zarar görülmüşse kullanmayınız



25°C'nin altında muhafaza ediniz



Üretici



Güneşten uzak tutunuz



YYYY Üretim tarihi, Yıl



Nemden Korununuz



YYYY-MM Son kullanma tarihi, Yıl-Ay



Geri dönüşümü paket



STERILE EO Steril Eo, Etilenoksit



Dikkat, Kullanma kılavuzuna bakınız



LOT Seri No



Boyalsız, Emilemez, Monofilaman



CE 1014

IFU-MA-rev-03-05-05-2017

Issue date: 11.09.2012

"EASSİ (Avrupa Cerrahi Sütür Sanayi Birliği) çeşitli suture ürün karakteristیکlerini sevgisiz ve resmî olarak tanımlamak için tasarlanmış bir sistem geliştirmiştir. Sembol kullanımına Y İbni Cihaz Direktifi (Medical Device Directive) (MDD 93/42/EEC) izin vermektedir ve polkü dil tercümesine gerek kalmadan üreticilerin kullanımlarına bağlı sağlama iznı tanımlamaktadır."



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

Sağlık Sokak No:33/5 Şişli/Beşiktaş/İSTANBUL

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

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

**BOZ**

GB

## Instructions for Use

## MONAMID® NYLON SUTURE

NONABSORBABLE SURGICAL SUTURE, U.S.P/ Eur.Ph./TSS5504

## DESCRIPTION

MONAMID nylon suture is a nonabsorbable, sterile surgical monofilament suture composed of the long-chain aliphatic polymers Nylon 6 or Nylon 6,6. MONAMID sutures are dyed black (C.I. color index no: 77266) or blue (C.I. color index no: 74160) to enhance visibility tissue. The suture is also available undyed (clear).

MONAMID suture meets all requirements established by the United States Pharmacopeia (U.S.P) and European Pharmacopeia for nonabsorbable surgical suture.

## INDICATIONS

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

## ACTIONS

MONAMID suture elicit a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While nylon is not absorbed, progressive hydrolysis of the nylon in vivo may result in gradual loss of tensile strength over time.

## CONTRAINDICATIONS

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, nylon suture should not be used where permanent retention of tensile strength is required.

## WARNINGS

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

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

Do not resterilize. Discard open packages and unused sutures. Acceptable surgical practices must be followed for the management of contaminated or infected wounds.

## PRECAUTIONS

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

MONAMID sutures, which are treated to enhance handling characteristics, require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstances and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

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

the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks.

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

## ADVERSE REACTIONS

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

## HOW SUPPLIED

MONAMID sutures are available as sterile, monofilament, black, blue or undyed (clear) strands in U.S.P sizes 10/0 thru 2 (metric sizes 0.2-5) in a variety of lengths with and without permanently attached needles. MONAMID sutures are also available attached to Polytetrafluoroethylene (PTFE) pledget.

MONAMID sutures are available in one, two, and three dozen boxes.

## STORAGE

Store below 25°C and keep away from sunlight.

Protect from humidity.

Do not use after expiry date.

## SYMBOLS USED ON LABELLING

|      |                                    |  |                                      |
|------|------------------------------------|--|--------------------------------------|
|      | Do not reuse!                      |  | Undyed, Non-absorbable, Monofilament |
|      | Do not resterilize                 |  | Catalogue Number                     |
|      | Do not use if pack age is damaged  |  | Store below 25°C                     |
|      | Manufacturer                       |  | Keep away from sunlight              |
| YYYY | Date of Manufacture/Year           |  | Protect from humidity                |
| YYMM | Expiry Date, Year-Month            |  | Recyclable pack                      |
|      | STERILE EO: Ethylene oxide         |  | Attention, See instruction for use   |
|      | Batch Number                       |  | CE 1014                              |
|      | Dyed, Non-absorbable, Monofilament |  |                                      |

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Issue date: 11.09.2012

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



BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.

