

## Surgical Sutures Absorbable

# Glikosorb

Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

Boz®



### Definition

Synthetic absorbable, coated, mid term wound support and mid term mass absorption.

### Material

Polyglycolic Acid (PGA)

### Coating

Calcium Stearate and polycaprolactone

### Structure

Braided - Multifilament

### Colour

Violet (dyed) or Beige (undyed)

### Size

EP : 0.4 to 8

USP : 8/0 to 6

### Tensile Strenght Retention

2. Week 75 % - 3. Week 50 %

### Mass Absorption

60-90 days

### Sterilization Method

Ethylene Oxide Gas

### Main Indication

Gastrointestinal Surgery

Gynaecology

Ophthalmic Surgery

Orthopedics

Urology

Skin closer - intracutaneous, subcutaneous.

Ligatures

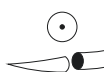
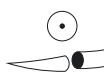
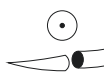
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| Needle Length and description |                                                                                     |                                                                                     | Product No | USP EP     | Length (cm) | Unit Pcs | Color  |
|-------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------|------------|-------------|----------|--------|
| 6 mm                          |                                                                                     |                                                                                     |            |            |             |          |        |
| 3/8<br>Spatula<br>220 Micron  |    |    | GS5401     | 8/0<br>0,4 | 45          | 12       | Violet |
| 3/8<br>Spatula<br>230 Micron  |    |    | GS1156     | 8/0<br>0,4 | 45          | 12       | Violet |
|                               |                                                                                     |                                                                                     | GS1252     | 7/0<br>0,5 | 30          | 12       | Violet |
| 6,6 mm                        |                                                                                     |                                                                                     |            |            |             |          |        |
| 1/2<br>Cobra<br>230 Micron    |    |    | GS5519     | 8/0<br>0,4 | 60          | 12       | Violet |
| 1/2<br>Cobra<br>280 Micron    |    |    | GS5518     | 7/0<br>0,5 | 60          | 12       | Violet |
| 8 mm                          |                                                                                     |                                                                                     |            |            |             |          |        |
| 1/2<br>Spatula<br>230 Micron  |  |  | GS1193     | 8/0<br>0,4 | 30          | 12       | Violet |
|                               |                                                                                     |                                                                                     | GS1195     | 8/0<br>0,4 | 45          | 12       | Violet |
| 1/2<br>Spatula<br>330 Micron  |  |  | GS1272     | 7/0<br>0,5 | 45          | 12       | Violet |
|                               |                                                                                     |                                                                                     | GS1395     | 6/0<br>0,7 | 45          | 12       | Violet |
| 1/2<br>Spatula<br>340 Micron  |  |  | GS5526     | 5/0<br>1,0 | 45          | 12       | Violet |
| 1/4<br>Spatula<br>230 Micron  |  |  | GS1190     | 8/0<br>0,4 | 45          | 12       | Violet |
| 1/4<br>Spatula<br>250 Micron  |  |  | GS5876     | 7/0<br>0,5 | 45          | 12       | Violet |
| 1/4<br>Spatula<br>340 Micron  |  |  | GS1268     | 7/0<br>0,5 | 45          | 12       | Violet |
|                               |                                                                                     |                                                                                     | GS1404     | 6/0<br>0,7 | 30          | 12       | Violet |
|                               |                                                                                     |                                                                                     | GS1405     | 6/0<br>0,7 | 45          | 12       | Violet |
|                               |                                                                                     |                                                                                     | GS1406     | 6/0<br>0,7 | 45          | 12       | Undyed |
|                               |                                                                                     |                                                                                     | GS1764     | 5/0<br>1,0 | 45          | 12       | Violet |

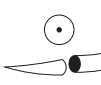
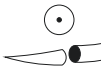
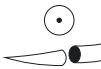
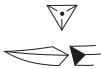
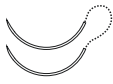
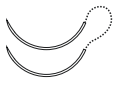
# Glikosorb

Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

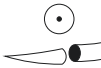
| Needle Length and description                |                                                                                     |                                                                                     | Product No | USP EP     | Length (cm) | Unit Pcs | Color  |
|----------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------|------------|-------------|----------|--------|
| 8 mm                                         |                                                                                     |                                                                                     |            |            |             |          |        |
| 1/4<br>Spatula<br>430 Micron                 |    |    | GS2362     | 4/0<br>1,5 | 45          | 12       | Violet |
| 1/4<br>Spatula<br>430 Micron                 |    |    | GS2363     | 4/0<br>1,5 | 45          | 12       | Violet |
| 3/8<br>Round Body, Taper Point<br>230 Micron |    |    | GS1207     | 8/0<br>0,4 | 30          | 12       | Violet |
| 3/8<br>Round Body, Taper Point<br>280 Micron |    |    | GS1413     | 6/0<br>0,7 | 45          | 12       | Violet |
|                                              |                                                                                     |                                                                                     | GS1426     | 6/0<br>0,7 | 45          | 12       | Violet |
|                                              |                                                                                     |                                                                                     | GS1768     | 5/0<br>1,0 | 45          | 12       | Violet |
| 10 mm                                        |                                                                                     |                                                                                     |            |            |             |          |        |
| 3/8<br>Round Body, Taper Point<br>280 Micron |  |  | GS1480     | 6/0<br>0,7 | 75          | 12       | Violet |
| 3/8<br>Reverse Cutting<br>330 Micron         |  |  | GS1496     | 6/0<br>0,7 | 45          | 12       | Violet |
| 3/8<br>Reverse Cutting<br>330 Micron         |  |  | GS1492     | 6/0<br>0,7 | 45          | 12       | Violet |
| 3/8<br>Inside Cutting<br>280 Micron          |  |  | GS1508     | 6/0<br>0,7 | 45          | 12       | Violet |
| 12 mm                                        |                                                                                     |                                                                                     |            |            |             |          |        |
| 3/8<br>Reverse Cutting<br>330 Micron         |  |  | GS1541     | 6/0<br>0,7 | 45          | 12       | Violet |
| 3/8<br>Spatula<br>280 Micron                 |  |  | GS1523     | 6/0<br>0,7 | 45          | 12       | Violet |
| 13 mm                                        |                                                                                     |                                                                                     |            |            |             |          |        |
| 1/2<br>Round Body, Taper Point<br>330 Micron |  |  | GS1560     | 6/0<br>0,7 | 45          | 12       | Violet |
|                                              |                                                                                     |                                                                                     | GS1564     | 6/0<br>0,7 | 75          | 12       | Violet |

