Digitally signed by Bolea Petru
Date: 2021.09.17 20:19:20 EEST
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

Boz Tıbbi Malzeme Sanayi ve Ticaret A.Ş.

Sağlık Mahallesi Sağlık 1 Sokak No:33/5 Çankaya ANKARA / TURKEY

ISO 13485:2016

Scope: Desing, manufacture and sales of sterile surgical sutures, gauze compress, absorbent bandage, absorbable oxidized regenerated cellulose haemostat, absorbable oxidized cellulose haemostat

Manufacturing of Sterile Surgical Sutures: 29 Ekim Mah. Necip Fazıl Bulv. No:71 Yenikent Sincan ANKARA
Manufacturing of Gauze Compress and Absorbent Bandage: 29 Ekim Mah. Necip Fazıl Bulv. No:71 Yenikent Sincan ANKARA
Manufacturing adress of absorbable oxidized regenerated cellulose haemostat, absorbable oxidized cellulose haemostat Malıköy Başkent OSB Mah. 4 Cad. No:17 Sincan ANKARA

Hereby, AKSSERT Audit and Certification Ltd. Co., certificates that the above stated company gave the appropriate management system according to the requirements of the above standard. This certificate valid for 3 years since the decision date as long as the system is effectively maintaned and surveillance audits are carried out. The validity of certificate can be checked through www.akssert.com, www.jas-anz.org/register. The Certificate is property of AKSSERT Audit and Certification Ltd. Co. and shall be returned if requested.

The reference standard is ISO 13485:2016

AKSSERT Audit and Certification Ltd. Co.

Certificate Number : 85277
Registration Date : 06.03.2017

Reissue Date : 30.01.2020
Expiry Date : 05.03.2023

Address: Mustafa Kemal Mah. 2157/1 Sokak No:5/7 Çankaya / ANKARA– TURKEY
Tel: +90 312 284 99 44(pbx)
E-mail: info@akssert.com **Web:** www.akssert.com

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2018.106.9142-1 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	: Malıköy Başkent OSB Mh. 4. Cad. No:17 Sincan ANKARA / TURKEY
Storage 2	: 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, Absorbable Haemostat Oxidized Regenerated Cellulose (ORC) - Class III Single Use, Sterile, Absorbable Haemostat Oxidized Cellulose (OC) - Class III
GMDN	: 38771
	Product Types are attached.
Certificate Number	: M.2018.106.9142
Report Number	: MD.3532.IB
Initial Assessment Date	: 07.11.2017
Registration Date	: 02.01.2018
Revision Date /No	: 14.01.2021/02
Expiry Date	: 01.01.2023

UDEM APPROVED 2292

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 sertificate 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 returnedupon 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 thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

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

This document containing 1 (one) pages is the Annex of the Certificate with the revision number 02, with the number M.2018.106.9142 and with the registration date of 02.01.2018 and with the revision date of 14.01.2021 issued for "Boz Tıbbi 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.

