



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.

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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.

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



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

