KONTROLLÜ
UNDER CONTROL

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	**REOXCEL Sigma Knit** **Absorbable Haemostat Oxidized Regenerated Cellulose (ORC)**
Properties	**Sterile, Single Use**
Dye	**Undyed (natural, beige-caramel)**
Insulation/Coating	-
Sizes	**For product models, see page 2**
GMDN NO	**38771**
Classification	**Class III, Rule 7**

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 List, see page 3, 4, 5 and 6

Notified Body : **UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. Mutlukent Mahallesi 2073 Sokak No:10 Ümitköy-ÇANKAYA Ankara Türkiye**

Notified Body No : **2292**

Certificate	Certificate No	Certificate Date	Date of Validity
EC Design-Examination Certificate	M.2018.106.9142-1	02.01.2018	01.01.2023
Full Quality Assuarance System	M.2018.106.9142	02.01.2018	01.01.2023

Place, Date **Ankara, 02.10.2023**

Signature

Digitally signed by Neruşceac Irina
Date: 2023.12.27 21:43:36 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANA

Digitally signed by Notari Vladimir
Date: 2023.12.28 17:49:48 EET
Reason: MoldSign Signature
Location: Moldova

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

REOXCEL Sigma Knit (Oxidized Regenerated Cellulose Haemostat) PRODUCT MODELS

PRODUCT CODE	PRODUCT SIZE	PRODUCT CODE	PRODUCT SIZE
RK1001*	2,6cm x 2,6cm	RK1001	2,6cm x 2,6cm
RK1001X*	2,6cm x 2,6cm	RK1001X	2,6cm x 2,6cm
RK1003*	2,6cm x 10cm	RK1003	2,6cm x 10cm
RK1003X*	2,6cm x 10cm	RK1003X	2,6cm x 10cm
RK2003*	5cm x 7,5cm	RK2003	5cm x 7,5cm
RK2003X*	5cm x 7,5cm	RK2003X	5cm x 7,5cm
RK3004*	7,6cm x 10,2cm	RK3004	7,6cm x 10,2cm
RK3004X*	7,6cm x 10,2cm	RK3004X	7,6cm x 10,2cm
RK6009*	15,2cm x 23cm	RK6009	15,2cm x 23cm

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DIRECTIVE/REGULATION/STANDARD/COMMON SPECIFICATION/GUIDANCE

NO	REFERENCE	TITLE
1	2017/745	Regulation (Eu) 2017/745 of the European Parliament and of the Council of 5 April 2017
2	EN ISO 13485:2016+A11:2021	Medical devices — Quality management systems —Requirements for regulatory purposes (ISO 13485:2016)
3	EN ISO 14971:2019+A11	Medical devices – Application of risk management to medical devices (ISO 14971:2019)
4	USP	United States Pharmacopeia (USP) 43 National Formulary (NF) 38 Oxidized Regenerated Cellulose Monograph
5	EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
6	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)
7	EN ISO 10993-3:2014	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
8	EN ISO 10993-4:2017	Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
9	EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
10	EN ISO 10993-6:2016	Biological evaluation of medical devices Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
11	EN ISO 10993-9:2021	Biological evaluation of medical devices Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)
12	EN ISO 10993-10:2023	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2021)
13	EN ISO 10993-11:2018	Biological evaluation of medical devices Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
14	EN ISO 10993-12:2021	Biological evaluation of medical devices Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
15	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)
16	EN ISO 10993-16:2017	Biological evaluation of medical devices Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2017)
17	EN ISO 10993-17:2009	Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)
18	EN ISO 10993-18:2020/ A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process - Amendment 1: Determination of the uncertainty factor (ISO 10993-18:2020/Amd 1:2022)
19	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
20	EN ISO 14630:2012	Non-active surgical implants - General requirements (ISO 14630:2012)
21	EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
22	EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006/Amd 2:2018)
23	EN ISO 11137-2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose - Amendment 1 (ISO 11137-2:2013/Amd 1:2022)