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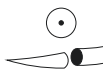
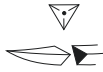
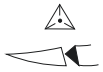
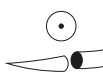
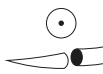
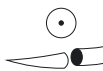
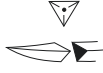
| Needle Length and description                              |                                                                                     |                                                                                     | Product No    | USP EP            | Length (cm) | Unit Pcs | Color  |
|------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|--------|
| <b>13 mm</b>                                               |                                                                                     |                                                                                     |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point<br><b>330 Micron</b> |    |    | <b>GS1561</b> | <b>6/0</b><br>0,7 | 45          | 12       | Violet |
| <b>1/2</b><br>Round Body, Taper Point<br><b>380 Micron</b> |    |    | <b>GS1885</b> | <b>5/0</b><br>1,0 | 75          | 12       | Violet |
| <b>1/2</b><br>Round Body, Taper Point<br><b>430 Micron</b> |    |    | <b>GS1894</b> | <b>5/0</b><br>1,0 | 75          | 12       | Violet |
| <b>3/8</b><br>Round Body, Taper Point<br><b>330 Micron</b> |    |    | <b>GS1580</b> | <b>6/0</b><br>0,7 | 45          | 12       | Violet |
|                                                            |                                                                                     |                                                                                     | <b>GS1590</b> | <b>6/0</b><br>0,7 | 75          | 12       | Violet |
| <b>3/8</b><br>Round Body, Taper Point<br><b>380 Micron</b> |    |    | <b>GS1914</b> | <b>5/0</b><br>1,0 | 75          | 12       | Violet |
| <b>3/8</b><br>Round Body, Taper Point<br><b>430 Micron</b> |  |   | <b>GS2432</b> | <b>4/0</b><br>1,5 | 45          | 12       | Violet |
|                                                            |                                                                                     |                                                                                     | <b>GS2434</b> | <b>4/0</b><br>1,5 | 60          | 12       | Violet |
| <b>3/8</b><br>Reverse Cutting<br><b>380 Micron</b>         |  |  | <b>GS1928</b> | <b>5/0</b><br>1,0 | 75          | 12       | Violet |
| <b>3/8</b><br>Reverse Cutting<br><b>560 Micron</b>         |  |  | <b>GS2456</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
| <b>3/8</b><br>Spatula<br><b>280 Micron</b>                 |  |  | <b>GS1605</b> | <b>6/0</b><br>0,7 | 45          | 12       | Violet |
| <b>3/8</b><br>Spatula<br><b>330 Micron</b>                 |  |  | <b>GS1873</b> | <b>5/0</b><br>1,0 | 60          | 12       | Violet |
| <b>3/8</b><br>Trocarn<br><b>330 Micron</b>                 |  |  | <b>GS2416</b> | <b>4/0</b><br>1,5 | 45          | 12       | Violet |

## 16 mm

|                                       |                                                                                     |                                                                                     |               |                   |    |    |        |
|---------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------|-------------------|----|----|--------|
| <b>1/2</b><br>Round Body, Taper Point |  |  | <b>GS1990</b> | <b>5/0</b><br>1,0 | 75 | 12 | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS1992</b> | <b>5/0</b><br>1,0 | 75 | 12 | Undyed |
|                                       |                                                                                     |                                                                                     | <b>GS2503</b> | <b>4/0</b><br>1,5 | 75 | 12 | Undyed |
|                                       |                                                                                     |                                                                                     | <b>GS2504</b> | <b>4/0</b><br>1,5 | 75 | 12 | Violet |

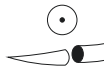
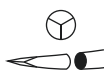
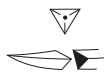
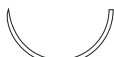
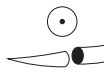
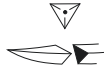
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| Needle Length and description  |                                                                                     |                                                                                     | Product No | USP EP     | Length (cm) | Unit Pcs | Color  |
|--------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------|------------|-------------|----------|--------|
| 16 mm                          |                                                                                     |                                                                                     |            |            |             |          |        |
| 1/2<br>Round Body, Taper Point |    |    | GS3005     | 3/0<br>2,0 | 75          | 12       | Violet |
| 3/8<br>Reverse Cutting         |    |    | GS1674     | 6/0<br>0,7 | 75          | 12       | Violet |
|                                |                                                                                     |                                                                                     | GS2014     | 5/0<br>1,0 | 45          | 12       | Undyed |
|                                |                                                                                     |                                                                                     | GS2540     | 4/0<br>1,5 | 75          | 12       | Violet |
|                                |                                                                                     |                                                                                     | GS3025     | 3/0<br>2,0 | 75          | 12       | Violet |
| 3/8<br>Inside Cutting          |    |    | GS2140     | 5/0<br>1,0 | 45          | 12       | Violet |
|                                |                                                                                     |                                                                                     | GS2144     | 5/0<br>1,0 | 75          | 12       | Violet |
|                                |                                                                                     |                                                                                     | GS2557     | 4/0<br>1,5 | 75          | 12       | Undyed |
|                                |                                                                                     |                                                                                     | GS3039     | 3/0<br>2,0 | 75          | 12       | Violet |
| 17 mm                          |                                                                                     |                                                                                     |            |            |             |          |        |
| 1/2<br>Round Body, Taper Point |  |  | GS2584     | 4/0<br>1,5 | 75          | 12       | Violet |
| 18 mm                          |                                                                                     |                                                                                     |            |            |             |          |        |
| 1/2<br>Round Body, Taper Point |  |  | GS5525     | 5/0<br>1,0 | 75          | 12       | Violet |
|                                |                                                                                     |                                                                                     | GS2613     | 4/0<br>1,5 | 75          | 12       | Violet |
|                                |                                                                                     |                                                                                     | GS3624     | 2/0<br>3,0 | 75          | 12       | Violet |
| 3/8<br>Round Body, Taper Point |  |  | GS3085     | 3/0<br>2,0 | 75          | 12       | Violet |
| 19 mm                          |                                                                                     |                                                                                     |            |            |             |          |        |
| 3/8<br>Reverse Cutting         |  |  | GS1706     | 6/0<br>0,7 | 75          | 12       | Violet |
|                                |                                                                                     |                                                                                     | GS2640     | 4/0<br>1,5 | 75          | 12       | Violet |
| 3/8<br>Reverse Cutting Premium |  |  | GS2211     | 5/0<br>1,0 | 45          | 12       | Violet |

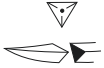
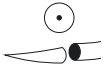
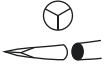
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| Needle Length and description         |                                                                                     |                                                                                     | Product No    | USP EP            | Length (cm) | Unit Pcs | Color  |
|---------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|--------|
| 20 mm                                 |                                                                                     |                                                                                     |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point |    |    | <b>GS2229</b> | <b>5/0</b><br>1,0 | 75          | 12       | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS2685</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS3142</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
| <b>1/2</b><br>Tapercutting            |    |    | <b>GS2673</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
| <b>3/8</b><br>Reverse Cutting         |  |  | <b>GS2250</b> | <b>5/0</b><br>1,0 | 75          | 12       | Undyed |
|                                       |                                                                                     |                                                                                     | <b>GS2716</b> | <b>4/0</b><br>1,5 | 45          | 12       | Undyed |
|                                       |                                                                                     |                                                                                     | <b>GS2719</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS3164</b> | <b>3/0</b><br>2,0 | 45          | 12       | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS3168</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS3663</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
| 22 mm                                 |                                                                                     |                                                                                     |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point |  |  | <b>GS2747</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS3196</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS3671</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS4575</b> | <b>1</b><br>4,0   | 75          | 12       | Violet |
| <b>3/8</b><br>Reverse Cutting         |  |  | <b>GS2763</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
|                                       |                                                                                     |                                                                                     | <b>GS3214</b> | <b>3/0</b><br>2,0 | 90          | 12       | Violet |

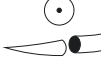
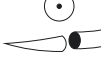
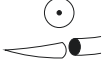
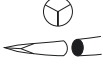
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Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

| Needle Length and description                                                                                                                                                                                 | Product No    | USP EP            | Length (cm) | Unit Pcs | Color  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|--------|
| <b>24 mm</b>                                                                                                                                                                                                  |               |                   |             |          |        |
| <b>1/2</b><br>Reverse Cutting               | <b>GS5524</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS5523</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3692</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
| <b>25 mm</b>                                                                                                                                                                                                  |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point       | <b>GS2788</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3252</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3746</b> | <b>2/0</b><br>3,0 | 100         | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3724</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
| <b>1/2</b><br>Tapercutting              | <b>GS3718</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
| <b>3/8</b><br>Reverse Cutting           | <b>GS2804</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3757</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
| <b>3/8</b><br>Inside Cutting            | <b>GS2812</b> | <b>4/0</b><br>1,5 | 45          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3284</b> | <b>3/0</b><br>2,0 | 45          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3763</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
| <b>26 mm</b>                                                                                                                                                                                                  |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point   | <b>GS2292</b> | <b>5/0</b><br>1,0 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS2828</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3313</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3318</b> | <b>3/0</b><br>2,0 | 90          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3786</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |

# Glikosorb

Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

| Needle Length and description                                                                                                                                                                                 | Product No    | USP EP            | Length (cm) | Unit Pcs | Color  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|--------|
| <b>26 mm</b>                                                                                                                                                                                                  |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point       | <b>GS4215</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS4592</b> | <b>1</b><br>4,0   | 90          | 12       | Violet |
| <b>1/2</b><br>Reverse Cutting               | <b>GS4230</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
| <b>3/8</b><br>Round Body, Taper Point       | <b>GS2841</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
| <b>3/8</b><br>Reverse Cutting               | <b>GS3345</b> | <b>3/0</b><br>2,0 | 75          | 12       | Undyed |
|                                                                                                                                                                                                               | <b>GS3346</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3821</b> | <b>2/0</b><br>3,0 | 75          | 12       | Undyed |
|                                                                                                                                                                                                               | <b>GS3822</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
| <b>30 mm</b>                                                                                                                                                                                                  |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point   | <b>GS3369</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3374</b> | <b>3/0</b><br>2,0 | 90          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS3858</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS4244</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS4608</b> | <b>1</b><br>4,0   | 75          | 12       | Violet |
| <b>1/2</b><br>Reverse Cutting           | <b>GS3882</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
|                                                                                                                                                                                                               | <b>GS4266</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
| <b>1/2</b><br>Tapercutting              | <b>GS3843</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |

# Glikosorb

Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

| Needle Length and description                                                                                             |  | Product No    | USP EP            | Length (cm) | Unit Pcs | Color  |
|---------------------------------------------------------------------------------------------------------------------------|--|---------------|-------------------|-------------|----------|--------|
| <b>30 mm</b>                                                                                                              |  |               |                   |             |          |        |
| <b>3/8</b><br>Reverse Cutting            |  | <b>GS2887</b> | <b>4/0</b><br>1,5 | 75          | 12       | Violet |
|                                                                                                                           |  | <b>GS3397</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                                                                                                           |  | <b>GS3891</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
|                                                                                                                           |  | <b>GS4273</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
| <b>32 mm</b>                                                                                                              |  |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point    |  | <b>GS5508</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
| <b>35 mm</b>                                                                                                              |  |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point  |  | <b>GS3411</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                                                                                                           |  | <b>GS3916</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
|                                                                                                                           |  | <b>GS3922</b> | <b>2/0</b><br>3,0 | 90          | 12       | Violet |
|                                                                                                                           |  | <b>GS4300</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
|                                                                                                                           |  | <b>GS4644</b> | <b>1</b><br>4,0   | 75          | 12       | Violet |
| <b>3/8</b><br>Reverse Cutting          |  | <b>GS3423</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                                                                                                           |  | <b>GS3933</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
| <b>36 mm</b>                                                                                                              |  |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point  |  | <b>GS5509</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
| <b>1/2</b><br>Reverse Cutting          |  | <b>GS4675</b> | <b>1</b><br>4,0   | 75          | 12       | Violet |

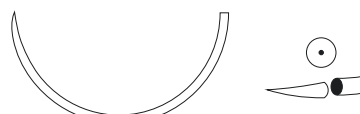
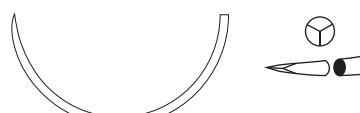
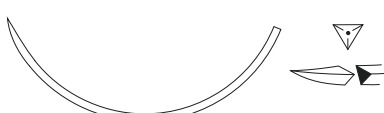
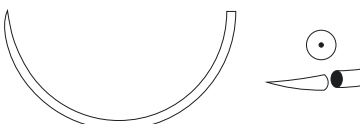
# Glikosorb

Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

| Needle Length and description                                                                                             | Product No    | USP EP            | Length (cm) | Unit Pcs | Color  |
|---------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|--------|
| <b>37 mm</b>                                                                                                              |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point    | <b>GS3950</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
|                                                                                                                           | <b>GS4337</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
|                                                                                                                           | <b>GS4681</b> | <b>1</b><br>4,0   | 75          | 12       | Violet |
| <b>1/2</b><br>Reverse Cutting            | <b>GS5507</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
|                                                                                                                           | <b>GS4354</b> | <b>0</b><br>3,5   | 90          | 12       | Violet |
|                                                                                                                           | <b>GS4994</b> | <b>2</b><br>5,0   | 75          | 12       | Violet |
| <b>40 mm</b>                                                                                                              |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point  | <b>GS3982</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
|                                                                                                                           | <b>GS4368</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
|                                                                                                                           | <b>GS4375</b> | <b>0</b><br>3,5   | 90          | 12       | Violet |
|                                                                                                                           | <b>GS4713</b> | <b>1</b><br>4,0   | 75          | 12       | Violet |
|                                                                                                                           | <b>GS4719</b> | <b>1</b><br>4,0   | 90          | 12       | Violet |
|                                                                                                                           | <b>GS5003</b> | <b>2</b><br>5,0   | 75          | 12       | Violet |
|                                                                                                                           | <b>GS5006</b> | <b>2</b><br>5,0   | 90          | 12       | Violet |
| <b>1/2</b><br>Reverse Cutting          | <b>GS4397</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
|                                                                                                                           | <b>GS4745</b> | <b>1</b><br>4,0   | 75          | 12       | Violet |
|                                                                                                                           | <b>GS4749</b> | <b>1</b><br>4,0   | 90          | 12       | Violet |
|                                                                                                                           | <b>GS5019</b> | <b>2</b><br>5,0   | 75          | 12       | Violet |

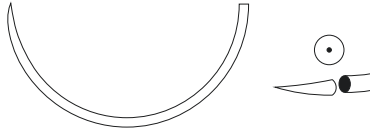
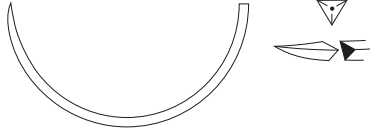
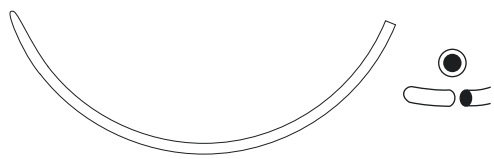
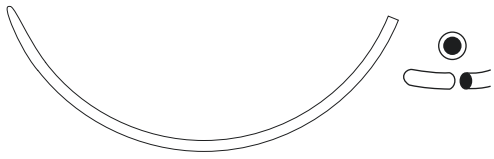
# Glikosorb

Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

| Needle Length and description  |                                                                                     | Product No | USP EP     | Length (cm) | Unit Pcs | Color  |
|--------------------------------|-------------------------------------------------------------------------------------|------------|------------|-------------|----------|--------|
| 40 mm                          |                                                                                     |            |            |             |          |        |
| 1/2<br>Reverse Cutting         |    | GS5023     | 2<br>5,0   | 90          | 12       | Violet |
| 1/2<br>Tapercutting            |    | GS4363     | 0<br>3,5   | 75          | 12       | Violet |
| 3/8<br>Reverse Cutting         |    | GS4756     | 1<br>4,0   | 75          | 12       | Violet |
|                                |                                                                                     | GS4408     | 0<br>3,5   | 75          | 12       | Violet |
| 45 mm                          |                                                                                     |            |            |             |          |        |
| 1/2<br>Round Body, Taper Point |  | GS4422     | 0<br>3,5   | 75          | 12       | Violet |
|                                |                                                                                     | GS4772     | 1<br>4,0   | 75          | 12       | Violet |
|                                |                                                                                     | GS5035     | 2<br>5,0   | 75          | 12       | Violet |
|                                |                                                                                     | GS5040     | 2<br>5,0   | 90          | 12       | Violet |
| 1/2<br>Tapercutting            |  | GS4766     | 1<br>4,0   | 75          | 12       | Violet |
|                                |                                                                                     | GS5738     | 2<br>5,0   | 75          | 12       | Violet |
| 3/8<br>Reverse Cutting         |  | GS4432     | 0<br>3,5   | 75          | 12       | Violet |
|                                |                                                                                     | GS4787     | 1<br>4,0   | 75          | 12       | Violet |
| Straight<br>Reverse Cutting    |  | GS2909     | 4/0<br>1,5 | 45          | 12       | Violet |
| 48 mm                          |                                                                                     |            |            |             |          |        |
| 1/2<br>Round Body, Taper Point |  | GS4796     | 1<br>4,0   | 75          | 12       | Violet |

