Digitally signed by Bolea Petru
Date: 2022.11.11 11:33:00 EET
Reason: MoldSign Signature
Location: Moldova

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)
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

KM-FR-85

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.

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 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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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

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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	**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, 4, 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 Desing Examination Certificate	M.2018.106.9177-1	15.01.2018	14.01.2023
Full Quality Assurance System	M.2018.106.9177	15.01.2018	14.01.2023

Place, Date **Ankara, 10.11.2021**

Signature
Name **Adil BOZ**
Position **General Manager**

Surgical, Polyglycolic Acid (PGA) Suture Product Models

Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
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
1. Harmonised Standards	
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 (ISO 11137-2:2013)
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 11138-2:2017)
EN ISO 11737-1: 2018	Sterilization of health care products - 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)

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

Document Number	Title of Document
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 (ISO 20417:2021)
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
4. Guidance Documents	
4.1. ASTM Documents	
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
4.2. Guidance MEDDEVs	
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
4.3. NB-MED Documents	
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
4.4. MDCG Documents	
MDCG 2018-1 Rev.4 April 2021	Guidance on BASIC UDI-DI and changes to UDI-DI
MDCG 2018-2 March 2018	Future EU medical device nomenclature - Description of requirements
MDCG 2018-3 Rev.1 June 2020	Guidance on UDI for systems and procedure packs
MDCG 2018-4 October 2018	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs
MDCG 2018-5 October 2018	UDI assignment to medical device software

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

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	**MONOKAPROL** **Surgical, Poly[glycolide(75%)-co-caprolactone(25%)] (PGCL) Suture**
Properties	**Sterile, Synthetic, Absorbable, Monofilament, Undyed or Violet colored, Uncoated, With or Without Needles, Single Use**
Dye	**Violet coloring material D&C Violet no.2- C.I. 60725** **Undyed (natural,beige)**
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, 4, 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 Desing Examination Certificate	M.2018.106.9177-1	15.01.2018	14.01.2023
Full Quality Assurance System	M.2018.106.9177	15.01.2018	14.01.2023

Place, Date **Ankara, 10.11.2021**

Signature
Name **Adil BOZ**
Position **General Manager**

Surgical, Poly[glycolide(75%)-co-caprolactone(25%)] (PGCL) Suture Product Models

Synthetic, Sterile, Absorbable, Monofilament, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
USP:	6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP:	0,7 1 1,5 2 3 3,5 4 5
Suture 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
1. Harmonised Standards	
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)
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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 health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
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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 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)

Document Number	Title of Document
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EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019, Corrected version 2020-06)
EN ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)
EN ISO 14630:2012	Non-active surgical implants - General requirements (ISO 14630:2012)
2. Pharmacopeia	
EP 10.0-01/ 2008:0666	European Pharmacopoeia 10.0-01/ 2008:0666 Sutures, Sterile Synthetic Absorbable Monofilament Monograph
USP 43/ NF 38	United States Pharmacopoeia Official Monographs / Absorbable Surgical Suture
3. Other Standards	
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EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
ISO 8601-1:2019	Date and time — Representations for information interchange — Part 1: Basic rules
ISO 13781:2017	Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing
TS 4020/ MAY 2016	Surgical needles
TS 4169/ FEB 1984	The Determination Of Hazardous Residues In Plastics Used For Health Purposes
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 (ISO 20417:2021)
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
4. Guidance Documents	
4.1. ASTM Documents	
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ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Document Number	Title of Document
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
4.2. Guidance MEDDEVs	
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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
4.3. NB-MED Documents	
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
4.4. MDCG Documents	
MDCG 2018-1 Rev.4 April 2021	Guidance on BASIC UDI-DI and changes to UDI-DI
MDCG 2018-2 March 2018	Future EU medical device nomenclature - Description of requirements
MDCG 2018-3 Rev.1 June 2020	Guidance on UDI for systems and procedure packs
MDCG 2018-4 October 2018	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs
MDCG 2018-5 October 2018	UDI assignment to medical device software
MDCG 2018-6 October 2018	Clarifications of UDI related responsibilities in relation to article 16
MDCG 2018-7 October 2018	Provisional considerations regarding language issues associated with the UDI database
MDCG 2019-1 January 2019	MDCG guiding principles for issuing entities rules on basic UDI-DI
MDCG 2019-2 February 2019	Guidance on application of UDI rules to device-part of products referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017