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

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

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

FR

Mode d'emploi

**MONAMID® FIL DE NYLON**

FIL CHIRURGICAL NON RESORBABLE, TRESSE, U.S.P./ E ur.Ph./TS5504

**DESCRIPTION**

MONAMID est un fil chirurgical stérile, monofilament, non résorbable composé de longues chaînes de polymères aliphatiques dits Nylon 6 ou Nylon 6.6. Le fil chirurgical MONAMID est coloré en bleu pour augmenter la visibilité dans le tissu (C.I. no d'index de couleur: 74169) ou en noir avec nr. d'index 77266.

Les fils MONAMID sont conformes aux exigences valables pour les fils de suture non résorbables de la Pharmacopée Américaine (U.S.P.) et la Pharmacopée Européenne (E.P.).

**INDICATIONS**

Le fil chirurgical MONAMID est utilisé pour la fermeture et/ou le raccrochage des tissus mous en général y compris les applications cardiovasculaires et nerveuses. Le fil MONAMID est pour utilisation unique.

**EFFICACITE**

Le fil chirurgical MONAMID peut manifester une faible réaction inflammatoire aigue dans le tissu, cette réaction est suivie d'une formation d'un tissu collagène fibreux. Bien que le fil en nylon soit un fil non résorbable, l'hydrolyse du nylon qui avance progressivement dans l'organisme peut causer une perte de la force de rupture du fil.

**CONTRE-INDICATIONS**

En fonction de la perte de résistance qui peut survenir dans l'organisme à long terme, le fil en nylon ne doit pas être utilisé pour les cas où l'on désire une résistance de rupture permanente.

**AVIS**

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

Le contact des fils avec les solutions de sel présents dans le cordon, la bile ou le système urinaire peut donner lieu à la formation de calcul.

Ne pas restériliser. Détruire les sachets ouverts et les fils non utilisables. Poursuivre les applications chirurgicales acceptables pour le traitement des plaies infectées et contaminées.

**PRECAUTIONS**

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

Les fils MONAMID nécessitent des techniques de noeuds supplémentaires avec des techniques de noeuds droits et carré selon la situation chirurgicale l'expérience du chirurgien peut augmenter la caractéristique d'utilisation.

L'utilisation des noeuds supplémentaires sont notamment convenables pour le nouage des fils monofilaments.

Pour que les extrémités des aiguilles et la région de connexion ne soient pas endommagées, tenir de la partie se trouvant entre le tiers (1/3) de la distance entre l'extrémité de la connexion et l'extrémité de l'aiguille et sa moitié (1/2). Reformuler les aiguilles peuvent causer la perte de force et la diminution de leur résistance contre les flexions et les ruptures. Les utilisateurs doivent être prudents lors de l'utilisation des aiguilles chirurgicales pour éviter les piqures d'aiguilles involontaires.

Détruire les produits contaminés et non utilisés selon les exigences régionales et d'installation.

Jeter les aiguilles usées dans les conteneurs "pointus".

**EFFETS SECONDAIRES**

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

**COMMERCIALISATION**

Les fils MONAMID existent dans les couleurs noires, bleues ou incolores (transparents), stériles, monofilaments, dans différentes tailles entre 10/0-2 (métrique 0.2-5.0) avec ou sans aiguille.

Les fils MONAMID se trouvent aussi branchés à des tampons d'ouate en Polytétrafluoroéthylène (PTFE).

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

**CONSERVATION**

Conserver sous température 25°C et loin de la lumière solaire.

Protéger de l'humidité.

Ne pas utiliser après la date limite de consommation.

**SIGNES UTILISES POUR L'ETIQUETAGE**

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

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



**BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.**  
 Bağlık Sokak No:33/5 Sıhhiye/ANKARA/TÜRKİYE  
 Tel: +90 (312) 435 50 80-81 Faks: +90 (312) 435 41 26  
 web: www.boztibbi.com e-mail: boz@boztibbi.com

## مونيولون® MONAMID® خيوط نايلونية خيوط جراحية غير قابلة للامتصاص U.S.P/ Eur. Ph/ TS5504

### التعريف :

تتكون خيوط مونيولون MONAMID الجراحية من النايلون 6 و النايلون 6,6 من بولياميرات الفتيك سلسلة طويلة، غير قابلة للامتصاص، حيث أنها خيوط معصمة تم صنعها بالنول الأرقى (معامل رقم 74160 للنايلون 6 و الأسود (معامل رقم 77266 للنايلون 6,6) وذلك لتسهيل تمييزها عن الأسيجة الحيوية. كما يمكن أن تكون الخيوط غير ملونة أيضاً تتميز خيوط مونيولون MONAMID بكافة المواصفات الفنية المطلوبة للمواصفات الأمريكية (U.S.P.) والأوروبية في مجال الخيوط.