# Glikosorb

Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

| Needle Length and description                                                                                              | Product No    | USP EP            | Length (cm) | Unit Pcs | Color  |
|----------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|-------------|----------|--------|
| <b>50 mm</b>                                                                                                               |               |                   |             |          |        |
| <b>1/2</b><br>Round Body, Taper Point<br> | <b>GS4454</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
|                                                                                                                            | <b>GS4459</b> | <b>0</b><br>3,5   | 90          | 12       | Violet |
|                                                                                                                            | <b>GS4812</b> | <b>1</b><br>4,0   | 75          | 12       | Violet |
|                                                                                                                            | <b>GS4818</b> | <b>1</b><br>4,0   | 90          | 12       | Violet |
|                                                                                                                            | <b>GS5066</b> | <b>2</b><br>5,0   | 75          | 12       | Violet |
|                                                                                                                            | <b>GS5070</b> | <b>2</b><br>5,0   | 90          | 12       | Violet |
| <b>1/2</b><br>Reverse Cutting<br>        | <b>GS4471</b> | <b>0</b><br>3,5   | 75          | 12       | Violet |
| <b>60 mm</b>                                                                                                               |               |                   |             |          |        |
| <b>Straight</b><br>Reverse Cutting<br>  | <b>GS3492</b> | <b>3/0</b><br>2,0 | 75          | 12       | Violet |
|                                                                                                                            | <b>GS4074</b> | <b>2/0</b><br>3,0 | 75          | 12       | Violet |
| <b>63 mm</b>                                                                                                               |               |                   |             |          |        |
| <b>3/8</b><br>Blunt<br>                 | <b>GS4858</b> | <b>1</b><br>4,0   | 75          | 12       | Violet |
| <b>64 mm</b>                                                                                                               |               |                   |             |          |        |
| <b>3/8</b><br>Blunt<br>                 | <b>GS4500</b> | <b>0</b><br>3,5   | 90          | 12       | Violet |
|                                                                                                                            | <b>GS4861</b> | <b>1</b><br>4,0   | 90          | 12       | Violet |

# Glikosorb

Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

| Non-Needle Suture                     | Product No    | USP EP            | Length (cm) | Unit Pcs | Color  |
|---------------------------------------|---------------|-------------------|-------------|----------|--------|
| <b>6x45 cm</b>                        |               |                   |             |          |        |
| <b>GLIKOSORB</b><br>Non-Needle Suture | <b>GS2950</b> | <b>3/0</b><br>2,0 | 6x45        | 12       | Violet |
|                                       | <b>GS3543</b> | <b>2/0</b><br>3,0 | 6x45        | 12       | Violet |
|                                       | <b>GS4137</b> | <b>0</b><br>3,5   | 6x45        | 12       | Violet |
|                                       | <b>GS4563</b> | <b>1</b><br>4,0   | 6x45        | 12       | Violet |
| <b>10x50 cm</b>                       |               |                   |             |          |        |
| <b>GLIKOSORB</b><br>Non-Needle Suture | <b>GS2954</b> | <b>3/0</b><br>2,0 | 10x50       | 12       | Violet |
|                                       | <b>GS3548</b> | <b>2/0</b><br>3,0 | 10x75       | 12       | Violet |
| <b>12x45 cm</b>                       |               |                   |             |          |        |
| <b>GLIKOSORB</b><br>Non-Needle Suture | <b>GS2344</b> | <b>4/0</b><br>1,5 | 12x45       | 12       | Violet |
|                                       | <b>GS2958</b> | <b>3/0</b><br>2,0 | 12x45       | 12       | Violet |
|                                       | <b>GS3552</b> | <b>2/0</b><br>3,0 | 12x45       | 12       | Violet |
|                                       | <b>GS4145</b> | <b>0</b><br>3,5   | 12x45       | 12       | Violet |
|                                       | <b>GS4554</b> | <b>1</b><br>4,0   | 12x45       | 12       | Violet |
| <b>17x45 cm</b>                       |               |                   |             |          |        |
| <b>GLIKOSORB</b><br>Non-Needle Suture | <b>GS2966</b> | <b>3/0</b><br>2,0 | 17x45       | 12       | Violet |
|                                       | <b>GS3558</b> | <b>2/0</b><br>3,0 | 17x45       | 12       | Violet |
| <b>150 cm</b>                         |               |                   |             |          |        |
| <b>GLIKOSORB</b><br>Non-Needle Suture | <b>GS1737</b> | <b>5/0</b><br>1,0 | 150         | 12       | Violet |
|                                       | <b>GS2326</b> | <b>4/0</b><br>1,5 | 150         | 12       | Violet |
|                                       | <b>GS2935</b> | <b>3/0</b><br>2,0 | 150         | 12       | Violet |

# Glikosorb

Surgical Suture, Polyglycolicacid (PGA) Absorbable, Synthetic, Braided

| Non-Needle Suture                     | Product No    | USP EP            | Length (cm) | Unit Pcs | Color  |
|---------------------------------------|---------------|-------------------|-------------|----------|--------|
| <b>150 cm</b>                         |               |                   |             |          |        |
| <b>GLIKOSORB</b><br>Non-Needle Suture | <b>GS3511</b> | <b>2/0</b><br>3,0 | 150         | 12       | Violet |
|                                       | <b>GS4114</b> | <b>0</b><br>3,5   | 150         | 12       | Violet |
|                                       | <b>GS4532</b> | <b>1</b><br>4,0   | 150         | 12       | Violet |

|                                       |               |                   |     |    |        |
|---------------------------------------|---------------|-------------------|-----|----|--------|
| <b>250 cm</b>                         |               |                   |     |    |        |
| <b>GLIKOSORB</b><br>Non-Needle Suture | <b>GS2332</b> | <b>4/0</b><br>1,5 | 250 | 12 | Violet |
|                                       | <b>GS2942</b> | <b>3/0</b><br>2,0 | 250 | 12 | Violet |
|                                       | <b>GS3518</b> | <b>2/0</b><br>3,0 | 250 | 12 | Violet |
|                                       | <b>GS4121</b> | <b>0</b><br>3,5   | 250 | 12 | Violet |
|                                       | <b>GS4541</b> | <b>1</b><br>4,0   | 250 | 12 | Violet |

# Prospektüs

## Prospectus

# GLIKOSORB

## Emilebilir Cerrahi Ameliyat İpliği

Absorbable Surgical Sutures

Lütfen dilinizi seçiniz  
Please select your language



TR

**GLIKOSORB**

Cerrahi, Poliglikolik Asit  
Emilebilir PGA Süturu  
Sentetik, Multifilaman, Örgülü, Undyed/Violet

**Kullanma Talimatı****TANIM**

GLIKOSORB glikolik asidin homopolimerinden oluşan sentetik, steril, emilebilir cerrahi poliglikolik asit (PGA) ipliklerdir. Poliglikolik asidin ampirik formülü  $(-O-CH_2-CO-O-CH_2-CO)_n$  şeklindedir. Cerrahi poliglikolik asit kalsiyum stearat  $(C_{18}H_{35}O_2)_n$  ve polikaprolakton  $(C_{12}H_{22}O)_n$  karışımından oluşur. GLIKOSORB iplik ve kaplama maddeyi inert, kolajen yapıda olmayan, antijenik ve yavaş eriyen malzemedir. Dokuda rahat görünürlüğü sağlamak için mor renge boyanmıştır (D&C Violet No.2 C.I. #60725/Solvent Violet 13).