ABSORBABLE HAEMOSTAT, OXIDIZED REGENERATED CELLULOSE (ORC) CLASS III					
PRODUCT CODE	PRODUCT CODE	PRODUCT SIZE	PRODUCT CODE	PRODUCT CODE	PRODUCT SIZE
RX0502	RX0502*	1,25cm x 5cm	BR0502	BR0502*	1,25cm x 5cm
RX0502X	RX0502X*	1,25cm x 5cm	BR0502X	BR0502X*	1,25cm x 5cm
RX1001	RX1001*	2,5cm x 2,5cm	BR1001	BR1001*	2,5cm x 2,5cm
RX1001X	RX1001X*	2,5cm x 2,5cm	BR1001X	BR1001X*	2,5cm x 2,5cm
RX1002	RX1002*	2,5cm x 5cm	BR1002	BR1002*	2,5cm x 5cm
RX1002X	RX1002X*	2,5cm x 5cm	BR1002X	BR1002X*	2,5cm x 5cm
RX1003	RX1003*	2,5cm x 7,5cm	BR2003	BR2003*	5cm x 7,5cm
RX1063	RX1063*	2,5cm x 9cm	BR2003X	BR2003X*	5cm x 7,5cm
RX2003	RX2003*	5cm x 7,5cm	BR2004	BR2004*	5cm x 10cm
RX2003X	RX2003X*	5cm x 7,5cm	BR2004X	BR2004X*	5cm x 10cm
RX2004	RX2004*	5cm x 10cm	BR2014	BR2014*	5cm x 35cm
RX2004X	RX2004X*	5cm x 10cm	BR2014X	BR2014X*	5cm x 35cm
RX2014	RX2014*	5cm x 35cm	BR3004	BR3004*	7,5cm x 10cm
RX2014X	RX2014X*	5cm x 35cm	BR3004X	BR3004X*	7,5cm x 10cm
RX3004	RX3004*	7,5cm x 10cm	BR4004	BR4004*	10cm x 10cm
RX3004X	RX3004X*	7,5cm x 10cm	BR4004X	BR4004X*	10cm x 10cm
RX4004	RX4004*	10cm x 10cm	BR4008	BR4008*	10cm x 20cm
RX4004X	RX4004X*	10cm x 10cm	BR4008X	BR4008X*	10cm x 20cm
RX4008	RX4008*	10cm x 20cm	BR6009	BR6009*	15cm x 23cm
RX4008X	RX4008X*	10cm x 20cm	BR6009X	BR6009X*	15cm x 23cm
RX6009	RX6009*	15cm x 23cm	BK1001	BK1001*	2,6cm x 2,6cm
RX6009X	RX6009X*	15cm x 23cm	BK1001X	BK1001X*	2,6cm x 2,6cm
RK1001	RK1001*	2,6cm x 2,6cm	BK1003	BK1003	2,6cm x 10cm
RK1001X	RK1001X*	2,6cm x 2,6cm	BK1003X	BK1003X*	2,6cm x 10cm
RK1003	RK1003*	2,6cm x 10cm	BK2003	BK2003*	5cm x 7,5cm
RK1003X	RK1003X*	2,6cm x 10cm	BK2003X	BK2003X*	5cm x 7,5cm
RK2003	RK2003*	5cm x 7,5cm	BK3004	BK3004*	7,6cm x 10,2cm
RK2003X	RK2003X*	5cm x 7,5cm	BK3004X	BK3004X*	7,6cm x 10,2cm
RK3004	RK3004*	7,6cm x 10,2cm	BK6009X	BK6009X*	15,2cm x 23cm
RK3004X	RK3004X*	7,6cm x 10,2cm	BF1002X	BF1002X*	2,6cm x 5,1cm
RK6009	RK6009*	15,2cm x 23cm	BF2003X	BF2003X*	5cm x 7,5cm
RF1002	RF1002*	2,6cm x 5,1cm	BF2004X	BF2004X*	5,1cm x 10,2cm
RF2003	RF2003*	5cm x 7,5cm	BF2007X	BF2007X*	5cm x 10cm
RF2004	RF2004*	5,1cm x 10,2cm	BF3003X	BF3003X*	7,5cm x 7,5cm
RF3003	RF3003*	7,5cm x 7,5cm	BF4004X	BF4004X*	10,2cm x 10,2cm
RF4004	RF4004*	10,2cm x 10,2cm			

