LISMEDFARM S.R.L.
Șos. Muncești, 167/B, MD – 2002, mun. Chișinău, Republica Moldova
tel.: 022-80-47-98, 022-55-64-38, 022-56-94-91, e-mail: oficiu@lismedfarm.md,
web: https://lismedfarm.md, c/f: 1003600113573, TVA: 0304618, director – Ecaterina Chitic

Anexa nr. 27
la Documentația standard
Ordinul Ministrului Finanțelor
nr. 115 din 15 septembrie 2021

DECLARAȚIE
privind neîncadrarea în situațiile ce determină excluderea de la procedura de atribuire

Operator economic
Lismedfarm S.R.L

Subsemnatul, Ecaterina Chitic, reprezentant împuternicit al Lismedfarm S.R.L. în calitate de ofertant declar pe propria răspundere, sub sancțiunea excluderii din procedura de achiziție publică și sub sancțiunile aplicabile faptei de fals în acte publice, că nu mă aflu în situația prevăzută la art. 19 din Legea privind achizițiile publice nr. 131 din 03.07.2015, respectiv în ultimii 5 ani nu am fost condamnat prin hotărâre definitivă a unei instanțe judecătorești pentru participarea la activități ale unei organizații criminale, pentru corupție, fraudă și/sau spălare de bani.

Subsemnatul declar că informațiile furnizate sunt complete şi corecte în fiecare detaliu şi înțeleg că autoritatea contractantă are dreptul de a solicita, în scopul verificării şi confirmării declarațiilor, orice documente doveditoare de care dispun.

Subsemnatul, Vlad Chitic reprezentant împuternicit al Lismedfarm S.R.L., în calitate de ofertant, la procedura de ocds-b3wdp1-MD-1737734481286 pentru atribuirea contractului de achiziție publică având ca obiect În scopul atribuirii contractelor subsecvente ca urmare a acordului-cadru (nr. ocds...30646 din 14.01.2025) încheiat prin procedura de achiziție publică ocds-b3wdp1-MD-1718205130646 din 12.06.2024 privind încheierea acordului-cadru - Achiziționarea endoprotezelor pentru anii 2025-2027 , codul CPV 33100000-1, la data de 07.02.2025, organizată de CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE, declar pe propria răspundere că:

a) nu am intrat în faliment ca urmare a hotărârii judecătorești;

b) mi-am îndeplinit obligațiile de plată a impozitelor, taxelor și contribuțiilor de asigurări sociale;

c) nu am fost condamnat, în ultimii 3 ani, prin hotărârea definitivă a unei instanțe judecătorești, pentru o faptă care a adus atingere eticii profesionale sau pentru comiterea unei greșeli în materie profesională;

d) toate informațiile și documentele prezentate pentru procedura de achiziție menționată mai sus sunt veridice și autentice;

e) nu suntem incluși în Lista de interdicție a operatorilor economici.

Subsemnatul declar că informațiile furnizate în scopul demonstrării îndeplinirii criteriilor de calificare și selecție sunt complete și corecte în fiecare detaliu și înțeleg ca autoritatea contractantă are dreptul de a solicita, în scopul verificării și confirmării declarațiilor, orice documente doveditoare de care dispun.

Înțeleg ca în cazul în care această declarație nu este conformă cu realitatea sunt pasibil de încălcarea prevederilor legislației penale privind falsul în declarații.

Data completării: 06.02.2025

Operator economic, *Lismedfarm S.R.L*

semnătura

L.Ș.

LISMEDFARM S.R.L.
Șos. Munceşti, 167/B, MD – 2002, mun. Chișinău, Republica Moldova
tel.: 022-80-47-98, 022-55-64-38, 022-56-94-91, e-mail: oficiu@lismedfarm.md,
web: https://lismedfarm.md, c/f: 1003600113573, TVA: 0304618, director – Ecaterina Chitic

Anexa nr. 8
la Documentația standard
Ordinul Ministrului Finanțelor
nr. 115 din 15 septembrie 2021

DECLARAŢIE
PRIVIND VALABILITATEA OFERTEI

Către CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE, MD-2005, Republica Moldova, mun. Chișinău, or. Chișinău, str. G. Vieru 22/2

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, **privind** În scopul atribuirii contractelor subsecvente ca urmare a acordului-cadru (nr. ocds...30646 din 14.01.2025) încheiat prin procedura de achiziție publică ocds-b3wdp1-MD-1718205130646 din 12.06.2024 privind încheierea acordului-cadru - Achiziționarea endoprotezelor pentru anii 2025-2027 (se indică obiectul achiziției) **prin procedura de achiziție** Licitație deschisă (tipul procedurii de achiziție)**,** pentru o durată de 30 (treizeci) zile, (durata în litere și cifre), respectiv până la data de 12.03.2025 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 06.02.2025

Cu stimă,
Ofertant/candidat
Vlad Chitic, director executiv
Lismedfarm S.R.L.

Digitally signed by Chitic Ecaterina
Date: 2025.02.06 21:35:04 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

ORDIN DE PLATA nr. **81** DATA EMITERII **06.02.2025 00:00:00** TIP.DOC. 4

PLATITI **19259.76** LEI **Nouasprezece Mii Doua Sute Cincizeci si Noua lei 76 bani**

PLATITOR **(R) "LISMEDFARM" S.R.L.**

Cod IBAN **MD65ML0000000000225156722**

CODUL FISCAL **1003600113573**

PRESTATORUL PLATITOR **BC'Moldindconbank'S.A.**

CODUL BANCII **MOLDMD2X**

BENEFICIAR **(R) CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE**

Cod IBAN **MD23TRPCCC518430B01859AA**

CODUL FISCAL **1016601000212**

PRESTATORUL BENEFICIAR **Ministerul Finantelor - Trezoreria de**

CODUL BANCII **TREZMD2X**

DESTINATIA PLATII **/P102/19259,76 Garantia pentru oferta in cuantum de 2% la procedura de achizitie publica nr. ocds-b3wdp1-MD-1737734481286**

TIPUL TRANSFERULUI NORMAL/URGENT **N**

L.S.