**KULLANILMALANI**

GLIKOSORB iplikler, oftalmik uygulamaları da dahil olduğu genel yumuşak dokuya kapama veya bağlama için kullanılmakla birlikte, Kalp-damar ve sinirsel dokularda kullanılmaz. GLIKOSORB iplik tek kullanımlıdır.

**ETKİLERİ**

Cerrahi PGA iplik dokuda hafif bir şekilde akut yangı reaksiyonu gösterebilir ve fibröz bağ dokusu oluşumu ortaya çıkar. Hidrolyz sonrasında PGA ipliğin mukavemeti azalır ve emilimi gerçekleşir. Hidrolyz sonucunda su ve karbondioksit meydana gelir ve yavaş yavaş dışlanır. Kütle kaybını takiben kapama mukavemetinin azalması ile emilim başlar. PGA iplik implantasyondan sonraki 2 hafta içerisinde orijinal gerilme mukavemetinin yaklaşık %75 ini muhafaza eder. USP 6-0 ve daha büyük olanlar üçüncü haftada orijinal gerilme mukavemetlerinin yaklaşık %50 sini, USP 7-0 ve daha küçük olanlar ise orijinal gerilme mukavemetlerinin yaklaşık %40 ını korur. İmplantasyondan sonra orijinal gerilme mukavemetlerinin tamamını döndürdü ve beşinci haftalarda kaybeder. 60-90 gün içerisinde ise tamamı emilir.

**KULLANILMAMASI GEREKEN YERLER**

Emilebilir olmasından dolayı uzun süreli dokü desteği gereken kapamalarda kullanılmamalıdır. Kalp-damar ve sinirsel dokularda kullanılmamalıdır.

**UYARILAR**

Yara ayırması riski, uygulanılan bölgeye ve kullanılan sürtü malzemesine göre değiştiğinden kullanıcının yara kapaması için sürtü kullanmadan önce emilebilir sürtürünün kullanıldığı cerrahi prosedürler ve tekniklere aşina olması gerekir. Doktorlar hastalarda kullanılabilecek sürtü sepmelerinden önce in vivo performansı (ETKİLERİ kısmının altında) dikkate almalıdır.

Deride 7 günden fazla kalıcı cilt sürtürülen bölgesel tahrişe sebep olabilir. Bu durumda sürtürü kesilmesi ya da uzaklaştırılmalıdır. Bazı durumlarda, özellikle ortopedik prosedürlerde, dış desteklerin immobilizasyonu cerrahın sağduyasına göre yönlendirilmelidir. İplik dahi atılabilirliği ve emilim gelecekteki için bu durum, emilebilir ipliklerin yaygın kan akımının olduğu dokuda kullanılmadığı göz önünde bulundurulmalıdır. İpliklerin kordon, safra ya da üriner sistemdeki gibi mevcut olan tuz çözültüleri ile uzun süreli teması tuz oluşumuna sebebiyet verebilir. Tekrar steril etmeyiniz. Açılış poşetleri ve kullanılmayan ipleri imha ediniz.

Kontamine veya iltihaplı yaraların tedavisi için kabul edilen cerrahi uygulamalar izlenmelidir.

**ÖNEMLER**

PGA ipliğinin veya diğer tüm cerrahi ipliklerin kullanımında ipliğe ve iğneye zarar vermekten kaçınılmalıdır. Forseps veya iğne tutucu gibi cerrahi aletlerin kullanımına bağlı ezme veya çarpma hatalarından kaçınılmalıdır. İğne ucu ve bağlama başlığının hasar görmemesi için, bağlanti ucu ve iğne ucu arasında mesafenin üçte bir (1/3) ile yarıya (1/2) arasındakı kısmattan tutun. İğneleri yeniden şekillendirmek, güçlerini kaybetmelerine ve bükülmeye ve kırılmalara karşı

diremlerinin azaltılması neden olabilir. İstem dışı iğne batmalarından kaçınmak için kullanıcılardan cerrahi iğne kullanırken dikkatli olmaları gerekir. PGA iplikler, kullanımı karıştırdığına artırmak için cerrahi şartlara ve cerrahin tecrübesine bağlı olarak garanti altına alınan kabul görmüş ölçü ve kare ölçüm teknikleri ile beraber ilave ölçümler gerektirir.

Yüksek sıcaklıklara uzun süre maruz bırakılmaması önerilir.

Kontamine ve kullanılmamış ürünlü bölge ve tesis gereksinimlerine uygun olarak imha ediniz.

Kullanılan iğneleri "kesici alet" kaplarına atınız.

**YAN ETKİLER**

Bu cihazın kullanımına bağlı yan etkiler; yaranın açılması, şişme, gerilme ya da gerginleşmenin olduğu bölgeğin kapatılmasında yeterli yara desteğinin sağlanamaması, yayılma, yanık beslenme ya da aşırı yayılma hastalardaki yara iyileşmesinin geçmesinden dolayı rahatsızlık veya hastalardaki yara desteğinin sağlanamaması, enfeksiyon, minimal akut dokü yangı reaksiyonu, ipliğin cilt üzerinde 7 günden daha fazla kalması durumunda bölgesel tahriş, ipliklerin yaygın kan akımının olduğu dokuda dışarı atılması ve emiliminin sürmesi, uzun süreli tuz çözültüleri ile temaslı üriner sistemde ve safra yolu (taç) oluşumu ve yaradığı geçici bölgeye tahriş içermektedir.

**PIYASAYARZ-SUNUŞ ŞEKLİ**

GLIKOSORB iplikler örgülü, boyanmış (mor) ve boyanmamış olarak U.S.P. 8/0 ve 6 (metrik 0.4 - 8) arasında, değişik boyalarda, iğneler olarak mevcuttur.

GLIKOSORB iplikler bir, iki veya üç düzlemlik kutularda bulunmaktadır.

GLIKOSORB iplikler steril olarak arz edilir.

**DEPOLAMA**

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

Nemden koruyunuz.

Son kullanma tarihinden sonra kullanmayınız.

**ETİKETLEMEDE KULLANILAN İŞRETLER**

2 tek kullanımlık



Tekrar steril etmeyiniz



Paket zarar görmüşse kullanmayınız



Üretici



YYYY-MM Üretim tarihi, Y4



YYYY-MM Son kullanma tarihi, Y4-Y4



STERILE EO Steril EO: Etilenoksit



LOT



Seri No



Boyalı, Emilebilir, Örgülü, Kaplamalı



Boyasız,Emilebilir,Örgülü,Kaplamalı



REF Katalog numarası



25°C'nin altında muhafaza ediniz



Güneğten uzak tutunuz



Nemden koruyunuz



Gen dönüşümlü paket



OKMAt, Kullanma Kılavuzuna bakınız



CE 2292

IFU-GS-rev-06-15-01-2018

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"EASSİ (Avrupa Cerrahi Sütür Sanayi Birliği) üyesi sütür ürün karıştırdıkları için sezişsiz ve resmî olarak tanımlanmış bir sistem geliştirmiş. Sembol kullanımda 1 tbbi cihaz (Medical Device Directive) (MDR 93/42/EEC) izin vermektedir ve çözümlü derin tecrübesine göre kalınmadı üretilen kullanıcılara bilgi sağlamasına imkan tanımaktadır. "



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

**GLIKOSORB**

Surgical, Polyglycolic Acid  
Absorbable PGA Suture  
Synthetic, Multifilament, Braided, Undyed/Violet

**Instruction for Use****DESCRIPTION**

GLIKOSORB Surgical Polyglycolic acid (PGA) suture; synthetic, sterile, absorbable, is homopolymer of glycolic acid. The empirical formula of polyglycolic acid is  $(-O-CH_2-CO-O-CH_2-CO-)_n$ . GLIKOSORB is coated with the mixture of calcium stearate  $(C_{18}H_{35}O_4)_2$  and polycaprolactone  $(C_{12}H_{22}O_5)_n$ . The suture and coating material are inert, noncollagenous, nonantigenic, and non-pyrogenic. Coloured violet (D&C Violet No. 2 C.I. # 60725 / Solvent Violet 13) to enhance visibility in tissue.