### مجالات الاستعمال

تستعمل خيوط مونيولون MONAMID الجراحية في عمليات القلب والأوعية الدموية الجراحية، وجراحات الأصباع والأوتار، وفي مجالات غلق جروح الأسيجة الخاصة (الخدوخ) بشكل عام أو في عملية ربطها. خيوط مونيولون MONAMID للاستعمال مرة واحدة فقط.

### التحذيرات

يمكن أن تؤثر خيوط مونيولون MONAMID على الأسيجة بعمل نقاط معها على شكل التهاب أو تئيج خفيف، هذا التأثير سؤاؤر تدريجيا وبشكل مؤقت على أطرافه في السبع الحيوي. خيوط مونيولون MONAMID النايلونية غير قابلة للامتصاص فإن عملية الهجرة الجازية في أوساط الأحياء المجهرية تؤدي إلى فقدان في متانة الخيط ما قد تؤدي إلى طعنه.

### الاماكن التي لا يجوز فيها استعماله

يجب عدم استخدامه في الأماكن والمواقع التي تتطلب بقاء الخيوط لفترة طويلة واستمرار مقاومتها للقطع ، وذلك بسبب احتمال فقدان مقاومتها للقطع في الأوساط التي تشهد فعاليات لأحياء المجهرية.

### التحذيرات

بسبب أن خطورة حدوث الفتح بالجروح (تقق) تختلف من منطقة إلى أخرى وتختلف أيضا حسب المواد المستخدمة، فانه يجب على مستخدمين خيوط مونيولون MONAMID أن يكون لهم اطلاع على الجراحية والتقنيات المأهولة المستعملة باستخدام الخيوط الجراحية غير القابلة للامتصاص قبل استخدام خيوط مونيولون MONAMID. لا يجوز إعادة تعقيمها ، فكلما اكتمل الطيف المطبق حتى لو كانت الخيوط غير مستعملة من الممكن أن تسبب هذه الخيوط تآكلين الحسي في الغدة الصفراء أو الحالب أو الكورون إذا طالت فترة تماسها مع المحاليل الملحية الموجودة في تلك الأجهزة الحيوية. يجب اتباع الطرق الجراحية المعقولة في الجروح المتفرقة أو المصاصة والمهلبية.

### التدبير

تجنب الحقن السريع بالإنارة أو خيوط مونيولون MONAMID عند الاستخدام تجنب الوقوع في أخطاء عملية حسب أو استخدام الخيوط خلال استخدام الأدوات الجراحية مثل الملقاط و المسامكات وغيرها من الأدوات.

من أجل زيادة فترات خيوط مونيولون MONAMID تكون تقييدات العدة المستوية والمربعة ستكون عند كفاية معصومة عن زووم عند إضافتها، بالإضافة إلى ضمانات تجربة وفخات الجراحين وشروط ومواصفات الجراحة. خيوط مونيولون مناسبة للتزويد من أجزاء العقد فيها.

لتجنب تلفات إبرة و المناطق الأراجم بالتعرض للأشعاع ، يجب أن يتم توجيه الإبرة في ثلث المساحة (3/1) إلى النصف (2/1) من مسافة واحدة من نهاية الإبرة إلى في هذه القطعة (إعادة التجميع) لكي لا تسبب قد القوة وتكون إلى مقاومة للثقل والكسر. يجب على المستخدمين توخي الحذر عند التعامل مع الإبر الجراحية لتجنب وخز الإبر غير المقصود. التخلص من المنتجات المؤلمة وغير المستخدمة يجب أن يكون وفقا للمتطلبات المحلية والمراعى ذات المسلة.