24	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)
25	EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018/Amd 1:2021)
26	EN ISO 11737-2:2020	Sterilization of medical devices- Microbiological methods- Part 2: Tests of sterility performed in the validation of a sterilization process (ISO 11737-2:2019)
27	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021)
28	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
29	EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
30	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)
31	EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019, Corrected version 2020-06)
32	EN ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)
33	EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
34	EN ISO 11607-1:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
35	EN ISO 11607-2:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
36	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
37	ISO 8601-1:2019/Amd 1:2022	Date and time — Representations for information interchange — Part 1: Basic rules — Amendment 1: Technical corrections
38	ISO 13781:2017	Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing
39	CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
40	CPMP/ICH/2736/99-Step 5 August 2003	ICH Topic Q 1 A (R2) Stability Testing of New Drug Substances and Drug Products
41	TS 4739/ MAR 1986	Methods of Identification of Textile Fibers
42	TS 10410/ OCT 1992	Methods For Sterility Control (For Medical Purposes) Part 3- Application Of Medicines, Medical And Surgical Materials To Inoculation Methods
43	ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
44	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
45	ASTM F88 / F88M-23	Standard Test Method for Seal Strength of Flexible Barrier Materials
46	ASTM D5276 - 19	Standard Test Method for Drop Test of Loaded Containers by Free Fall
47	MEDDEV 2. 4/1 Rev. 9	MEDICAL DEVICES: Guidance document - Classification of medical devices
48	MEDDEV 2. 2/3 rev.3	'Use-by' date for medical devices
49	MEDDEV 2.7/1 Rev.04	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC

50	MEDDEV 2.12/2 rev2	Post-Market Clinical Follow-up Studies
51	MEDDEV 2.12-1 rev 8	Guidelines on a Medical Devices Vigilance System
52	NB-MED/2.5.1/Rec5-rev4	Technical Documentation
53	NB-MED/2.5.1/Rec6-rev4	Renewal of EC Design-Examination and Type-Examination Certificates
54	NB-MED/2.5.2/Rec1-rev4	Subcontracting - QS related
55	NB-MED/2.12/Rec1-rev11	Post-Marketing Surveillance (PMS) post market/production
56	NB-MED/2.13/Rec1-rev3	CE-Marking of pre-MDD devices
57	MDCG 2018-1 Rev. 4	Guidance on basic UDI-DI and changes to UDI-DI
58	MDCG 2018-2	Future EU medical device nomenclature - Description of requirements
59	MDCG 2018-3 Rev.1	Guidance on UDI for systems and procedure packs
60	MDCG 2018-4	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs
61	MDCG 2018-6	Clarifications of UDI related responsibilities in relation to article 16
62	MDCG 2018-7	Provisional considerations regarding language issues associated with the UDI database
63	MDCG 2019-1	MDCG guiding principles for issuing entities rules on basic UDI-DI
64	MDCG 2019-2	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
65	MDCG 2019-4	Timelines for registration of device data elements in EUDAMED
66	MDCG 2019-5	Registration of legacy devices in EUDAMED
67	MDCG 2019-7	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)
68	MDCG 2019-9 Rev.1	Summary of safety and clinical performance
69	MDCG 2020-3 Rev.1	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
70	MDCG 2020-5	Guidance on clinical evaluation – Equivalence
71	MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
72	MDCG 2020-7	Guidance on PMCF plan template
73	MDCG 2020-8	Guidance on PMCF evaluation report template
74	MDCG 2020-15	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
75	MDCG 2021-1 Rev. 1	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
76	MDCG 2021-5	Guidance on standardisation for medical devices
77	MDCG 2021-10	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices
78	MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
79	MDCG 2021-13 Rev.1	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

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80	MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
81	MDCG 2021-24	Guidance on classification of medical devices
82	MDCG 2021-25	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
83	MDCG 2022-7	Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU)
84	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745

KM-AS-ORC-rev00-25.08.2023