Document Number	Title of Document
MDCG 2019-4 April 2019	Timelines for registration of device data elements in EUDAMED
MDCG 2019-5 April 2019	Registration of legacy devices in EUDAMED
MDCG 2019-7 June 2019	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)
MDCG 2020-3 March 2020	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2020-7 April 2020	Guidance on PMCF plan template
MDGC 2020-8 April 2020	Guidance on PMCF evaluation report template
MDCG 2020-15 August 2020	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
MDCG 2020-18 December 2020	MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers
MDCG 2021-1 Rev.1 May 2021	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
MDCG 2021-09 May 2021	MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers
MDCG 2021-10 June 2021	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices
MDCG 2021-13 Rev.1 July 2021	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR
MDCG 2021-19 July 2021	Guidance note integration of the UDI within an organisation's quality management system
MDCG 2021-25 October 2021	Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
4.5. Directive	
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	**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

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

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	**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, 4, 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 Desing Examination Certificate	M.2018.106.9177-1	15.01.2018	14.01.2023
Full Quality Assurance System	M.2018.106.9177	15.01.2018	14.01.2023

Place, Date **Ankara, 10.11.2021**

Signature
Name **Adil BOZ**
Position **General Manager**

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
1. Harmonised Standards	
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 (ISO 11137-2:2013)
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 11138-2:2017)
EN ISO 11737-1: 2018	Sterilization of health care products - 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)

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

Document Number	Title of Document
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 (ISO 20417:2021)
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
4. Guidance Documents	
4.1. ASTM Documents	
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
4.2. Guidance MEDDEVs	
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
4.3. NB-MED Documents	
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
4.4. MDCG Documents	
MDCG 2018-1 Rev.4 April 2021	Guidance on BASIC UDI-DI and changes to UDI-DI
MDCG 2018-2 March 2018	Future EU medical device nomenclature - Description of requirements
MDCG 2018-3 Rev.1 June 2020	Guidance on UDI for systems and procedure packs
MDCG 2018-4 October 2018	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs
MDCG 2018-5 October 2018	UDI assignment to medical device software

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

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	**FASTLAK** **Surgical, Poly[glycolide(90%)-co-lactide (10 %)] (Rapid PGLA) Suture**
Properties	**Sterile, Synthetic, Rapid Absorbable, Braided, Multifilament, Undyed, Coated, With or Without Needles, Single Use**
Dye	**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, article for 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 see page 3, 4, 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 Desing Examination Certificate	M.2018.106.9177-1	15.01.2018	14.01.2023
Full Quality Assurance System	M.2018.106.9177	15.01.2018	14.01.2023

Place, Date **Ankara, 10.11.2021**

Signature
Name **Adil BOZ**
Position **General Manager**

Surgical, Poly[glycolide(90%)-co-lactide (10 %)] (Rapid PGLA)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
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
1. Harmonised Standards	
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 (ISO 11137-2:2013)
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 11138-2:2017)
EN ISO 11737-1: 2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
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EN ISO 10993-6:2016	Biological evaluation of medical devices- Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
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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)

Document Number	Title of Document
EN ISO 10993-13:2010	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
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EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019, Corrected version 2020-06)
EN ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)
EN ISO 14630:2012	Non-active surgical implants - General requirements (ISO 14630:2012)
2. Pharmacopeia	
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 / Absorbable Surgical Suture
3. Other Standards	
EN 868-5: 2018	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
EN ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
ISO 8601-1:2019	Date and time — Representations for information interchange — Part 1: Basic rules
ISO 13781:2017	Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing
TS 4020/ MAY 2016	Surgical needles
TS 4169/ FEB 1984	The Determination Of Hazardous Residues In Plastics Used For Health Purposes
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 (ISO 20417:2021)
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)

Document Number	Title of Document
4. Guidance Documents	
4.1. ASTM Documents	
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
4.2. Guidance MEDDEVs	
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
4.3. NB-MED Documents	
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
4.4. MDCG Documents	
MDCG 2019-5 April 2019	Registration of legacy devices in EUDAMED
MDCG 2019-7 June 2019	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)
MDCG 2020-3 March 2020	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2020-7 April 2020	Guidance on PMCF plan template
MDGC 2020-8 April 2020	Guidance on PMCF evaluation report template

Document Number	Title of Document
MDCG 2020-15 August 2020	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
MDCG 2020-18 December 2020	MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers
MDCG 2021-1 Rev.1 May 2021	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
MDCG 2021-09 May 2021	MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers
MDCG 2021-10 June 2021	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices
MDCG 2021-13 Rev.1 July 2021	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR
MDCG 2021-19 July 2021	Guidance note integration of the UDI within an organisation's quality management system
MDCG 2021-25 October 2021	Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
MDCG 2019-7 June 2019	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)
MDCG 2020-3 March 2020	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2020-7 April 2020	Guidance on PMCF plan template
MDGC 2020-8 April 2020	Guidance on PMCF evaluation report template
MDCG 2020-15 August 2020	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
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MDCG 2021-13 Rev.1 July 2021	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR
4.5. Directive	
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	**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, 4, 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 Desing Examination Certificate	M.2018.106.9177-1	15.01.2018	14.01.2023
Full Quality Assurance System	M.2018.106.9177	15.01.2018	14.01.2023