ABSORBABLE HAEMOSTAT, OXIDIZED CELLULOSE (OC) CLASS III					
PRODUCT CODE	PRODUCT CODE	PRODUCT SIZE	PRODUCT CODE	PRODUCT CODE	PRODUCT SIZE
ZC0502	ZC0502*	1,25cm x 5cm	ZC2014	ZC2014*	5cm x 35cm
ZC0502X	ZC0502X*	1,25cm x 5cm	ZC2014X	ZC2014X*	5cm x 35cm
ZC1001	ZC1001*	2,5cm x 2,5cm	ZC3004	ZC3004*	7,5cm x 10cm
ZC1001X	ZC1001X*	2,5cm x 2,5cm	ZC3004X	ZC3004X*	7,5cm x 10cm
ZC1002	ZC1002*	2,5cm x 5cm	ZC4004	ZC4004*	10cm x 10cm
ZC1002X	ZC1002X*	2,5cm x 5cm	ZC4004X	ZC4004X*	10cm x 10cm
ZC2003	ZC2003*	5cm x 7,5cm	ZC4008	ZC4008*	10cm x 20cm
ZC2003X	ZC2003X*	5cm x 7,5cm	ZC4008X	ZC4008X*	10cm x 20cm
ZC2004	ZC2004*	5cm x 7cm	ZC6009	ZC6009*	15cm x 23cm
ZC2004X	ZC2004X*	5cm x 7cm	ZC6009X	ZC6009X*	15cm x 23cm

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

CERTIFICATE

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 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 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.

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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 Tıbbi 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

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 Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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 Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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 Lenghts:	Variety of lengths, from 10 cm to 500 cm

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

Needle Lenghts :	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 Lenghts:	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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 Lenghts:	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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.

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

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 Tıbbi 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 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 Lenghts:	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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 Metalic 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 Lenghts:	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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 mm .....150 mm
Height = 1 mm ..... 2 mm

UDEM APPROVED 2292

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

BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

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	**FASTSORB** **Surgical, Polyglycolic Acid (Rapid PGA) Suture**
Properties	**Sterile, Synthetic, Rapid Absorbable, Braided, Multifilament, Undyed, Coated, With or Without Needles, Single Use**
Dye	**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**

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

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

Standards:
-For Applicable Standards see page 3 and 4

Notified Body	**UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. 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 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, 14.06.2021**

Signature
Name **Aysel KOSE**
Position **Management Representative**

Surgical, Polyglycolic Acid (Rapid PGA) Suture Product Models

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 Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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.

APPLICABLE STANDARDS LIST

Document Number	Title of Document
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 556-1: 2001	Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised medical devices
EN 1422:2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041: 2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
EN ISO 11137-1:2015	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)
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
EN ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
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EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5:2009	Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6:2016	Biological evaluation of medical devices- Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
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 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)

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APPLICABLE STANDARDS LIST

Document Number	Title of Document
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
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 / Suture 4189- Absorbable Surgical Suture
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
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
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
TS 10410/ OCT 1992	Methods For Sterility Control (For Medical Purposes) 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
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ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1840 - 10(2016)	Standard Terminology for Surgical Suture Needles
ASTM F88 / F88M - 15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D5276 - 19	Standard Test Method for Drop Test of Loaded Containers by Free Fall
MEDDEV 2. 4/1 Rev. 9 June 2010	MEDICAL DEVICES: Guidance document - Classification of medical devices
MEDDEV 2. 2/3 rev.3 June 1998	'Use-by' date for medical devices
MEDDEV 2.7/1 revision 4 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 January 2012	Post-Market Clinical Follow-up Studies
MEDDEV 2.12-1 rev 8 January 2013	Guidelines on a Medical Devices Vigilance System
NB-MED/2.5.1/Rec5-rev4	Technical Documentation
NB-MED/2.5.1/Rec6-rev4	Renewal of EC Design-Examination and Type-Examination Certificates
NB-MED/2.5.2/Rec1-rev4	Subcontracting - QS related
NB-MED/2.12/Rec1-rev11	Post-Marketing Surveillance (PMS) post market/production
NB-MED/2.13/Rec1-rev3	CE-Marking of pre-MDD devices
EC–DIRECTIVES ON MED. DEVICES/ 2007	Guidelines on A Medical Devices Vigilance System

BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

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	**GLIKOLAK** **Surgical, Poly[glycolide (90%)-co-lactide (10%)] (PGLA) 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** **Undyed (natural,beige)**
Insulation/Coating	**Poly(glycolide-co-lactide)(30/70) + Calcium stearate**
Product Models	**For product models see page 2**
Lot No	**2101001..... 2112099**
GMDN No	**17471**
Classification	**Class III , Rule 8**

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

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

Standards:
-For Applicable Standards see page 3 and 4

Notified Body	**UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. 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 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, 14.06.2021**

Signature
Name **Aysel KOSE**
Position **Management Representative**

Surgical, Poly[glycolide (90%)-co-lactide (10%)] (PGLA) 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:	
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 Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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.

APPLICABLE STANDARDS LIST

Document Number	Title of Document
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 556-1: 2001	Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised medical devices
EN 1422:2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041: 2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
EN ISO 11137-1:2015	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)
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
EN ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
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EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5:2009	Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6:2016	Biological evaluation of medical devices- Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
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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)

APPLICABLE STANDARDS LIST

Document Number	Title of Document
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
EP 10.0-01/ 2008:0667	European Pharmacopoeia 10.0-01/ 2008:0667 Sutures, Sterile Synthetic Absorbable Braided Monograph
USP 43/ NF 38	United States Pharmacopoeia Official Monographs / Suture 4189- Absorbable Surgical Suture
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
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
ISO 13781:2017	Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing
TS 4020/ MAY 2016	Surgical needles
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ASTM F1840 - 10(2016)	Standard Terminology for Surgical Suture Needles
ASTM F88 / F88M - 15	Standard Test Method for Seal Strength of Flexible Barrier Materials
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NB-MED/2.5.1/Rec6-rev4	Renewal of EC Design-Examination and Type-Examination Certificates
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NB-MED/2.12/Rec1-rev11	Post-Marketing Surveillance (PMS) post market/production
NB-MED/2.13/Rec1-rev3	CE-Marking of pre-MDD devices
EC–DIRECTIVES ON MED. DEVICES/ 2007	Guidelines on A Medical Devices Vigilance System

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BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

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	**GLIKOSORB** **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** **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**

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

DIRECTIVES

General applicable directives:

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

Standards:

-For Applicable Standards see page 3 and 4

Notified Body	**UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. 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 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, 14.06.2021**

Signature
Name **Aysel KOSE**
Position **Management Representative**

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:	
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 Lenghts :	Variety of lengths, from 10 cm to 500 cm
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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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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)

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APPLICABLE STANDARDS LIST

Document Number	Title of Document
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)
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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 / Suture 4189- Absorbable Surgical Suture
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
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
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
TS 10410/ OCT 1992	Methods For Sterility Control (For Medical Purposes) 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
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ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1840 - 10(2016)	Standard Terminology for Surgical Suture Needles
ASTM F88 / F88M - 15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D5276 - 19	Standard Test Method for Drop Test of Loaded Containers by Free Fall
MEDDEV 2. 4/1 Rev. 9 June 2010	MEDICAL DEVICES: Guidance document - Classification of medical devices
MEDDEV 2. 2/3 rev.3 June 1998	'Use-by' date for medical devices
MEDDEV 2.7/1 revision 4 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 January 2012	Post-Market Clinical Follow-up Studies
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EC–DIRECTIVES ON MED. DEVICES/ 2007	Guidelines on A Medical Devices Vigilance System

BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

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	**MONAMID** **Surgical, Polyamide 6-6,6 (PA) Suture**
Properties	**Synthetic, Sterile, Non-Absorbable, Monofilament, Blue or Black colored, Uncoated Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, Single Use**
Dye	**Blue coloring material (C.I. – colour index no 74160)** **Black coloring material (C.I. – colour index no. 77266)**
Insulation/Coating	**Uncoated**
Product Models	**For product models see page 2**
Lot No	**2101001..... 2112099**
GMDN No	**38000**
Classification	**Class III , Rule 8**

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

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

Standards:
-For Applicable Standards List see page 3 and 4

Notified Body	**UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. 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 Phone +31.70.345.8570 - Fax +31.70.346.7299 – EmergoEurope@ul.com**

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

Place, Date **Ankara, 14.06.2021**

Signature
Name **Aysel KOSE**
Position **Management Representative**

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

Synthetic, Sterile, Non-Absorbable, Monofilament, Blue or Black colored, Uncoated Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
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
Suture Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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.