CODUL TRANZACTIEI **101**

DATA PRIMIRII **06.02.2025**

DATA EXECUTARII **06.02.2025 00:00:00**

SEMNATURILE EMITENTULUI

SEMNATURA PRESTATORU

B.C. «MOLDINDCONBANK» S.A.
mun. Chişinău
EX 06.02.2025
MD-2012, Republica Moldova,
mun. Chişinău, str. Armenească, 38.

Digitally signed by Extras MICB
Date: 2025.02.06 11:32:31 +02:00
Reason: MICB Extract
Location: Moldova Chisinau

REVISION TRACKING PAGE

Revision Date	Revision No	Revision Explanation
07.03.2018	0	First Edition
04.12.2018	1	Second Edition
14.09.2020	2	Third Edition
18.08.2021	3	Fourth Edition
10.08.2022	4	Fifth Edition

PREPARED	APPROVED
	

MANUFACTURER NAME AND ITS ADRESS, THE ADRESS OF MANUFACTORY FIELD AND DESIGNING PLACE

MANUFACTURER:

Ormed Grup Medikal Tur. Sağ. Hiz. San. Ve Tic.Ltd.Şti.

THE ADRESS OF MANUFACTURER:

Macun Mahallesi 177.Cadde No:19 H/7 Yenimahalle/ANKARA

DESIGN, PRODUCTION AND CONTROL:

Macun Mahallesi 177.Cadde No:19 H/7 Yenimahalle/ANKARA

PACKING AND STORING

Macun Mahallesi 177.Cadde No:19 H/7 Yenimahalle/ANKARA

BOTTLE STERILIZATION (ASEPTIC FILLING)

Macun Mahallesi 177.Cadde No:19 H/7 Yenimahalle/ANKARA

PROCESS OF OUR SOURCES- THE LEGAL ENTITY AND ADRESS OF EO STERILIZATION:

AYA Validasyon Ambalaj Sterilizasyon A.Ş.

Fatih Mahallesi 3105 Cad. No:8 Kazan / ANKARA – TÜRKİYE

1) PRODUCT LIST AND GMDN EXPLANATIONS

PRODUCT NAME OGM Bone Cement
OGM Vertebroplasty Cement

BRANDS OGM

No	Name	Ref No	UBB	GMDN
Bone Cement				
1	OGM1 20 Standard Viscosity Bone Cement(1x20g)	1012/S	8682024000017	35217
2	OGM3 20 Low Viscosity Bone Cement(1x20g)	2809/L	8682024000024	35217
3	OGM1 40 Standard Viscosity Bone Cement(1x40g)	1201/S	8682024000055	35217
4	OGM3 40 Low Viscosity Bone Cement (1x40 g)	1510/L	8682024000062	35217
5	OGM1 60 Standard Viscosity Bone Cement (1x60 g)	1881/S	8682024000093	35217
6	OGM3 60 Low Viscosity Bone Cement (1x60 g)	1923/L	8682024000109	35217
	Vertebroplasty Bone Cement			
7	OGM VTB 12,5 Vertebroplasty Cement (1x12,5g)	0308/VTB	8682024000147	35217
8	OGM VTB 15 Vertebroplasty Cement (1x15 g)	2023/VTB	8682024000284	35217
9	OGM VTB 20 Vertebroplasty Cement (1x20 g)	2071/VTB	8682024000291	35217
10	OGM VTB 25 Vertebroplasty Cement (1x25 g)	1406/VTB	8682024000130	35217

All technical drawings and product flow charts of the products are available in Technical drawings TD-04. Production Flow charts and Technical file are in TD-05.

TECHNICAL FIELD:

MD0202, MD7006, MDS. Inactive Implantable Medical Device.

MARKET:

There have been no adverse events, recalls or notifications to the competent authority after the sale of our products.

CE Certificate No: 2195-MED-1921201

2) INTENDED USE AND INDICATIONS OF THE DEVICE:

OGM Bone cement is a radiopaque acrylic bone cement based on polymethylmethacrylate used in orthopedic surgeries. It becomes ready for use as a result of exothermic polymerization after mixing the powder and liquid two components. This mixture, which is polymerized before use, aims to increase the adhesion of joint implants to the bone in orthopedic surgeries. Surgical Radiopaque Bone Cement is indicated for fixation of the prosthesis to living bone in orthopedic musculoskeletal surgical procedures for severe joint fragmentation as a result of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, sickle cell anemia, collagen disease, trauma or other conditions and revision of past arthroplasty procedures. Cement is also indicated for fixing pathological fractures where loss of bone material or recalcitrance of the fracture has rendered more conventional procedures ineffective.

OGM VTB Vertebroplasty bone cement is injected into a partially collapsed vertebral body (broken spine). Cement strengthens bones, reduces fracture, relieves pain and is used to provide mechanical stability in case of osteoporosis or tumor infiltration.

It is a self-polymerizable acrylic compound containing powder consisting of Benzoyl Peroxide combined with Methyl Methacrylate polymer and Methyl Methacrylate, a liquid monomer activated with N,N dimethyl p-toluidene. When the monomer and polymer are properly mixed, N,N dimethyl p-toluide activates the Benzoyl Peroxide and initiates the monomer polymerization.

The polymerization process takes place progressively. The mixture is initially liquid and then cream, which then becomes doughy and eventually solid. This reaction is exothermic.