Place, Date **Ankara, 10.11.2021**

Signature
Name **Adil BOZ**
Position **General Manager**

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
1. Harmonised Standards	
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 (ISO 11137-2:2013)
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 11138-2:2017)
EN ISO 11737-1: 2018	Sterilization of health care products - 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)

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

Document Number	Title of Document
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 (ISO 20417:2021)
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
4. Guidance Documents	
4.1. ASTM Documents	
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
4.2. Guidance MEDDEVs	
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
4.3. NB-MED Documents	
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
4.4. MDCG Documents	
MDCG 2018-1 Rev.4 April 2021	Guidance on BASIC UDI-DI and changes to UDI-DI
MDCG 2018-2 March 2018	Future EU medical device nomenclature - Description of requirements
MDCG 2018-3 Rev.1 June 2020	Guidance on UDI for systems and procedure packs
MDCG 2018-4 October 2018	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs
MDCG 2018-5 October 2018	UDI assignment to medical device software

Document Number	Title of Document
MDCG 2018-6 October 2018	Clarifications of UDI related responsibilities in relation to article 16
MDCG 2018-7 October 2018	Provisional considerations regarding language issues associated with the UDI database
MDCG 2019-1 January 2019	MDCG guiding principles for issuing entities rules on basic UDI-DI
MDCG 2019-2 February 2019	Guidance on application of UDI rules to device-part of products referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017
MDCG 2019-4 April 2019	Timelines for registration of device data elements in EUDAMED
MDCG 2019-5 April 2019	Registration of legacy devices in EUDAMED
MDCG 2019-7 June 2019	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)
MDCG 2020-3 March 2020	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2020-7 April 2020	Guidance on PMCF plan template
MDGC 2020-8 April 2020	Guidance on PMCF evaluation report template
MDCG 2020-15 August 2020	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
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MDCG 2021-19 July 2021	Guidance note integration of the UDI within an organisation's quality management system
MDCG 2021-25 October 2021	Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
4.5. Directive	
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	**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, 4, 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 Desing Examination Certificate	M.2018.106.9177-1	15.01.2018	14.01.2023
Full Quality Assurance System	M.2018.106.9177	15.01.2018	14.01.2023

Place, Date **Ankara, 10.11.2021**

Signature
Name **Adil BOZ**
Position **General Manager**

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

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EN 1422:2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
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EN ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)
EN ISO 11737-1: 2018	Sterilization of health care products - 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)
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EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

Document Number	Title of Document
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EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
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EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019, Corrected version 2020-06)
EN ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)
EN ISO 14630:2012	Non-active surgical implants - General requirements (ISO 14630:2012)
2. Pharmacopeia	
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 / Absorbable Surgical Suture
3. Other Standards	
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EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
EN ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
ISO 8601-1:2019	Date and time — Representations for information interchange — Part 1: Basic rules
ISO 13781:2017	Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing
TS 4020/ MAY 2016	Surgical needles
TS 4169/ FEB 1984	The Determination Of Hazardous Residues In Plastics Used For Health Purposes
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 (ISO 20417:2021)

Document Number	Title of Document
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
4. Guidance Documents	
4.1. ASTM Documents	
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
4.2. Guidance MEDDEVs	
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
4.3. NB-MED Documents	
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
4.4. MDCG Documents	
MDCG 2019-5 April 2019	Registration of legacy devices in EUDAMED
MDCG 2019-7 June 2019	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)
MDCG 2020-3 March 2020	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2020-7 April 2020	Guidance on PMCF plan template

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

KM-FR-85

EC DESIGN EXAMINATION CERTIFICATE

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

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

Company Name	: Boz Tıbbi Malzeme Sanayi ve Ticaret A.Ş.
Company Address	: Sağlık Mh. Sağlık 1 Sk. No:33/5 Sıhhiye Çankaya ANKARA / TURKEY
Manufacturing and Storage	: 29 Ekim Mh. Necip Fazıl Blv. No:71 Yenikent Sincan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Section 4)
Product	: Single use, Sterile, Synthetic Monofilament/Multifilament, Absorbable Surgical Sutures - Class III
GMDN	: 17471, 13908, 16584, 45814

Product Types are attached.

Certificate Number	: M.2018.106.9177-1
Report Number	: MD.3532.IB
Initial Assessment Date	: 07.11.2017
Registration Date	: 15.01.2018
Revision Date /No	: 14.01.2021/01
Expiry Date	: 14.01.2023

UDEM APPROVED 12292

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

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

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 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9177-1 and with the registration date of 15.01.2018 and with the revision date of 14.01.2021 issued for "Boz 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.

