BOZ TIBBİ
MALZEME SANAYİ VE TİCARET A.Ş.

Declaration of Conformity

Manufacturer	**BOZ TIBBİ MALZEME SANAYİ VE TİCARET A.Ş.**
Address	**Sağlık Mah. Sağlık Sokak No:33/5 Sıhhiye-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	**1901001..... 1912099**
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 Harmonized Standards see page 3 and 4

Notified Body	**ELEKTROTECHNICKY ZKUŠEBNÍ ÚSTAV** **Pod lisem 129,171 02 Praha 8 - Troja**
Notified Body No	**CE 1014**

Certificate	Certificate No	Certificate Date	Date of Validity
EC Design Examination Certificate	MED 150154	10.11.2015	09.11.2020
EC Certificate full quality assurance system	MED 150152	10.11.2015	09.11.2020

Place, Date **Ankara, 02.01.2019**

Digitally signed by Bolea Petru
Date: 2021.02.22 08:18:16 EET
Reason: MoldSign Signature
Location: Moldova

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.

HARMONIZED STANDARDS LIST

Document Number	Title of Document
EP9.0-01/2008:0324	European Pharmacopoeia 9.0-01/ 2008:0324 Sutures, Sterile Non-absorbable Monograph.
USP 40/ NF 35	United States Pharmacopoeia 6298 Suture / Official Monographs- Nonabsorbable Surgical Suture
EN ISO 13485: 2012	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14630: 2012	Non Active Surgical Implants- General Requirements
EN ISO 14971:2012	Medical devices - Application of risk management to 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
EN 556-1: 2001	Sterilisation of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised medical devices
EN 60068-2-31:2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens
EN 60068-2-47: 2005	Environmental testing Part 2-47: Tests - Mounting of specimens for vibration, impact and similar dynamic tests
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
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
EN ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11737-1: 2006	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)
EN 868-5: 2009	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 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016	Biological evaluation of medical devices- Part 6: Tests for local effects after implantation
EN ISO 10993-7:2008	Biological evaliation of medical devices part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Systemic toxicity tests

HARMONIZED STANDARDS LIST

Document Number	Title of Document
EN ISO 10993-18:2009	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2:Validation requirements for forming, sealing and assembly processes
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
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
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
EN 14698-2:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
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
TS 4169/ FEB 1984	The Determination Of Hazardous Residues In Plastics Used For Health Purposes
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 - 98(2009)	Standard Test Method for Drop Test of Loaded Containers by Free Fall
ASTM D999 - 08(2015)	Standard Test Methods for Vibration Testing of Shipping Containers
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	Guidelines on a Medical Devices Vigilance System