يجب إلقاء الإبر المستخدمة في حاويات التقييدات "الأدوات الحادة".

### التأثيرات الجانبية

من الممكن أن تحدث تهيجات مؤقتة في مناطق الجروح أو تورسات أو اصابات أو التهابات أو تفاعلات التهابية عند تماس لفترة طويلة مع المحاليل الملحية الموجودة في الجهاز البولي.

### اشكال عرضه في الأسواق

يتم عرضه في الأسواق على شكل خيوط مونيولون MONAMID مونيولون بلون أزرق أو سواد أو عدمة اللون (نظاف) معصمة بطول تتراوح ما بين (0,2 – 5 متر U.S.P 0/10 و 2. تتوفر خيوط مونيولون مرابطة مع نثر اقزور البوليأين (PTE) أيضا. خيوط مونيولون MONAMID متوفرة بطول منسلسلة مع الأرة أو بونديها. خيوط مونيولون MONAMID متوفرة في عبء تحتوي على زينة احادية أو ثنائية أو ثلاثية. خيوط مونيولون MONAMID تستخدم لمرة واحدة فقط.

### التخزين

يجب أن يتم عملية التخزين في درجات حرارة أقل من 25 درجة مئوية وبعيدة عن أشعة الشمس والرطوبة. لا تستخدموا الخيوط للأنفة الصلاحية.

## الرموز المستخدمة في البطاقة

|                                                                                   |                                                                                   |                                                 |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------|
|  |  | لا تستعمل مرة واحد                              |
|  |  | لا يتم بجزءا التعقيم مرة أخرى                   |
| رقم الكولاج                                                                       |  | لا تستخدم إذا كانت العدة تالفة                  |
|  |  | المصنع                                          |
| تخطت تمت 25 درجة مئوية                                                            |  | YYYYYY تاريخ الإنتاج / السنة                    |
|  |  | YYYYYY-MM تاريخ انتهاء الصلاحية / السنة / الشهر |
| تخطت بعدا عن أشعة الشمس                                                           |  | معطى لامتانة                                    |
|  |  | LOT رقم الدفعة                                  |
| تخطت في مكان جاف بعدا عن الرطوبة                                                  |  | رقم الدفعة                                      |
|  |  | ملون، غير قابل للامتصاص، أحادي اللون            |
| قابلة لإعادة التدوير                                                              |  |                                                 |
|  |  |                                                 |
| تحذير، انظر إشارات الاستخدام                                                      |  |                                                 |
|  |  |                                                 |
| 1014                                                                              |  |                                                 |

Issue date: 11.09.2012

IFU-MA-REV-03-05-05-2017

"قامت الرابطة الأوروبية للصناعة المعادات الجراحية (EASSI) بتطوير نظام مصمم لتعريف مختلف خصائص منتجات المعادات الجراحية بشكل مرئي وبديهي. كما أن إدارة الأجهزة الطبية (EC Directive 93/42/EEC) (Medical Device Directive) أتاحت إمكانية استخدام الرموز. وتوصيل المعلومات من المصنعين إلى المستخدمين مباشرة دون الحاجة إلى الترجمة عدة لمعات".



BOZ TIBBİ NALZEME SANAYİ VE TİCARET A.Ş.  
Sağlık Sokak No:33/5 ŞİRKİYE/ANKARA/T.C.  
Tel: +90 (312) 435 50 80-81 Faks: +90 (312) 435 41 26  
web: www.boztibbi.com e-mail: boz@boztibbi.com