Poly[glycolide(90%)-co-lactide(10%)] (PGLA) GMDN NO:17471
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Suture 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.
Poly[glycolide(90%)-co-lactide(10%)] (Rapid Absorbable PGLA) GMDN NO:17471
Synthetic, Sterile, Rapid Absorbable, Multifilament, Braided, Undyed Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Suture 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.
Polyglycolic acid (PGA) GMDN NO:13908
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8
Suture 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.

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

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.
Mutlukent Mahallesi 2073. Sokak (Eski 93 Sokak) No:10 Ümitköy – Çankaya – ANKARA
T:03124430390 F:03124430376 info@udemltd.com.tr www.udem.com.tr

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Polyglycolic acid (Rapid Absorbable PGA) **GMDN NO:13908**
Synthetic, Sterile, Rapid Absorbable, Multifilament, Braided, Undyed Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8
Suture 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.
Polydioxanone (PDO) **GMDN NO:16584**
Synthetic, Sterile, Absorbable, Monofilament, Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,5 0,7 1 1,5 2 3 3,5 4 5
Suture 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.
Poly[glycolide(75%)-co-caprolactone(25%)] (PGCL) **GMDN NO:45814**
Synthetic, Sterile, Absorbable, Monofilament, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,7 1 1,5 2 3 3,5 4 5
Suture 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.

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

EC CERTIFICATE

Full Quality Assurance System

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

M.2018.106.9177-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Boz Tıbbi Malzeme Sanayi ve Ticaret A.Ş.
Company Address	: Sağlık Mh. Sağlık 1 Sk. No:33/5 Sıhhiye Çankaya ANKARA / TURKEY
Manufacturing and Storage	: 29 Ekim Mh. Necip Fazıl Blv. No:71 Yenikent Sincan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Single use, Sterile, Synthetic Monofilament/Multifilament, Absorbable Surgical Sutures - Class III
GMDN	: 17471, 13908, 16584, 45814

Product Types are attached.

Certificate Number	: M.2018.106.9177
Report Number	: MD.3532.IB
Initial Assessment Date	: 07.11.2017
Registration Date	: 15.01.2018
Revision Date /No	: 14.01.2021/01
Expiry Date	: 14.01.2023

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

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC 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 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9177 and with the registration date of 15.01.2018 and with the revision date of 14.01.2021 issued for "Boz 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.

Poly[glycolide(90%)-co-lactide(10%)] (PGLA) GMDN NO:17471
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Suture 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.
Poly[glycolide(90%)-co-lactide(10%)] (Rapid Absorbable PGLA) GMDN NO:17471
Synthetic, Sterile, Rapid Absorbable, Multifilament, Braided, Undyed Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5
Suture 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.
Polyglycolic acid (PGA) GMDN NO:13908
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8
Suture 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.

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

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Polyglycolic acid (Rapid Absorbable PGA) GMDN NO:13908
Synthetic, Sterile, Rapid Absorbable, Multifilament, Braided, Undyed Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6
EP: 0,4 0,5 0,7 1 1,5 2 3 3,5 4 5 6 6 7 8
Suture 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.
Polydioxanone (PDO) GMDN NO:16584
Synthetic, Sterile, Absorbable, Monofilament, Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,5 0,7 1 1,5 2 3 3,5 4 5
Suture 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.
Poly[glycolide(75%)-co-caprolactone(25%)] (PGCL) GMDN NO:45814
Synthetic, Sterile, Absorbable, Monofilament, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,7 1 1,5 2 3 3,5 4 5
Suture 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.

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.

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

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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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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

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

CERTIFICATE

EC Design-Examination Certificate

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

With the expire of the certificate M.2020.106.13692 the validity of the certificate M.2020.106.13692-1 will also end.

Company Name	: Boz 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 (Section 4)
Product	: Single use, Sterile Nonabsorbable Surgical Sutures - Class III Single use, Sterile Nonabsorbable Teflon Pledget - Class III
GMDN	: 13910, 38000, 13909, 13909, 13906, 31744, 13909, 15971

Product Types are attached.

Certificate Number	: M.2020.106.13692-1
Report Number	: MD.3532.IB
Initial Assessment Date	: 08.11.2019
Registration Date	: 29.06.2020
Revision Date /No	: -
Expiry Date	: 27.05.2024

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

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

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 3 (three) pages is the Annex of the Certificate with the number M.2020.106. 13692-1 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 Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş
Mutlukent Mahallesi 2073. Sokak (Eski 93 Sokak) No:10 Ümitköy – Çankaya – ANKARA
T:03124430390 F:03124430376 info@udemltd.com.tr www.udem.com.tr

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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.

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This document containing 3 (three) pages is the Annex of the Certificate with the number M.2020.106. 13692-1 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, 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

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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.

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

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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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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

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