Injected into a partially collapsed vertebral body (broken spine). Cement strengthens bones, reduces fracture, relieves pain and is used to provide mechanical stability in case of osteoporosis or tumor infiltration. The success rate in relieving pain is 75-85%. (A) Indications Designed and recommended to fill vertebral bodies with structural changes secondary to osteoporosis, tumor infiltration, selected trauma cases.

3) PRODUCT FAMILY/CONTENT

DEVICE SIZE AND CONTENT INFORMATION

Standard Viscosity

Product Name	**Reference No**	**Barcode**
OGM1 20 Standard Viscosity Bone Cement (1x20 g)	1012/S	8682024000017
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	17,80 g	
Benzoyl Peroxide	0,2 g	
Barium Sulphate	2 g	Barium Sulphate
Total Powder Amount	**20 g ± 1 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	9,8 ml	
N,N dimethyl p-toluidene	0,2 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**10 ml ± 0,5 ml**	

Product Name	**Reference No**	**Barcode**
OGM1 40 Standard Viscosity Bone Cement (1x40 g)	1201/S	8682024000055
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	35,60 g	
Benzoyl Peroxide	0,4 g	
Barium Sulphate	4 g	Barium Sulphate
Total Powder Amount	**40 g ± 2 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	19,6 ml	
N,N dimethyl p-toluidene	0,4 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**20 ml ± 1 ml**	

Product Name	**Reference No**	**Barcode**
OGM1 60 Standard Viscosity Bone Cement (1x60 g)	1881/S	8682024000093
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	53,4 g	
Benzoyl Peroxide	0,6 g	
Barium Sulphate	6 g	Barium Sulphate
Total Powder Amount	**60 g ± 3 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	29,4 ml	
N,N dimethyl p-toluidene	0,6 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**30 ml ± 1,5 ml**	

ORMED GRUP MEDIKAL TUR.SAG.HIZ.SAN.VE TIC.LTD.STI	**PRODUCTION DESCRIPTION** **OGM Bone Cement** **OGM VTB Vertebroplasty Cement**	Document No: TD.02-03 Publishing Date: 07.03.2018 Revision No: 04 Revision Date: 10.08.2022

Low Viscosity

Product Name	Reference No	Barcode
OGM3 20 Low Viscosity Bone Cement (1x20 g)	2809/L	8682024000024
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	17,80 g	
Benzoyl Peroxide	0,2 g	
Barium Sulphate	2 g	Barium Sulphate
Total Powder Amount	**20 g ± 1 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	9,8 ml	
N,N dimethyl p-toluidene	0,2 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**10 ml ± 0,5 ml**	

Product Name	Reference No	Barcode
OGM3 40 Low Viscosity Bone Cement (1x40 g)	1510/L	8682024000062
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	35,60 g	
Benzoyl Peroxide	0,4 g	
Barium Sulphate	4 g	Barium Sulphate
Total Powder Amount	**40 g ± 2 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	19,6 ml	
N,N dimethyl p-toluidene	0,4 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**20 ml ± 1 ml**	

Product Name	Reference No	Barcode
OGM3 60 Low Viscosity Bone Cement (1x60 g)	1923/L	8682024000109
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	53,4 g	
Benzoyl Peroxide	0,6 g	
Barium Sulphate	6 g	Barium Sulphate
Total Powder Amount	**60 g ± 3 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	29,4 ml	
N,N dimethyl p-toluidene	0,6 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**30 ml ± 1,5 ml**	

ORMED GRUP MEDİKAL TUR.SAG.HİZ.SAN.VE TİC.LTD.ŞTİ	**PRODUCTION DESCRIPTION** **OGM Bone Cement** **OGM VTB Vertebroplasty Cement**	Document No: TD.02-03 Publishing Date: 07.03.2018 Revision No: 04 Revision Date: 10.08.2022

Vertebroplasty Bone Cement

Product Name	Reference No	Barcode
OGM VTB 12,5 Vertebroplasty Bone Cement (1x12,5g)	0308/VTB	8682024000147
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	7,42 g	
Benzoyl Peroxide	0, 8g	
Barium Sulphate	5 g	Barium Sulfate
Total Powder Amount	**12,5 g ± 0,625 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	4,9 ml	
N,N dimethyl p-toluidene	0,1 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**5 ml ± 0,25 ml**	

Product Name	Reference No	Barcode
OGM VTB 20 Vertebroplasty Bone Cement (1x20 g)	2071/VTB	8682024000291
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	11,872 g	
Benzoyl Peroxide	0,128 g	
Barium Sulphate	8 g	Barium Sulfate
Total Powder Amount	**12,5 g ± 0,625 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	7,84 ml	
N,N dimethyl p-toluidene	0,16 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**8 ml ± 0,4 ml**	

Product Name	Reference No	Barcode
OGM VTB 15 Vertebroplasty Bone Cement (1x15 g)	2023/VTB	8682024000284
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	8,904 g	
Benzoyl Peroxide	0,096 g	
Barium Sulphate	6 g	Barium Sulfate
Total Powder Amount	**15 g ± 0,75 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	5,88 ml	
N,N dimethyl p-toluidene	0,12 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**6 ml ± 0,3 ml**	

Product Name	Reference No	Barcode
OGM VTB 25 Vertebroplasty Bone Cement (1x25 g)	1406/VTB	8682024000130
Powder Component Content	**Amount**	**Raw Material**
Polymethyl methacrylate	14,84 g	
Benzoyl Peroxide	(0,16 g)	
Barium Sulphate	10 g	Barium Sulfate
Total Powder Amount	**25 g ± 1,25 g**	
Liquid Component Content	**Amount**	**Raw Material**
Methyl Methacrylate	9,8 ml	
N,N dimethyl p-toluidene	0,2 ml	
Hydroquinone	Trace Amount	
Total Liquid Amount	**10 ml ± 0,5 ml**	

Standards by raw materials:

Bone Cement;
In the powder mixture; There are Polymethyl methacrylate, Barium sulfate and Benzoyl Peroxide.