BOZ



# Declaration of Conformity

|                    |                                                                                                                                                                                                                   |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer       | BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.                                                                                                                                                                          |
| Address            | Sağlık Mah. Sağlık 1 Sk. No:33/5 Çankaya / ANKARA / TÜRKİYE                                                                                                                                                       |
| Product Name       | <b>MONAMID</b><br>Surgical, Polyamide 6-6,6 (PA) Suture                                                                                                                                                           |
| Properties         | Synthetic, Sterile, Non-Absorbable, Monofilament, Blue or Black colored, Uncoated Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, Single Use |
| Dye                | Blue coloring material (C.I. – colour index no 74160)<br>Black coloring material (C.I. – colour index no. 77266)                                                                                                  |
| Insulation/Coating | Uncoated                                                                                                                                                                                                          |
| Product Models     | For product models see page 2                                                                                                                                                                                     |
| Lot No             | 2101001..... 2112099                                                                                                                                                                                              |
| GMDN No            | 38000                                                                                                                                                                                                             |
| Classification     | Class III , Rule 8                                                                                                                                                                                                |

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body. It conforms to Conformity Assessment Route Annex 2, and Route Annex 2 article 4 of the 93/42/EEC directive.

## DIRECTIVES

### General applicable directives:

-Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 Included Amendment 2007/47/EC concerning medical devices (MDD 93/42/EEC).

### Standards:

-For Applicable Standards List see page 3 and 4

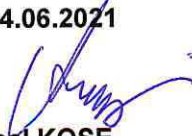
|                  |                                                                                                                                                 |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Notified Body    | UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.<br>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<br>Phone +31.70.345.8570 - Fax +31.70.346.7299 – EmergoEurope@ul.com |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|

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

Place, Date Ankara, 14.06.2021

Signature  
Name  
Position

  
Aysel KOSE  
Management Representative

|                             |                               |                    |                              |                           |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|
| Document Code :<br>YT-DC-MA | Effective Date:<br>11.09.2012 | Revision No:<br>08 | Revision Date:<br>14.06.2021 | Number of Pages:<br>1 / 4 |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|



**Surgical, Polyamide 6-6,6 (PA) Suture Product Models**

**Synthetic, Sterile, Non-Absorbable, 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, Suture Length, Needle Length, Needle Shape and Needle properties:**

|                           |                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>USP:</b>               | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                      |
| <b>EP:</b>                | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Suture Lengths :</b>   | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>   | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>    | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b> | Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point. |

## APPLICABLE STANDARDS LIST

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

KM-FR-85

|                             |                               |                    |                              |                           |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|
| Document Code :<br>YT-DC-MA | Effective Date:<br>11.09.2012 | Revision No:<br>08 | Revision Date:<br>14.06.2021 | Number of Pages:<br>3 / 4 |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|

## APPLICABLE STANDARDS LIST

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

KM-FR-85

|                             |                               |                    |                              |                           |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|
| Document Code :<br>YT-DC-MA | Effective Date:<br>11.09.2012 | Revision No:<br>08 | Revision Date:<br>14.06.2021 | Number of Pages:<br>4 / 4 |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|



# EC DESIGN EXAMINATION CERTIFICATE

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

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

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

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

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

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

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

GMDN : 17471, 13908, 16584, 45814

Product Types are attached.

Certificate Number : M.2018.106.9177-1

Report Number : MD.3532.IB

Initial Assessment Date : 07.11.2017

Registration Date : 15.01.2018

Revision Date /No : 14.01.2021/01

Expiry Date : 14.01.2023

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

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



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

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

E-mail: [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)



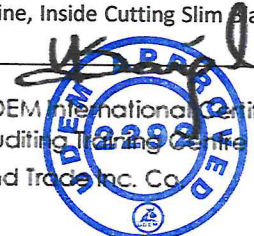
This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9177-1 and with the registration date of 15.01.2018 and with the revision date of 14.01.2021 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme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

|                                                                                                                                                                                                                                                                                                                                                                                                                               |                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <b>Poly[glycolide(90%)-co-lactide(10%)] (PGLA)</b>                                                                                                                                                                                                                                                                                                                                                                            | <b>GMDN NO:17471</b> |
| 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. |                      |
| <b>Poly[glycolide(90%)-co-lactide(10%)] (Rapid Absorbable PGLA)</b>                                                                                                                                                                                                                                                                                                                                                           | <b>GMDN NO:17471</b> |
| 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. |                      |
| <b>Polyglycolic acid (PGA)</b>                                                                                                                                                                                                                                                                                                                                                                                                | <b>GMDN NO:13908</b> |
| 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.

