



C E R T I F I C A T E

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

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

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

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

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

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

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

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

Product Types are attached.

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


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

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



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

Surgical Silk Suture Product Models GMDN No: 13910 Class III

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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