



# EC CERTIFICATE

## EC Design-Examination Certificate For Medical Devices

### MDD 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 Tıbbi Malzeme Sanayi ve Ticaret A.Ş.  
Company Address : Sağlık Mah. Sağlık Sok. No:33/5 Sıhhiye Çankaya ANKARA / TURKEY  
Manufacturing and Storage : 29 Ekim Mah. Necip Fazıl Bulv. No:71 Yenikent Sincan ANKARA / TURKEY  
Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive – Annex II  
(Including 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-1  
Initial Assessment Date : 07.11.2017  
Registration Date : 15.01.2018  
Revision Date /No : -  
Expiry Date : 14.01.2023

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

CE  
2292



The EC desing examination certificate refers to the above mentioned product.It certifies that the desing documentation of the product complies with Annex II,article 4 of the 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 man ufacturer 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 currency 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 number M.2018.106.9177-1 and with the registration date of 15.01.2018 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.	
<b>Polyglycolic acid (Rapid Absorbable PGA)</b>	<b>GMDN NO:13908</b>



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

**USP:** 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6

**EP:** 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8

**Suture Lengths:** Variety of lengths, from 10 cm to 500 cm

**Needle Lengths:** Variety of lengths, from 3 mm to 150 mm

**Needle Shapes:** 1/2, 3/8, 1/4, 5/8, Straight, J, SKI

**Needle Properties:** Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

**Polydioxanone (PDO) GMDN NO:16584**

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

**USP:** 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2

**EP:** 0,5 0,7 1 1,5 2 3 3,5 4 5

**Suture Lengths:** Variety of lengths, from 10 cm to 500 cm

**Needle Lengths:** Variety of lengths, from 3 mm to 150 mm

**Needle Shapes:** 1/2, 3/8, 1/4, 5/8, Straight, J, SKI

**Needle Properties:** Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

**Poly[glycolide(75%)-co-caprolactone(25%)] (PGCL) GMDN NO:45814**

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

**USP:** 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2

**EP:** 0,7 1 1,5 2 3 3,5 4 5

**Suture Lengths:** Variety of lengths, from 10 cm to 500 cm

**Needle Lengths:** Variety of lengths, from 3 mm to 150 mm

**Needle Shapes:** 1/2, 3/8, 1/4, 5/8, Straight, J, SKI

**Needle Properties:** Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micropoint, Straight Cutting, Lancet, Spatula, Tapercutting, Taperpoint Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.