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





# EC CERTIFICATE

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

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

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

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

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

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

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

GMDN : 17471, 13908, 16584, 45814

Product Types are attached.

Certificate Number : M.2018.106.9177

Report Number : MD.3532.IB

Initial Assessment Date : 07.11.2017

Registration Date : 15.01.2018

Revision Date /No : 14.01.2021/01

Expiry Date : 14.01.2023

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

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



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY  
Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76  
E-mail: info@udemltd.com.tr www.udem.com.tr



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

|                                                                                                                                                                                                                                                                                                                                                                                                                                      |                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <b>Poly[glycolide(90%)-co-lactide(10%)] (PGLA)</b>                                                                                                                                                                                                                                                                                                                                                                                   | <b>GMDN NO:17471</b> |
| 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:                                                                                                                                                                          |                      |
| <b>USP:</b> 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                                               |                      |
| <b>EP:</b> 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                                             |                      |
| <b>Suture Lengths :</b> Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                     |                      |
| <b>Needle Lengths :</b> Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                      |                      |
| <b>Needle Shapes :</b> 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                          |                      |
| <b>Needle Properties:</b> 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. |                      |
| <b>Poly[glycolide(90%)-co-lactide(10%)] (Rapid Absorbable PGLA)</b>                                                                                                                                                                                                                                                                                                                                                                  | <b>GMDN NO:17471</b> |
| 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:                                                                                                                                                                                      |                      |
| <b>USP:</b> 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                                               |                      |
| <b>EP:</b> 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                                             |                      |
| <b>Suture Lengths :</b> Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                     |                      |
| <b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                       |                      |
| <b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                           |                      |
| <b>Needle Properties:</b> 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. |                      |
| <b>Polyglycolic acid (PGA)</b>                                                                                                                                                                                                                                                                                                                                                                                                       | <b>GMDN NO:13908</b> |
| 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:                                                                                                                                                                          |                      |
| <b>USP:</b> 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6                                                                                                                                                                                                                                                                                                                                                                   |                      |
| <b>EP:</b> 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8                                                                                                                                                                                                                                                                                                                                                                                     |                      |
| <b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                      |                      |
| <b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                       |                      |
| <b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                           |                      |
| <b>Needle Properties:</b> 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. |                      |



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|                                                                                                                                                                                                                                                                                                                                                                                                                                      |                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <b>Polyglycolic acid (Rapid Absorbable PGA)</b>                                                                                                                                                                                                                                                                                                                                                                                      | <b>GMDN NO:13908</b> |
| 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:                                                                                                                                                                                      |                      |
| <b>USP:</b> 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6                                                                                                                                                                                                                                                                                                                                                                   |                      |
| <b>EP:</b> 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8                                                                                                                                                                                                                                                                                                                                                                                     |                      |
| <b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                      |                      |
| <b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                       |                      |
| <b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                           |                      |
| <b>Needle Properties:</b> 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. |                      |
| <b>Polydioxanone (PDO)</b>                                                                                                                                                                                                                                                                                                                                                                                                           | <b>GMDN NO:16584</b> |
| 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:                                                                                                                                                                                              |                      |
| <b>USP:</b> 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                                                    |                      |
| <b>EP:</b> 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                                                 |                      |
| <b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                      |                      |
| <b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                       |                      |
| <b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                           |                      |
| <b>Needle Properties:</b> 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. |                      |
| <b>Poly[glycolide(75%)-co-caprolactone(25%)] (PGCL)</b>                                                                                                                                                                                                                                                                                                                                                                              | <b>GMDN NO:45814</b> |
| 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:                                                                                                                                                                                    |                      |
| <b>USP:</b> 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                                                         |                      |
| <b>EP:</b> 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                                                     |                      |
| <b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                      |                      |
| <b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                       |                      |
| <b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                           |                      |
| <b>Needle Properties:</b> Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point. |                      |



# C E R T I F I C A T E

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

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

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

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

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

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

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

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

Product Types are attached.