APPLICABLE STANDARDS LIST

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

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APPLICABLE STANDARDS LIST

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

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BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

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	**MONOPROLEN** **Surgical, Polypropylene (PP) Suture**
Properties	**Synthetic, Sterile, Non-Absorbable, Monofilament, Blue colored, Uncoated, Surgical Sutures are with or without Teflon pledget accessory, loop, single or with double needle or without needle, Single Use**
Dye	**Blue coloring material (C.I.-color index no 61568)**
Insulation/Coating	**Uncoated**
Product Models	**For product models see page 2**
Lot No	**2101001..... 2112099**
GMDN No	**13909**
Classification	**Class III , Rule 8**

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

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

Standards:
-For Applicable Standards List see page 3 and 4

Notified Body	**UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. 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 Phone +31.70.345.8570 - Fax +31.70.346.7299 – EmergoEurope@ul.com**

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

Place, Date **Ankara, 14.06.2021**

Signature
Name **Aysel KÖSE**
Position **Management Representative**

Surgical, Polypropylene (PP) Suture Product Models

Synthetic, Sterile, Non-Absorbable, 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, Suture 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
Suture Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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.

APPLICABLE STANDARDS LIST

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

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APPLICABLE STANDARDS LIST

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

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BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

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	**MONOWIRE** **Surgical, Stainless Steel Wire**
Properties	**Sterile, Nonabsorbable, Monofilament, Uncoated Stainless Steel Wire, Surgical Sutures are loop, single or with double needle or without needle, Single Use**
Dye	**None / Natural Metallic Colour**
Insulation/Coating	**-**
Product Models	**For product models see page 2**
Lot No	**2101001..... 2112099**
GMDN No	**15971**
Classification	**Class IIb , Rule 8**

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

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

Standards:
-For Applicable Standards List see page 5 and 6

Notified Body	**UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. 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 Phone +31.70.345.8570 - Fax +31.70.346.7299 – EmergoEurope@ul.com**

Certificate	Certificate No	Certificate Date	Date of Validity
EC Certificate full quality assurance system	M.2020.106.13692	29.06.2020	27.05.2024

Place, Date **Ankara, 14.06.2021**

Signature
Name **Aysel KOSE**
Position **Management Representative**

Surgical, Stainless Steel Wire Product Models

Sterile, Non-Absorbable, Monofilament, Uncoated, Natural Metallic Colour 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:	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
Suture Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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.

APPLICABLE STANDARDS LIST

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

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APPLICABLE STANDARDS LIST

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

KM-FR-85

BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

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	**POLISIL** **Surgical, Polyester (PET) Suture**
Properties	**Synthetic, Sterile, Non-Absorbable, 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, Single Use**
Dye	**Green coloring material (D&C Blue#6 C.I.61565)** **White (Undyed)**
Insulation/Coating	**Silicon coated**
Product Models	**For product models see page 2**
Lot No	**2101001..... 2112099**
GMDN No	**13906**
Classification	**Class III , Rule 8**

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

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

Standards:
-For Applicable Standards List see page 3 and 4

Notified Body	**UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. 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 Phone +31.70.345.8570 - Fax +31.70.346.7299 – EmergoEurope@ul.com**

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

Place, Date **Ankara, 14.06.2021**

Signature
Name **Aysel KOSE**
Position **Management Representative**

Surgical, Polyester (PET) Suture Product Models

Synthetic, Sterile, Non-Absorbable, 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, 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, 3, 4, 5
EP:	0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7
Suture Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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.