In the liquid mixture; There are Methyl Methacrylate, N, N dimethyl p-toluidene, Hydoquinone.

Effect of Powder Component Content on the Product:

Polymethyl methacrylate: Bone cement is its main raw material. After reacting, it solidifies and ensures the adhesion of the implant to the body.

Benzoyl peroxide: It is a reaction initiator.

Barium Sulphate: It gives the orthopedic cement its radio-opacity property.

Effect of Liquid Component Content on the Product:

Methyl Methacrylate: When combined with polymethyl methacrylate, polymerization takes place.

N,N dimethyl p-toluidene: It makes cement easier to cure cold.

Hydroquinone: It prevents premature polymerization under certain conditions such as high temperature and heat exposure.

4) PATIENT POPULATION

It is suitable for all patient populations except those with known or presumed hypersensitivity to the ingredients of bone cement, during pregnancy and lactation, and patients with severe renal impairment.

5) CLASSIFICATION

No	Name	Rule	Class	Ref No	UBB	GMDN
Bone Cement						
1	OGM1 20 Standard Viscosity Bone Cement(1x20g)	2017/745 MDR Annex 8 Rule **8**	IIb	1012/S	8682024000017	35217
2	OGM3 20 Low Viscosity Bone Cement(1x20g)	2017/745 MDR Annex 8 Rule **8**	IIb	2809/L	8682024000024	
3	OGM1 40 Standard Viscosity Bone Cement(1x40g)	2017/745 MDR Annex 8 Rule **8**	IIb	1201/S	682024000055	
4	OGM3 40 Low Viscosity Bone Cement (1x40 g)	2017/745 MDR Annex 8 Rule **8**	IIb	1510/L	8682024000062	
5	OGM1 60 Standard Viscosity Bone Cement (1x60 g)	2017/745 MDR Annex 8 Rule **8**	IIb	1881/S	8682024000093	
6	OGM3 60 Low Viscosity Bone Cement (1x60 g)	2017/745 MDR Annex 8 Rule **8**	IIb	1923/L	8682024000109	
7	**Vertebroplasty Bone Cement**	2017/745 MDR Annex 8 Rule **8**	IIb	0308/VTB	8682024000147	
8	OGM VTB 12,5 Vertebroplasty Cement (1x12,5g)	2017/745 MDR Annex 8 Rule **8**	IIb	2023/VTB	8682024000284	

9	OGM VTB 15 Vertebroplasty Cement (1x15 g)	2017/745 MDR Annex 8 Rule **8**	IIb	2071/VTB	8682024000291	
10	OGM VTB 20 Vertebroplasty Cement (1x20 g)	2017/745 MDR Annex 8 Rule **8**	IIb	1406/VTB	8682024000130	

Applicable Description	- **All implantable devices and long-term surgically invasive devices fall in Class IIb, except in the following cases.** - Medical devices implanted in the teeth are in Class IIa. - Medical devices used in direct contact with the heart, central circulatory system or central nervous system are in Class III. Medical devices that have a biological effect or are completely or mostly absorbed are in Class III. - Medical devices that undergo chemical changes in the body or are used to administer drugs, except those placed inside the teeth, are in Class III. - Breast implants fall into Class III. - Shoulder, knee and hip replacement devices fall in Class III. - - All devices that, when used separately, are considered to be a medical product and that are an integral part of a substance that will act on the human body by action, are in Class III.
GMDN Code Explanation	35217 - Polymer or metal prosthetic implants to living bone
	A substance made from methylmethacrylate, polymethylmethacrylate, methacrylic acid esters or copolymers containing polymethylmethacrylate (PMMA) and polystyrene, used in arthroplastic treatments of joints to fix it. It can also be used as a filler in case of bone pathologies. The tool may contain an antibiotic.
Conformity Assessment	2017/745 MDR Medical Device Regulation Annex 8 Rule 8

- INTENDED USER

Designed for use by healthcare professionals.

- NUMBER OF USE

Single Use

6) CONTRAINDICATIONS OF THE DEVICE

Bone Cement is contraindicated in patients who are allergic to any of the ingredients of the product. The use of the product is contraindicated in case of infectious arthritis and active infection of the joint or joints to be replaced, or in the presence of a history of such infection. Use of the product is also contraindicated where a lack of musculoskeletal or neuromuscular alignment in the affected limb would render the procedure inappropriate.

For Vertebroplasty Bone Cement; Hemorrhagic diathesis and infection are absolute contraindications. Vertebral body lesions with epidural extension are a relative contraindication because of the danger of spinal cord compression.

6) SAFETY AND WARNINGS

Before using bone cement, the user should be well acquainted with its properties, processing and application. It is recommended that the user fully exercise the mixing, handling and placement procedures before using for the first time.

When mixing liquid and powder components, care must be taken to fully utilize the contents of the ampoule and bag. The liquid monomer and the powder component must be thoroughly mixed. Data from in vitro studies indicate that monomer loss is primarily dependent on the frequency of mixing and secondarily on the duration of mixing.

However, care should be taken not to knead the product for too long to prevent the polymerization process from progressing to the point where the cement loses sufficient softness and flexibility to fill the bone cavities and fix it to the prosthesis.

After application, During the completion of the in situ polymerization of the product, To ensure correct fixation, the position of the prosthesis must be kept stable without being moved. Completion of polymerization takes place on the patient and is an exothermic reaction in which a significant amount of heat is released. Temperatures seen during polymerization, reported up to 110° Celsius. The long-term effects of the heat generated and the resulting tissue damage are unknown. Special precautions should be taken to detect and compensate for the temporary drop in blood pressure that may occur when the product is implanted in the bone.