**INDICATIONS**

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

**ACTIONS**

PGA suture elicits a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of PGA suture occurs by means of hydrolysis gradually and decreases the strength in the body. After hydrolysis it's executed from the body as carbon dioxide and water. Absorption begins as a loss of tensile strength followed by a loss of mass. PGA suture retains approximately 75% of the original tensile strength (Break Strength Retention-BSR) at two weeks post implantation. At three weeks, approximately 50% of the original tensile strength (Break Strength Retention-BSR) is retained for sizes 6-0 and larger and approximately 40% of its original tensile strength (Break Strength Retention-BSR) is retained for sizes 7-0 and smaller. All of the original tensile strength (Break Strength Retention-BSR) is lost between four and five weeks post implantation. In 60-90 days it is totally absorbed.

**CONTRAINDICATIONS**

The suture being absorbable should not be used where extended approximation of tissue is required. The suture should not be used for cardiovascular and neurological tissues.

**WARNINGS**

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) when selecting a suture for use in patients.

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

Under some circumstances, notably orthopedic procedures, immobilization of joint by external support may be employed at the discretion of the surgeon. Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply, as suture extrusion and delayed absorption may occur.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts may result in calculus formation. Do not re-sterilize. Discard open packages and unused sutures.

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

**PRECAUTIONS**

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

To avoid damaging needle points and 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.

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

Avoid prolonged exposure to elevated temperatures.

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 the device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculus formation in urinary and biliary tracts when prolonged contact with salt solution such as urine and bile occurs, and transitory local irritation at wound site.

**HOW SUPPLIED**

GLIKOSORB sutures are available braided, dyed (violet) and undyed strands in sizes 8/0 thru 6 (metric sizes 0.4 – 8) in a variety of lengths, with a variety of needles. GLIKOSORB sutures are available in one, two and three dozen boxes. GLIKOSORB suture is supplied sterile.

**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, Absorbable, Braided, Coated |
|  | Do not re-sterilize                   |  | Catalogue Number                    |
|  | Do not use if pack age is damaged     |  | Store below 25°C                    |
|  | Manufacturer                          |  | Keep away from sunlight             |
|  | YYYY-MM Date of Manufacture, Year     |  | Protect from humidity               |
|  | YYYY-MM Expiry Date, Year-Month       |  | Recyclable pack                     |
|  | STERILE EO Sterile EO: Ethylene oxide |  | Attention, See instruction for use  |
|  | LOT Batch Number                      |  | 2292                                |
|  | Dyed, Absorbable, Braided, Coated     |                                                                                   |                                     |

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"EASII(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."

**İBOZ TİBBİ MALZEME SANAYİ VE TİCARET A.Ş.**  
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**Boz**  
TİBBİ MALZEMELER

FR

**GLIKOSORB****Mode d'emploi**

Chirurgie, Acide polyglycolique  
PGA absorbable, Suture  
Synthétique, Multifilament, Tressé, Non coloré/Violet

**DESCRIPTION**

GLIKOSORB Suture d'Acide Polyglycolique : synthétique, stérile, absorbable, est un homopolymère de l'acide glycolique. La formule empirique de l'acide glycolique est  $(-O-CH_2-CO-O-CH_2-CO-)_n$ . GLIKOSORB est revêtu avec le mélange de calcium stéarate  $(C_{18}H_{35}O_6)$  et polycaprolactone  $(C_{16}H_{32}O_5)$ . La suture et le matériel de revêtement sont inertes, non collagènes, non antigéniques, et non-pyrogènes. Il est coloré en violet (D&C Violet No. 2 C.I. # 60729 Solvent Violet 13) pour permettre la visibilité dans le tissu.

**INDICATIONS**

La suture de GLIKOSORB est indiquée pour l'usage général dans l'approximation et/ou la fermeture du tissu mou, couvrant aussi l'usage dans les procédures ophtalmiques mais non pour l'usage dans les tissus cardiovasculaires et neurologiques. La suture de GLIKOSORB est pour utilisation unique.

**EFFICACITÉ**

La suture PGA suscite une réaction inflammatoire aigue minimale dans le tissu et une croissance de tissu connectif fibreuse. Une perte progressive de force et une absorption éventuelle de la suture PGA survient par l'hydrolyse peu à peu et diminue la force dans le corps. Après l'hydrolyse, elle est rejetée du corps comme du carbone dioxyde et eau. L'absorption commence comme une perte de force extensible suivie d'une perte de masse. La suture de PGA réticent approximativement les 75% de la force extensible originale après une implantation de deux semaines. A trois semaines, environ les 50% de la force extensible originale sont retenus par les USP 6-0 et supérieurs et environ les 40% de la force extensible originale sont retenus pour les USP 7-0 et inférieurs. Elle perd la totalité de sa force de tension originale dans la quatrième et cinquième semaine après l'implantation. Elle est entièrement absorbée dans 60-90 jours.

**CONTRA-INDICATIONS**

Les sutures étant absorbables ne doivent pas être utilisées dans les zones nécessitant un soutien de longue durée. Les sutures ne doivent pas être utilisées pour les tissus cardiovasculaires et neurochirurgicaux.

**AVERTISSEMENTS**

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

Les sutures épidurales qui doivent rester en place plus de 7 jours peuvent causer une irritation localisée et doivent être découpées ou enlevées de cette zone comme indiqué. Dans certains cas, notamment dans les procédures orthopédiques, l'immobilisation du joint par le support externe peut être utilisé à la discrétion du chirurgien.

Comme une extrusion de suture et une absorption retardée peuvent survenir dans l'utilisation des sutures absorbables dans les tissus avec une faible fourniture de sang, il faut tenir en compte cette situation.

Comme avec tout corps étranger, le contact prolongé de toute suture avec les solutions de sel, telles que celles trouvées dans les voies urinaires ou biliaires peuvent résulter à la formation de calcul. Ne pas ré-stériliser. Détruire les sachets ouverts et les sutures non utilisées.

Une pratique chirurgicale acceptable doit être poursuivie pour la gestion des plaies contaminées ou infectées.

**PRÉCAUTIONS**

Risques de la manipulation de PGA ou d'autres matériaux de suture, on doit être attentif à éviter d'endommager la suture et l'aiguille. Éviter les endommagements comme le broyage et le serrage résultant de l'application des outils chirurgicaux comme le forceps ou le porte-aiguille.

Pour éviter d'endommager les points de l'aiguille et les zones de détente, agrippez l'aiguille dans une zone tierce (1/3) à une-demi (1/2) de la distance de l'extrémité forcée à la pointe. Le remodelage des aiguilles peut leur causer une perte de force et les rendre moins résistants à la flexion et à la rupture. Les utilisateurs doivent faire attention à la manipulation des aiguilles chirurgicales pour éviter les piqûres d'aiguilles accidentelles. Les sutures PGA qui sont traitées pour augmenter les caractéristiques de manipulation demandent la technique chirurgicale acceptée des nœuds droits et carrés avec des jets supplémentaires comme garanti par les circonstances chirurgicales et les expériences du chirurgien.