APPLICABLE STANDARDS LIST

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

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APPLICABLE STANDARDS LIST

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

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BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

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	**POLIDIOX** **Surgical, Polydioxanone (PDO) Suture**
Properties	**Sterile, Synthetic, Absorbable, Monofilament, Violet colored, Uncoated, With or Without Needles, Single Use**
Dye	**Violet coloring material D&C Violet no.2- C.I. 60725**
Insulation/Coating	**-**
Product Models	**For product models see page 2**
Lot No	**2101001..... 2112099**
GMDN No	**16584**
Classification	**Class III , Rule 8**

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

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

Standards:
-For Applicable Standards see page 3 and 4

Notified Body	**UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. 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 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, 14.06.2021**

Signature
Name **Aysel KOSE**
Position **Management Representative**

Surgical, Polydioxanone (PDO) Suture Product Models

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 Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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.

APPLICABLE STANDARDS LIST

Document Number	Title of Document
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 556-1: 2001	Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised medical devices
EN 1422:2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041: 2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
EN ISO 11137-1:2015	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)
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
EN ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11737-1: 2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5:2009	Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6:2016	Biological evaluation of medical devices- Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
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 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)

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APPLICABLE STANDARDS LIST

Document Number	Title of Document
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
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 / Suture 4189- Absorbable Surgical Suture
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
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
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
TS 10410/ OCT 1992	Methods For Sterility Control (For Medical Purposes) 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
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1840 - 10(2016)	Standard Terminology for Surgical Suture Needles
ASTM F88 / F88M - 15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D5276 - 19	Standard Test Method for Drop Test of Loaded Containers by Free Fall
MEDDEV 2. 4/1 Rev. 9 June 2010	MEDICAL DEVICES: Guidance document - Classification of medical devices
MEDDEV 2. 2/3 rev.3 June 1998	'Use-by' date for medical devices
MEDDEV 2.7/1 revision 4 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 January 2012	Post-Market Clinical Follow-up Studies
MEDDEV 2.12-1 rev 8 January 2013	Guidelines on a Medical Devices Vigilance System
NB-MED/2.5.1/Rec5-rev4	Technical Documentation
NB-MED/2.5.1/Rec6-rev4	Renewal of EC Design-Examination and Type-Examination Certificates
NB-MED/2.5.2/Rec1-rev4	Subcontracting - QS related
NB-MED/2.12/Rec1-rev11	Post-Marketing Surveillance (PMS) post market/production
NB-MED/2.13/Rec1-rev3	CE-Marking of pre-MDD devices
EC–DIRECTIVES ON MED. DEVICES/ 2007	Guidelines on A Medical Devices Vigilance System

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BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

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	**SILK** **Surgical, Silk Suture**
Properties	**Natural, Sterile, Non-Absorbable, Multifilament, Braided, Black or Undyed colored, Silicon Coated, Surgical Sutures are loop, single or with double needle or without needle, Single Use**
Dye	**Black; Hematein HCK (C.I. – colour index no. 75290)** **Undyed – Natural colour**
Insulation/Coating	**Silicone Coated**
Product Models	**For product models see page 2**
Lot No	**2101001..... 2112099**
GMDN No	**13910**
Classification	**Class III , Rule 8**

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

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

Standards:
-For Applicable Standards List see page 3 and 4

Notified Body	**UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. 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 Phone +31.70.345.8570 - Fax +31.70.346.7299 – EmergoEurope@ul.com**

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

Place, Date **Ankara, 14.06.2021**

Signature
Name **Aysel KOSE**
Position **Management Representative**

Surgical, Silk Suture Product Models

Natural, Sterile, Non-Absorbable, 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, Suture 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
Suture Lenghts :	Variety of lengths, from 10 cm to 500 cm
Needle Lenghts :	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.

APPLICABLE STANDARDS LIST

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

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APPLICABLE STANDARDS LIST

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

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