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

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

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 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](http://www.udem.com.tr).



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY  
Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76  
E-mail: [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)



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

**Surgical Silk Suture Product Models GMDN No: 13910 Class III**

|                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>USP:</b>                                                                                                                                                                                                                                                                         | 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4                                                                                                                                                                                                                                                                                                                                                     |
| <b>EP:</b>                                                                                                                                                                                                                                                                          | 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Thread Lengths :</b>                                                                                                                                                                                                                                                             | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                             | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                              | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                           | 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**

|                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                                                          | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                      |
| <b>EP:</b>                                                                                                                                                                                                                                                                                           | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Thread Lengths :</b>                                                                                                                                                                                                                                                                              | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                                              | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                                               | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                                            | 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**

|                                                                                                                                                                                                                                                           |                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| <b>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</b> |                                                       |
| <b>USP:</b>                                                                                                                                                                                                                                               | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2 |
| <b>EP:</b>                                                                                                                                                                                                                                                | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                 |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                    | Variety of lengths, from 10 cm to 500 cm              |

|                           |                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Needle Lengths :</b>   | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>    | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b> | 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**

|                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                                                                  | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                      |
| <b>EP:</b>                                                                                                                                                                                                                                                                                                   | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                                                                       | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                                                      | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                                                       | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                                                    | 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**

|                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                                                                                   | 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5                                                                                                                                                                                                                                                                                                                                                             |
| <b>EP:</b>                                                                                                                                                                                                                                                                                                                    | 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                                                                                        | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                                                                       | Variety of lengths, from 5 mm to 110 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                                                                        | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                                                                     | 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**

|                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                         | 6/0, 5/0, 4/0, 3/0, 2/0                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>EP:</b>                                                                                                                                                                                                                                                          | 0,7 1 1,5 2 3                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                              | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                             | Variety of lengths, from 5 mm to 110 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                              | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                           | 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**

|                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                               | 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7                                                                                                                                                                                                                                                                                                                                                                 |
| <b>EP:</b>                                                                                                                                                                                                                                                | 1 1,5 2 3 3,5 4 5 6 6 7 8 9                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                    | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                   | Variety of lengths, from 10 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                    | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                 | 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**

|                                                                                                |                     |
|------------------------------------------------------------------------------------------------|---------------------|
| <b>Sterile, Nonabsorbable, Non-woven, White colored and in the following dimension ranges:</b> |                     |
| <b>Width</b>                                                                                   | = 3 mm ..... 150 mm |
| <b>Length</b>                                                                                  | = 3 mm .....150 mm  |
| <b>Height</b>                                                                                  | = 1 mm ..... 2 mm   |



# C E R T I F I C A T E

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

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

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

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

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

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

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

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

Product Types are attached.

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

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

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



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY  
Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76  
E-mail: [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)



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

**Surgical Silk Suture Product Models GMDN No: 13910 Class III**

|                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>USP:</b>                                                                                                                                                                                                                                                                         | 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4                                                                                                                                                                                                                                                                                                                                                     |
| <b>EP:</b>                                                                                                                                                                                                                                                                          | 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Thread Lengths :</b>                                                                                                                                                                                                                                                             | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                             | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                              | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                           | 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**

|                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                                                          | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                      |
| <b>EP:</b>                                                                                                                                                                                                                                                                                           | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Thread Lengths :</b>                                                                                                                                                                                                                                                                              | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                                              | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                                               | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                                            | 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**

|                                                                                                                                                                                                                                                           |                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| <b>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</b> |                                                       |
| <b>USP:</b>                                                                                                                                                                                                                                               | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2 |
| <b>EP:</b>                                                                                                                                                                                                                                                | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                 |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                    | Variety of lengths, from 10 cm to 500 cm              |

|                           |                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Needle Lengths :</b>   | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>    | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b> | 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**

|                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                                                                  | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                      |
| <b>EP:</b>                                                                                                                                                                                                                                                                                                   | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                                                                       | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                                                      | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                                                       | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                                                    | 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**