Éviter l'exposition prolongée aux températures élevées.

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

**EFFETS SECONDAIRES**

Les effets secondaires liés à l'utilisation de l'appareil couvrent la déhiscence de la plaie, le manque de soutien de plaie pour les zones de gonflement, d'extension ou d'élargissement, le manque de soutien de plaie pour les patients souffrants étant donné de leur âge, la malnutrition ou leur faiblesse, l'infection, la réaction inflammatoire aigue minimale, l'irritation locale dans le cas où la suture reste plus de 7 jours sur la peau, l'extrusion de suture et l'absorption retardée dans le tissu avec une fourniture faible sanguine, la formation de calcul dans les voies urinaires et biliaires lorsqu'il existe un contact prolongé avec la solution de sel comme la bile d'urine et l'irritation locale provisoire dans la zone de plaie.

**COMMERCIALISATION**

Les sutures GLIKOSORB sont disponibles en tresse, teintées (violet) et sans couleur dans les dimensions de 8-10 threads (dimension métrique 0.4 - 8) dans une variété de longueurs avec une variété d'aiguilles. Les sutures GLIKOSORB sont disponibles dans des boîtes à une, deux et trois douzaines. Les sutures de GLIKOSORB sont stériles.

**CONSERVATION**

Conservation à la température de 25°C et garder loin des rayons solaires.

Protéger de l'humidité.

Ne pas utiliser après la date limite de consommation.

**SIGNES UTILISÉS POUR L'ÉTIQUETAGE**

|                                                                                   |                                              |                                                                                   |                                                |
|-----------------------------------------------------------------------------------|----------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------|
|  | Pour utilisation unique                      |  | Sans teinture, absorbable, tressé, revêtu      |
|  | Ne pas stériliser à nouveau                  |  | Numéro de catalogue                            |
|  | Ne pas utiliser si l'emballage est endommagé |  | Conservé sous 25°C                             |
|  | Fabricant                                    |  | Protéger du soleil                             |
|  | YYYY-MM Date de production, Année            |  | Conservé dans un lieu sec                      |
|  | YYYY-MM Date d'expiration, Année - mois      |  | Emballage recyclable                           |
|  | Stérile EO: oxyde d'éthylène                 |  | Attention, Voir les instructions d'utilisation |
|  | No de série                                  |  | 2292                                           |

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\*EASIS (Association d'Industrie de la Suture Européenne de Chirurgie) a développé un système commun pour identifier comme intuitif et imagé les caractéristiques des différents produits de suture. Le Directif sur les Dispositifs Médicaux (MDD 93/42/EEC) permet à l'utilisateur le symbole et il permet les informations aux utilisateurs des fabricants sans obliger à traduire en plusieurs langues.

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**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>GLIKOSORB</b><br>Surgical, Polyglycolic Acid (PGA) Suture                                                                                    |
| Properties                                                                                                                                                                                                                                                                                                        | Sterile, Synthetic, Absorbable, Braided, Multifilament, Undyed or Violet colored, Coated, With or Without Needles, Single Use                   |
| Dye                                                                                                                                                                                                                                                                                                               | Violet coloring material D&C Violet no.2- C.I. 60725<br>Undyed (natural,beige)                                                                  |
| Insulation/Coating                                                                                                                                                                                                                                                                                                | Calcium stearate + polycaprolactone                                                                                                             |
| Product Models                                                                                                                                                                                                                                                                                                    | For product models see page 2                                                                                                                   |
| Lot No                                                                                                                                                                                                                                                                                                            | 2101001..... 2112099                                                                                                                            |
| GMDN No                                                                                                                                                                                                                                                                                                           | 17471                                                                                                                                           |
| Classification                                                                                                                                                                                                                                                                                                    | Class III , Rule 8                                                                                                                              |
| <i>We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards.All supporting documentations are retained under the premises of the manufacturer and the notified body.<br/>It conforms to Conformity Assesment Route Annex 2 of 93/42/EEC</i> |                                                                                                                                                 |
| <b>DIRECTIVES</b><br><b>General applicable directives:</b><br>- Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 Included Amendment 2007/47/EC concerning medical devices (MDD 93/42/EEC).                                                                                                   |                                                                                                                                                 |
| <b>Standards:</b><br>-For Applicable Standards see page 3, 4, 5 and 6                                                                                                                                                                                                                                             |                                                                                                                                                 |
| Notified Body                                                                                                                                                                                                                                                                                                     | UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.<br>Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-Çankaya ANKARA TÜRKİYE |
| Notified Body No                                                                                                                                                                                                                                                                                                  | CE 2292                                                                                                                                         |

|                                    |                                                                                                                                  |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| European Authorised Representative | EMERGO Prinsessegracht 20 2514 AP The Hague The Netherlands<br>Phone +31.70.345.8570 - Fax +31.70.346.7299 – EmergoEurope@ul.com |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|

| Certificate                       | Certificate No    | Certificate Date | Date of Validity |
|-----------------------------------|-------------------|------------------|------------------|
| EC Desing Examination Certificate | M.2018.106.9177-1 | 15.01.2018       | 14.01.2023       |
| Full Quality Assurance System     | M.2018.106.9177   | 15.01.2018       | 14.01.2023       |

Place, Date                      Ankara, 10.11.2021

Signature  
Name  
Position

  
Adil BOZ  
General Manager

**Surgical, Polyglycolic Acid (PGA) Suture Product Models**

**Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:**

|                           |                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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. |

## APPLICABLE STANDARDS LIST

| Document Number                | Title of Document                                                                                                                                                                                                |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Harmonised Standards</b> |                                                                                                                                                                                                                  |
| <b>EN ISO 13485: 2016</b>      | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)                                                                                                             |
| <b>EN ISO 14971:2019</b>       | Medical devices - Application of risk management to medical devices (ISO 14971:2019)                                                                                                                             |
| <b>EN 556-1: 2001</b>          | Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised medical devices                                                  |
| <b>EN 1422:2014</b>            | Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods                                                                                                                    |
| <b>EN ISO 15223-1:2016</b>     | 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)                           |
| <b>EN 1041: 2008+A1:2013</b>   | Information supplied by the manufacturer of medical devices                                                                                                                                                      |
| <b>EN ISO 11135:2014</b>       | 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)                        |
| <b>EN ISO 11137-1:2015</b>     | Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) |
| <b>EN ISO 11137-2:2015</b>     | Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)                                                                                               |
| <b>EN ISO 11138-1:2017</b>     | Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)                                                                                                  |
| <b>EN ISO 11138-2:2017</b>     | Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)                                                      |
| <b>EN ISO 11737-1: 2018</b>    | Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)                                                         |
| <b>EN ISO 11737-2:2020</b>     | 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)               |
| <b>EN ISO 10993-1:2020</b>     | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)                                               |
| <b>EN ISO 10993-3:2014</b>     | Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)                                                                          |
| <b>EN ISO 10993-4:2017</b>     | Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)                                                                                             |
| <b>EN ISO 10993-5:2009</b>     | Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)                                                                                                             |
| <b>EN ISO 10993-6:2016</b>     | Biological evaluation of medical devices- Part 6: Tests for local effects after implantation (ISO 10993-6:2016)                                                                                                  |
| <b>EN ISO 10993-7:2008</b>     | Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)                                                                                                     |
| <b>EN ISO 10993-11:2018</b>    | Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)                                                                                                              |
| <b>EN ISO 10993-12:2021</b>    | Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)                                                                                               |

