ORMED GRUP MEDIKAL TUR.SAG.HIZ.SAN.VE.TIC.LTD.ŞTİ	Document No: TD.16 Issue No: 07.03.2018 Revision No / Date: 06/ 25.05.2022

MANUFACTURER	Ormed Grup Medikal Tur. Sağ. Hiz. San. Ve Tic.Ltd.Şti.
ADRESS	Macun Mahallesi 177.Cadde No:19 H/7 Yenimahalle/ANKARA
DEVICE NAME	OGM 1A Bone Cement, OGM 3A Bone Cement TF01.03
CLASSIFICATION	Class III Rule 13
SRN	TR-CA-077
Basıc - UDI	8682024000TD03YT
GMDN	35217
CONFORMITY ASSESSMENT ROUTE	Ek IV

We declare that the above products are in compliance with the provisions of 2017/745 MDR Medical Device Regulation. All supporting documents are kept within the manufacturer.

We declare that we will fulfill the obligations imposed by the quality system and that we will keep the quality system adequately and effectively.

We declare to the institute that we will establish and keep up to date a systematic procedure for the application of appropriate tools to examine the experience gained with devices in the post-production stages and to take necessary corrective action, including the provisions set out in Annex X. The characteristics of a device and / or performance if there is any malfunction or damage, SZUTEST (NB 2195) and Turkey Pharmaceuticals and we will promptly inform the Medical Devices Institution, also can cause a patient in the operating instructions or the user's death or health conditions seriously deteriorate. The same article (ii) of subparagraph (i) If any technical or any technical or medical reason connected with the medical reason that causes recalled systematically the reasons specified device immediately SZUTEST (NB 2195) and Turkey Pharmaceuticals and notify the Medical Devices Institution . Write by the manufacturer.

APPLIED STANDARDS

STANDARD NO	STANDARD DEFINITION
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 15223-1:2016, Corrected version 2017-03)
EN 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 11135:2020	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 / AC: 2009	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
EN ISO 10993-1:2021	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2015	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2010	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6: 2017	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
EN ISO 10993-7/A1: 2022	Biological evaliation of medical devices part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2014	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
EN ISO 14971:2020	Medical devices - Application of risk management to medical devices
EN 17141:2020	Cleanrooms and associated controlled environments. Biocontamination control

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Location: Moldova

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14644-1:2016	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2:2016	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14630:2013	Non-active surgical implants - General requirements
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11138-2:2017	Sterilization of health care products. Biological indicators. Biological indicators for ethylene oxide sterilization processes
EN ISO 11140-1:2015	Sterilization of health care products - Chemical indicators - Part 1: General requirements
EN ISO 13408-1:2015	Sterilization of health care products - Chemical indicators - Part 1: General requirements
EN ISO 11737-1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
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
EN 556-2:2015	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
TS ISO 5833:2014	Implants for surgery — Acrylic resin cements
MEDDEV 2.7.1 REV.4:2016	Article overviews of the new MEDDEV 2.7/1 rev 4 for clinical evaluation of medical devices, including a quality plan to comply with the new revision.
MEDDEV 2.12.1 REV.8:2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV 2.12.2 REV.2:2012	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
ASTM F1980-07:2011	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1980-16:2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
NBOG 2010-1:2010	Guidance for Notified Bodies auditing suppliers to medical device manufacturers
MEDDEV 2.12.2 REV.2:2012	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
ASTM F1980-07:2011	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1980-16:2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
NBOG 2010-1:2010	Guidance for Notified Bodies auditing suppliers to medical device manufacturers
NOTIFIED BODY ID	SZUTEST Uygunluk Değerlendirme Anonim Şirketi Tatlısu Mahallesi, Akif İnan Sk. No:1 34774 Ümraniye / İSTANBUL /Türkiye iSTANBUL, **NB 2195**
EC CERTIFICATE NUMBER	2195-MED-1921201-D01
EC AND DESIGN CERTIFICATE DATE	31.07.2019
DESIGN REVIEW CERTIFICATE NUMBER	MM0731-P001-R001,MM0731-P001-R002
ISSUE DATE, PLACE	07.03.2018 ANKARA
AUTHORIZED PERSONNEL NAME, SIGN	KENAN KARA

No	Adı
Bone Cement	
1	OGM1A 20 Standard Viscosity Bone Cement With Gentamicin (1x20 g)
2	OGM3A 20 Low Viscosity Bone Cement With Gentamicin (1x20 g)
3	OGM1A 40 Standard Viscosity Bone Cement With Gentamicin (1x40 g)
4	OGM3A 40 Low Viscosity Bone Cement With Gentamicin (1x40 g)
5	OGM1A 60 Standard Viscosity Bone Cement With Gentamicin (1x60 g)
6	OGM3A 60 Low Viscosity Bone Cement With Gentamicin (1x60 g)