Liquid monomer is highly volatile and flammable, Adequate ventilation must be provided in the operating room to eliminate maximum monomer vapor. Precaution should be taken when mixing the two components to avoid excessive exposure to concentrated monomer vapors which may cause irritation to the respiratory tract, eyes and possibly the liver. The liquid component is a strong lipid solvent. Caused contact dermatitis in susceptible individuals. Wearing a second pair of surgical gloves and following strict mixing instructions can reduce the likelihood of hypersensitivity reactions. The compound should not be allowed to come into direct contact with sensitive tissues or be absorbed by the body. Soft contact lens manufacturers recommend removing such lenses “in environments where hazardous and irritating vapours are present.” Soft contact lenses are highly permeable and should not be used in the operating room while mixing Methyl methacrylate. Due to the lack of sufficient information, the use of the product in young patients is not recommended. Use in pregnancy: Although the results of teratology studies in animals are negative, the benefits need to be weighed against the potential hazards to the mother or foetus for use by women who are pregnant or may become pregnant. Data from clinical trials have shown that strict adherence to effective surgical principles and techniques is an absolute necessity. Deep wound infection is a serious post-operative complication and may require complete removal of the prosthesis and placed cement. Deep wound infection may be latent and may not manifest itself for several years after surgery.

The monomer should be handled very carefully as they are volatile liquids and are potentially irritating:

- Avoid unnecessary contact with skin and mucous membranes. The use of two pieces of gloves is recommended.

- Avoid contact with vapors generated during cement mixing. Open the neck of the ampoule carefully to avoid cuts or splashes. When the ampoule is opened for the first time, quickly pour it into the mixing bowl and add the polymer.

Warnings;

- Do not use products past the expiry date indicated on the product label.
- It is disposable. It is used for one patient only. In case of reuse, there are risks of mechanical, physicochemical and biological contamination.
- Discard any open or damaged sterile packages.
- Handle with care and store in dry, dark places below 25C
- Do not re-sterilize any component.
- For use by professionals, healthcare professionals.
- It is recommended not to keep cement and mixing elements above 25C. Higher temperature means less time to work with cement; if the temperature drops, the working time will also increase.
- Air ingress into the cement should be prevented because it can cause air bubbles to form in the paste-like mixture and at the bone interface. This should be avoided both in the mixture and during transfer and application.
- Medical professionals with experience with the method should perform pertutanous vertebroplasty in a medical center with all the necessary supplies so that the normal procedure can occur and in the event of an undesirable patient reaction, the case can be promptly treated.
- It should be noted that increased application pressure can potentially damage the vertebral body and surrounding soft tissue.

- Viscosity increases progressively after mixing. After waiting for a certain time and cement strength increases; It is normal to state that there is an increase in viscosity, which increases the resistance to application and produces a reduction in cement pressure on the vertebrae.

PATIENT INFORMATION

- Surgeons should inform patients of the limitations of reconstruction and the need to protect the implant from full weight-bearing until adequate healing is achieved.
- Surgeons should inform patients that the product has a limited service life and may need to be replaced in the future..
- Surgeons should warn the patient of surgical risks and potential adverse effects.
- Dental procedures, endoscopic examinations, and other minor surgical procedures have been associated with transient bacteremia. Instruct the patient to inform their doctor that they are carrying an artificial hip replacement so that their doctor can decide whether to use antibiotic prophylaxis for such procedures..

In vertebroplasty; Paravertebral structures may be damaged as a result of cement coming out. In this case, spinal cord compression, intercostal neuralgia, cement penetration into the intervertebral space, Complications such as perivertebral filling of veins and arteries (danger of embolism), infection and post-procedure pain are possibleThe application must be done under the imaging method (real-time imaging) to prevent the cement from leaking out or to detect undesirable events in a timely manner. Immediate operative intervention should be available for the surgical removal of the described complications. Comprehensive radiological examination should be performed preoperatively to prevent possible risks (eg, vertebral body lesions, vascularization of the vertebrae or edema). Incomplete filling of the vertebral body with bone cement may result in inadequate reduction of acute pain and weakening of the long-term stability of the treated vertebral body.

8) SIDE EFFECTS

Transient blood pressure drops are infrequently seen following prosthetic bed preparation or immediately after implantation of endoprostheses with PMMA bone cements. In individual cases, serious complications such as severe allergic reactions such as cardiac arrest, anaphylactic shock or even sudden death may occur. In order to avoid pulmonary and cardiovascular complications such as pulmonary embolism and cardiac arrest, it is recommended to thoroughly wash the implantation site with isotonic solution (pulse lavage application) before bone cement is placed.

In the event of pulmonary or cardiovascular events, the blood volume should be monitored and if necessary increased. Anesthesiological measures should be taken in cases of acute respiratory failure.

The following adverse effects have been observed with the use of polymethyl methacrylate bone cements: thrombophlebitis, hemorrhage, trochanteric bursitis.

Other side effects observed: myocardial infarction, short-term cardiac arrhythmia, cerebrovascular event.

Beyond that, complications are possible during any surgical procedure.

There are complications that may occur after vertebroplasty procedures:

- Infiltration of cement into the vertebral canal or adjacent vessels;
- Infection;
- Bleeding;
- Increasing pain in the back;
- Vertebra veya bitişik kaburga kırılması;
- Numbness, tingling in the spine;
- paralysis.
- vasovagal reaction

- Cardiac rhythm changes
- Acute myocardial infarction
- Cardiorespiratory arrest
- Cerebrovascular event
- Pulmonary thromboembolism
- Superficial and deep infection

- Cement leaking into blood vessels
- Bone fragment mobilization during injection
- Cement penetration into the perivertebral space

It can potentially affect the marrow, nerve roots, peritoneal intrathoracic contents, or retroperitoneum.