|                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                                                                                   | 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5                                                                                                                                                                                                                                                                                                                                                             |
| <b>EP:</b>                                                                                                                                                                                                                                                                                                                    | 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                                                                                        | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                                                                       | Variety of lengths, from 5 mm to 110 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                                                                        | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                                                                     | 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**

|                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                         | 6/0, 5/0, 4/0, 3/0, 2/0                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>EP:</b>                                                                                                                                                                                                                                                          | 0,7 1 1,5 2 3                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                              | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                             | Variety of lengths, from 5 mm to 110 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                              | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                           | 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**

|                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                               | 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7                                                                                                                                                                                                                                                                                                                                                                 |
| <b>EP:</b>                                                                                                                                                                                                                                                | 1 1,5 2 3 3,5 4 5 6 6 7 8 9                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                    | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                   | Variety of lengths, from 10 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                    | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                 | 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**

|                                                                                                |                     |
|------------------------------------------------------------------------------------------------|---------------------|
| <b>Sterile, Nonabsorbable, Non-woven, White colored and in the following dimension ranges:</b> |                     |
| <b>Width</b>                                                                                   | = 3 mm ..... 150 mm |
| <b>Length</b>                                                                                  | = 3 mm .....150 mm  |
| <b>Height</b>                                                                                  | = 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](http://www.udem.com.tr).

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

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

E-mail: [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)



**Surgical Silk Suture Product Models GMDN No: 13910 Class III**

|                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>USP:</b>                                                                                                                                                                                                                                                                         | 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4                                                                                                                                                                                                                                                                                                                                                     |
| <b>EP:</b>                                                                                                                                                                                                                                                                          | 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Thread Lengths :</b>                                                                                                                                                                                                                                                             | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                             | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                              | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                           | 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**

|                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                                                          | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                      |
| <b>EP:</b>                                                                                                                                                                                                                                                                                           | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Thread Lengths :</b>                                                                                                                                                                                                                                                                              | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                                              | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                                               | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                                            | 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**

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| <b>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</b> |                                                       |
| <b>USP:</b>                                                                                                                                                                                                                                               | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2 |
| <b>EP:</b>                                                                                                                                                                                                                                                | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                 |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                    | Variety of lengths, from 10 cm to 500 cm              |

|                           |                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Needle Lengths :</b>   | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>    | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b> | 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**

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| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                                                                  | 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2                                                                                                                                                                                                                                                                                                                                                      |
| <b>EP:</b>                                                                                                                                                                                                                                                                                                   | 0,2 0,3 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                                                                       | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                                                      | Variety of lengths, from 3 mm to 150 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                                                       | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                                                    | 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**

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                                                                                   | 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5                                                                                                                                                                                                                                                                                                                                                             |
| <b>EP:</b>                                                                                                                                                                                                                                                                                                                    | 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                                                                                        | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                                                                                       | Variety of lengths, from 5 mm to 110 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                                                                                        | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                                                                                     | 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**

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>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:</b> |                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>USP:</b>                                                                                                                                                                                                                                                         | 6/0, 5/0, 4/0, 3/0, 2/0                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>EP:</b>                                                                                                                                                                                                                                                          | 0,7 1 1,5 2 3                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Thread Lengths:</b>                                                                                                                                                                                                                                              | Variety of lengths, from 10 cm to 500 cm                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Needle Lengths :</b>                                                                                                                                                                                                                                             | Variety of lengths, from 5 mm to 110 mm                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Needle Shapes :</b>                                                                                                                                                                                                                                              | 1/2, 3/8, 1/4, 5/8, Straight, J, SKI                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Needle Properties:</b>                                                                                                                                                                                                                                           | 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**

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|------------------------------------------------------------------------------------------------|---------------------|
| <b>Sterile, Nonabsorbable, Non-woven, White colored and in the following dimension ranges:</b> |                     |
| <b>Width</b>                                                                                   | = 3 mm ..... 150 mm |
| <b>Length</b>                                                                                  | = 3 mm .....150 mm  |
| <b>Height</b>                                                                                  | = 1 mm ..... 2 mm   |