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| Document Code :<br>YT-DC-GS | Effective Date:<br>11.09.2012 | Revision No:<br>08 | Revision Date:<br>10.11.2021 | Number of Pages:<br>3 / 6 |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|

| Document Number           | Title of Document                                                                                                                                                                           |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EN ISO 10993-13:2010      | Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)                            |
| EN ISO 10993-18:2020      | Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)                              |
| EN ISO 11607-1:2020       | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)                                  |
| EN ISO 11607-2:2020       | Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)                                        |
| EN ISO 14644-1:2015       | Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)                                                  |
| EN ISO 14644-2:2015       | Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015) |
| EN ISO 14644-3:2019       | Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019, Corrected version 2020-06)                                                                      |
| EN ISO 14644-5:2004       | Cleanrooms and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)                                                                                                   |
| EN ISO 14630:2012         | Non-active surgical implants - General requirements (ISO 14630:2012)                                                                                                                        |
| <b>2. Pharmacopeia</b>    |                                                                                                                                                                                             |
| EP 10.0-01/ 2008:0667     | European Pharmacopoeia 10.0-01/ 2008:0667 Sutures, Sterile Synthetic Absorbable Braided Monograph                                                                                           |
| EP 10.0-01/ 2008:0666     | European Pharmacopoeia 10.0-01/ 2008:0666 Sutures, Sterile Synthetic Absorbable Monofilament Monograph                                                                                      |
| USP 43/ NF 38             | United States Pharmacopoeia Official Monographs / Absorbable Surgical Suture                                                                                                                |
| <b>3. Other Standards</b> |                                                                                                                                                                                             |
| EN 868-5: 2018            | Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods                  |
| EN ISO 10993-10:2013      | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)                                                                         |
| EN ISO 11137-3:2017       | Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)                                |
| EN ISO 15223-1:2021       | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)                                                  |
| EN 17141:2020             | Cleanrooms and associated controlled environments - Biocontamination control                                                                                                                |
| ISO 8601-1:2019           | Date and time — Representations for information interchange — Part 1: Basic rules                                                                                                           |
| ISO 13781:2017            | Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing                                                                                  |
| TS 4020/ MAY 2016         | Surgical needles                                                                                                                                                                            |
| TS 4169/ FEB 1984         | The Determination Of Hazardous Residues In Plastics Used For Health Purposes                                                                                                                |

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| Document Code :<br>YT-DC-GS | Effective Date:<br>11.09.2012 | Revision No:<br>08 | Revision Date:<br>10.11.2021 | Number of Pages:<br>4 / 6 |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|

| Document Number                      | Title of Document                                                                                                                               |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| TS 10410/ OCT 1992                   | Methods For Sterility Control (For Medical Purposes)<br>Part 3- Application Of Medicines, Medical And Surgical Materials To Inoculation Methods |
| EN ISO 20417:2021                    | Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)                                                               |
| CEN ISO/TR 24971:2020                | Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)                                                                  |
| <b>4. Guidance Documents</b>         |                                                                                                                                                 |
| <b>4.1. ASTM Documents</b>           |                                                                                                                                                 |
| 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                                                                            |
| <b>4.2. Guidance MEDDEVs</b>         |                                                                                                                                                 |
| 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                                                                                                |
| <b>4.3. NB-MED Documents</b>         |                                                                                                                                                 |
| 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                                                                                                                   |
| <b>4.4. MDCG Documents</b>           |                                                                                                                                                 |
| MDCG 2018-1 Rev.4<br>April 2021      | Guidance on BASIC UDI-DI and changes to UDI-DI                                                                                                  |
| MDCG 2018-2<br>March 2018            | Future EU medical device nomenclature - Description of requirements                                                                             |
| MDCG 2018-3 Rev.1<br>June 2020       | Guidance on UDI for systems and procedure packs                                                                                                 |
| MDCG 2018-4<br>October 2018          | Definitions/descriptions and formats of the UDI core elements for systems or procedure packs                                                    |
| MDCG 2018-5<br>October 2018          | UDI assignment to medical device software                                                                                                       |

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| Document Code :<br>YT-DC-GS | Effective Date:<br>11.09.2012 | Revision No:<br>08 | Revision Date:<br>10.11.2021 | Number of Pages:<br>5 / 6 |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|

| Document Number                            | Title of Document                                                                                                                                                                                                                    |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MDCG 2018-6<br>October 2018                | Clarifications of UDI related responsibilities in relation to article 16                                                                                                                                                             |
| MDCG 2018-7<br>October 2018                | Provisional considerations regarding language issues associated with the UDI database                                                                                                                                                |
| MDCG 2019-1<br>January 2019                | MDCG guiding principles for issuing entities rules on basic UDI-DI                                                                                                                                                                   |
| MDCG 2019-2<br>February 2019               | Guidance on application of UDI rules to device-part of products referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017                                                                                                   |
| MDCG 2019-4<br>April 2019                  | Timelines for registration of device data elements in EUDAMED                                                                                                                                                                        |
| MDCG 2019-5<br>April 2019                  | Registration of legacy devices in EUDAMED                                                                                                                                                                                            |
| MDCG 2019-7<br>June 2019                   | Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)                                                            |
| MDCG 2020-3<br>March 2020                  | Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD                                                           |
| MDCG 2020-7<br>April 2020                  | Guidance on PMCF plan template                                                                                                                                                                                                       |
| MDGC 2020-8<br>April 2020                  | Guidance on PMCF evaluation report template                                                                                                                                                                                          |
| MDCG 2020-15<br>August 2020                | MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States                                                                                             |
| MDCG 2020-18<br>December 2020              | MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers                                                                                                                                                           |
| MDCG 2021-1 Rev.1<br>May 2021              | Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional                                                                                                                |
| MDCG 2021-09<br>May 2021                   | MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers                                                                                                 |
| MDCG 2021-10<br>June 2021                  | The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices                                                                                                                                      |
| MDCG 2021-13 Rev.1<br>July 2021            | Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR |
| MDCG 2021-19<br>July 2021                  | Guidance note integration of the UDI within an organisation's quality management system                                                                                                                                              |
| MDCG 2021-25<br>October 2021               | Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC                                                                   |
| <b>4.5. Directive</b>                      |                                                                                                                                                                                                                                      |
| <b>EC-DIRECTIVES ON MED. DEVICES/ 2007</b> | Guidelines on A Medical Devices Vigilance System                                                                                                                                                                                     |

KM-FR-85

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|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|
| Document Code :<br>YT-DC-GS | Effective Date:<br>11.09.2012 | Revision No:<br>08 | Revision Date:<br>10.11.2021 | Number of Pages:<br>6 / 6 |
|-----------------------------|-------------------------------|--------------------|------------------------------|---------------------------|



# EC DESIGN EXAMINATION CERTIFICATE

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

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

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

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

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

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

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

GMDN : 17471, 13908, 16584, 45814

Product Types are attached.

Certificate Number : M.2018.106.9177-1

Report Number : MD.3532.IB

Initial Assessment Date : 07.11.2017

Registration Date : 15.01.2018

Revision Date /No : 14.01.2021/01

Expiry Date : 14.01.2023

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

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



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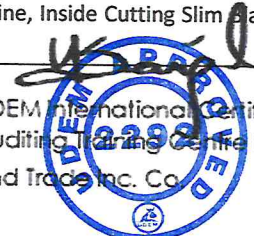
This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9177-1 and with the registration date of 15.01.2018 and with the revision date of 14.01.2021 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme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



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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:                                                                                                                                                                               |                      |
| 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



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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. |                      |



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>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 Tibbi Malzeme Sanayi ve Ticaret A.Ş.

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

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

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

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

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

Product Types are attached.

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

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

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



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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 Tibbi Malzeme Sanayi ve Ticaret A.Ş.

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

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

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

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

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

Product Types are attached.

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

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

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



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**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).

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**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   |