When applying, the requirements of modern cementing technology should be taken into account in order to limit undesirable side effects and to ensure a strong and long-term anchorage of the bone cement in the vertebral body.

9) SIGNIFICANT INFORMATIONS FOR DOCTORS

Adverse reactions affecting the cardiovascular system have been attributed to leakage of unpolymerized liquid monomer into the circulatory system. Recent data show that the monomer is converted to methacrylic acid by rapid hydrolysis, and a significant portion of the circulating methacrylate is in the form of free acid rather than methyl ester.

No link has yet been established between varying circulating methyl methacrylate/methacrylic acid concentrations and changes in blood pressure. Reported hypotensive episodes were primarily those with high or high normal blood pressure, seen in patients with hypovolemia and pre-existing cardiovascular anomalies. If a hypotensive reaction occurs, this may begin 10-165 seconds after bone cement application. This can take from 30 seconds to 56 minutes.

Although the etiology of cardiac arrest is unclear, it may result directly from embolic effects or from hypoxia induced by a pulmonary embolic event. Clinical experience has shown that meticulous cleaning of the medullary cavity prior to cement placement can significantly reduce fat, bone marrow and air embolism. Placement of liquid cement under pressure into a clean medullary canal has been shown to significantly improve the filling of bone cavities, contributing significantly to the safety of the bone cement interface. Precautions should be taken during continuous application of cement from the distal to the proximal position to prevent lamination in the cement..

10) PREPARATION AND APPLICATION

After mixing the cement powder with the monomer liquid, a fast-setting, formable paste is formed and placed in bone cavities for fixation and/or filling purposes. A dose is prepared when all the cement powder contained in a sachet is mixed with all the monomer liquid in an ampoule. The amount of cement paste required depends on the specific surgical intervention performed and the technique used. Before starting the operation, at least one more dose of bone cement should be available as a spare.

OPENING UNDER STERILE CONDITIONS

Open the outer blister pack from the designated opening under sterile conditions so that the powder pack and the glass ampoule remain sterile when removed. Before opening the powder package, collect the contents by shaking or tapping it lightly, so you will prevent dust loss. To facilitate the opening of the glass ampoule, a predetermined breaking point was created in the neck region between the body and the head of the ampoule.It should not be opened the ampoule on the mixing device to avoid mixing cullet into the cement.

MIXING INGREDIENTS:

The relative ratios of both components, i.e. powder and monomer, are exactly matched. Therefore, the sachet and ampoule must be completely emptied in order to obtain the optimum mixture. Cement components should only be filled into the mixing bowl just

before mixing. Filling and mixing processes should be done under sterile conditions. The entire ampoule is poured into the Pet container with the powder and the mixing process takes place here. Mixing time is 30 seconds. During this time, the two components are mixed with each other by mixing them properly. The result is a composition in the form of a homogeneous dough. This composition is ready to be processed as soon as it becomes non-sticky to the rubber glove. Always mix the entire contents of one sachet with the entire contents of one ampoule of monomer liquid.

Bone cement used in vertebroplasty; can be applied to the spine with an approved delivery system for percutaneous vertebroplasty or kyphoplasty that provides fixed and controlled injection. For the use of the system, the manufacturer's user manual should be consulted. Real-time x-ray control (laterolateral) is required during intravertebral administration. In case of leakage of paravertebral cement, cement injection should be stopped immediately; After the viscosity of the cement has increased, injection can be continued. A separate contralateral access can be applied when vertebral padding is not sufficient. After augmentation, a mandrin should be placed on the injection needle to prevent cement residues from remaining in the soft tissue after the injection needle is removed.

Working and freezing times are dependent on temperature, mixing process and humidity, and particularly the direct ambient temperature, i.e. the temperature of the cement powder, mixing system, table and hands are important. High temperature shortens standby, working and freezing times.

11) MECHANISM OF IMPACT

Bone cement is a space-filling substance formed as a result of polymerization of methyl methacrylate triggered by the combination of prepolymerized solid particles and liquid monomers. Before each application, the user manual of the manufacturer should be read and the paste and freezing times of the cement should be observed. Since cement does not form a chemical bond with the bone and is not an adhesive with its physical properties, it only serves to fill the gaps between the bone and the implant. Among the bone-cement-implant interfaces, cement is the weakest bone interface. The most important feature of cement is that it immediately stabilizes the implant. It provides a definite primary stabilization to the prosthesis; but does not increase secondary biological detection. Since it is a viscoelastic polymer, it provides the transfer of loads reaching the prosthesis to the bone with its elastic modulus close to the bone. Causes less stress shielding on the proximal femur than cementless prostheses. In order for the cement to adhere well to the bone, the bone surface should be clean, its relationship with the cortex should be in a large area, its thickness should be as equal as possible in the metaphysis and medulla, and the cement should be applied with low viscosity and pressure.

In the powder part of the cement, there are PMMA or MMA copolymers containing dibenzoyl peroxide (BPO), which is a reaction initiator. The powder also contains the radiopacifiers zirconium dioxide or barium sulfate. In addition to the powder, antibiotics or dyes can be added. Neither dyestuff, antibiotic, nor radiopacifier play a role in chemical reactions. The initial reaction and free radicals are formed following the interaction of BPO, which is the initiator, in the powder and the activator DMpT in the liquid. By mixing the

powder with the liquid, the powder absorbs the liquid and becomes a sticky, viscous liquid. This pasty structure is formed as a result of a chemical reaction called radical polymerization, and liquid monomers turn into polymers. When two of the increasing polymer chains meet, they combine with each other to form the non-reactive polymer molecule. Therefore, there are no free radicals in the environment. During this exothermic reaction, heat is released. For one hundred grams of MMA, 52 kJ (kilo joules) of heat is generated. Maximum heat generation is between about 60 and 120 °C, although it is affected by the chemical content of the cement, the powder-liquid ratio and the radiopacifier. High heat; Although necrosis causes local circulation disruption and fibrous tissue formation, incomplete polymerization can lead to chemical necrosis. As shown in in vitro studies, if the cement mass is thick, the ambient temperature is high, and the monomer/polymer ratio is increased, more heat is produced as the cement hardens (freezesCollagen is known to be denatured above 56 °C. Ancak in vivo çalışmalarda ısının genelde 50 °C'nin üzerine pek çıkmadığı vurgulanmıştır. The reasons for this include the cooling effect of the local blood flow, the metal handle of the prosthesis dissipates heat, the relatively wide bone-cement interface, and the poor heat conduction of the cement.

11) STORAGE

It should be stored in a dark environment below 25 °C.

It is flammable. Keep away from sources that may cause ignition.

13) SHELF LIFE/STERILITY

Shelf life is determined as 36 months for sterile products.

Shelf life is printed on the folding box, protective aluminum sleeve and inner bag. If the specified date has passed, do not use the product.

Monomer is filled with aseptic filling, then the final product (liquid and powder together) was sterilized by the ethylene oxide method.

The contents of opened or damaged protective aluminum sheaths or ampoule blisters cannot be resterilized and must therefore be discarded.If the cement powder turns yellow, do not use the cement.

13) INSTRUCTION FOR USE

Usage Instruction is located in TD.15.02 -User's Manual section.

14) RAW MATERIALS INFORMATION

Hammaddelere göre standartlar:

Bone Cement;

In the powder mixture; Contains Polymethyl methacrylate, Barium sulfate and Benzoyl Peroxide.

In the liquid mixture; Contains Methyl Methacrylate, N, N dimethyl p-toluidene, Hydroquinone.

Raw materials for all products are specified in the "3) Product Family/Content, Device Size and Content Information" section of this document.

Raw Material Characteristics: MSDS and analysis certificates of the main raw material forming the powder component of Bone Cement were obtained from the supplier company. (ref. CE Technical File Part 5 Production-
Raw Material Information)

14 PRODUCT LABEL AND PACKAGING INFORMATION

The product consists of 2 components: powder and liquid. The powder part is placed in a pet container. The liquid component is presented in a bottle (ampoule). The bottle is packed in blister. Liquid and solid components together become blister packaging and packaging. Finally, another packaging is made outside the blister packaging. So each component is packed 3 times.

- **Label Information**

Ormed bone cement is sent to the end user as sterile. For single use only before expiration date. The product should not be used if the packaging has been compromised or previously opened. All information and warnings about the product are on the product label. (bknz. TD15.01 Label)

Label content;

- Product description
- Referance number
- Lot number
- Production date
- Expiration date
- Manufacturer name
- Manufacturer address
- Notified body number
- Barcode

17) CONTENT INFORMATION

DRUG CONTENT

Bone Cement does not contain drugs.

ANIMAL TISSUE CONTENT

Bone Cement does not contain animal tissue.

CONTENT OF HUMAN BLOOD AND DERIVATIVES

Bone Cement does not contain human blood and derivatives.

17) PERFORMANCE and SAFETY

Product Performance Criteria

Our product performance criteria are determined by market and user requirements. Requirement checks are described in Annex I Basic Requirements of the 93/42/EEC Medical Device Directive and under the heading Harmonized Standards.

Performance tests in the annexes of TS ISO: 5833:2014 were applied to the Bone Cement product. Tests were made on sterile and aged product. Because the aged product is more challenging than the unaged product. Requires testing on aged products, with the possibility of chemical and physical changes in the product or its packaging during the aging period. In addition, since gentamicin added bone cement is a more biologically critical product, the tests were applied to gentamicin added sterile bone cement. The tests performed are given below. Test reports are given in the appendices. The performance criteria determined accordingly are listed below:

Determination of the stability of the liquid component: The flow time (viscosity) of the liquid component is determined before and after accelerated aging by heating.

Determination of the pulping time of the bone cement liquid-powder mixture intended to be used in paste form: The bone cement is mixed and the time taken from the start of mixing until the mixture no longer sticks to the glove is recorded.

Determination of the maximum temperature and setting time for the liquid-powder mixture: When the powder and liquid ingredients are mixed, the exothermic reaction is monitored and the maximum temperature reached by the batch is recorded. The setting time is defined as the time it takes to reach the temperature midway between the ambient temperature and the maximum temperature.

Determination of intrusion of liquid-powder mixture of bone cement intended for use in paste form: The bone cement is compacted into a container with a perforated bottom surface. The length of penetration into the holes is measured after the bone cement has hardened.

Determination of compressive strength of polymerized bone cement

Determination of flexural modulus and flexural strength of polymerized bone cement

Sterile Low Viscosity Bone Cement Test Results						
Test Name	**Standard No**	**Report No**	**Report Date**	**Acceptance Criteria**	**Lab**	**Conclusion-Evaluation**
Liquid Component Flow Time	ISO 5833-EkA	131118-15	27.11.2018	<%10	Aya Validasyon	%8 Suitable.
Doughing The time	ISO 5833-EkB	131118-15	27.11.2018	< 5dk	Aya Validasyon	2min 45sec Suitable.
Hardening The time	ISO 5833-EkC	131118-15	27.11.2018	3-15 dk	Aya Validasyon	4min Suitable.
Maximum Heat	ISO 5833-EkC	131118-15	27.11.2018	85-95℃	Aya Validasyon	91,2℃ Suitable.
intrusion determination	ISO 5833-EkD	131118-15	27.11.2018	> 2mm	Aya Validasyon	4.2mm Suitable.
Pressure Strength	ISO 5833-EkE	131118-15	27.11.2018	> 70MPa	Aya Validasyon	144 MPa Suitable.
Bending strength and Bending module	ISO 5833-EkF	131118-15	27.11.2018	Dayanımı > 50 Modülü> 1800	Aya Validasyon	Strength: 69 MPa Module: 7530 MPa Suitable.
Non-Sterile Low Viscosity Bone Cement Test Results						
Test Name	**Standard No**	**Report No**	**Report Date**	**Acceptance Criteria**	**Lab**	**Conclusion-Evaluation**
Liquid Component Flow Time	ISO 5833-EkA	081118-11	23.11.2018	<%10	Aya Validasyon	%9 Suitable.
Doughing The time	ISO 5833-EkB	081118-11	23.11.2018	< 5min	Aya Validasyon	3 dk Suitable.
Hardening The time	ISO 5833-EkC	081118-11	23.11.2018	3-15 min	Aya Validasyon	5 dk Suitable.
Maximum Heat	ISO 5833-EkC	081118-11	23.11.2018	85-95℃	Aya Validasyon	93,5℃ Suitable.
intrusion determination	ISO 5833-EkD	081118-11	23.11.2018	> 2mm	Aya Validasyon	4.0 mm Suitable.
Pressure Strength	ISO 5833-EkE	081118-11	23.11.2018	> 70MPa	Aya Validasyon	143 MPa Suitable.

Bending strength and Bending module	ISO 5833-EkF	081118-11	23.11.2018	Strength > 50 Module> 1800	Aya Validasyon	Strength: 64 MPa Module>: 8961 MPa Suitable.

Product Safety Criteria

The safety criteria of our product are determined by the market and user requirements. Requirement checks are described in Annex I Basic Requirements of the 93/42/EEC Medical Device Directive and under the heading Harmonized Standards. The performance criteria determined accordingly are listed below:

Criterion	Declaration
Biocompatibility	The product will be biocompatible.
Clean Room Validation	Products must be produced in a clean room.
Sterilization Validation	Products must be sterilized with ethyleneoxide and remain sterile for the life of the product.
Packaging Validation	The products in the package must be sterile and show the required performance.
Wash Validation	Washing validation of the bottle in which the liquid is placed should be done.
Aseptic Filling	Filling of the liquid should be carried out aseptically.
Powder Mixing Validation	It should be verified that the powder is homogeneously mixed.
Bulb Wash Validation	Washing of ampoules should be validated.
Aseptic Filling Validation	Aseptic filling should be validated. The process in which the liquid raw material is filled into the bottle and sealed must be validated.

The table below is based on ISO 10993-1, Evaluation and Testing, version 2018. E markings (E) indicate the testing requirements for biological safety assessment according to ISO 10993-1. There is no difference in production technologies, content amounts, purpose of use and any other issue between Gentamicin-added OGM Antibiotic and non-added. In this sense, OGM Bone Cement with Gentamicin was subjected to biocompatibility tests because it has an extra content and is a more critical sample in biological and mechanical terms according to scientific

Table A.1 — Endpoints to be addressed in a biological risk assessment

Medical device categorization by			Endpoints of biological evaluation														
Nature of Body Contact		Contact Duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (> 30 d)	Physical and/or chemical information	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Material mediated pyrogenicity [a]	Acute systemic toxicity [b]	Subacute toxicity [b]	Subchronic toxicity [b]	Chronic toxicity [b]	Implantation effects [b,c]	Hemocompatibility	Genotoxicity [d]	Carcinogenicity [d]	Reproductive/developmental toxicity [d,e]	Degradation [f]
Surface device	Intact skin	A	X	E	E	E											
		B	X	E	E	E											
		C	X	E	E	E											
	Mucosal membrane	A	X	E	E	E											
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E			
	Breached or compromised surface	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E	E		
External communicating device	Blood path, indirect	A	X	E	E	E	E	E					E				
		B	X	E	E	E	E	E	E				E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
	Tissue/bone/dentin [c]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Circulating blood	A	X	E	E	E	E	E					E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

data.

Table A.1 *(continued)*

Medical device categorization by			Endpoints of biological evaluation														
Nature of Body Contact		Contact Duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (> 30 d)	Physical and/or chemical information	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Material mediated pyrogenicity [a]	Acute systemic toxicity [b]	Subacute toxicity [b]	Subchronic toxicity [b]	Chronic toxicity [b]	Implantation effects [b,c]	Hemocompatibility	Genotoxicity [d]	Carcinogenicity [d]	Reproductive/ developmental toxicity [d,e]	Degradation [f]
Implant device	Tissue/ bone	A	X	E	E	E	E	E				E		E			
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	X	E	E	E	E	E				E	E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

[a] Refer to ISO 10993-11, Annex F.

[b] Information obtained from implantation assessments can be appropriate to address acute systemic toxicity, subacute toxicity, subchronic toxicity and chronic toxicity.

[c] Relevant implantation routes should be considered. For instance devices in contact with intact mucosal membranes should ideally be studied/ considered in contact with intact mucosal membranes.

[d] If the device can contain substances known to be carcinogenic, mutagenic and/or toxic to reproduction, this should be considered in the risk assessment.

[e] Reproductive and developmental toxicity should be addressed for novel materials, materials with a known reproductive or developmental toxicity, devices with relevant target populations (e.g., pregnant women), and/or devices where there is the potential for local presence of device materials in the reproductive organs.

[f] Degradation information should be provided for any devices, device components or materials remaining within the patient, that have the potential for degradation.

[g] X means prerequisite information needed for a risk assessment.

[h] E means endpoints to be evaluated in the risk assessment (either through the use of existing data, additional endpoint-specific testing, or a rationale for why assessment of the endpoint does not require an additional data set). If a device is manufactured from novel materials, not previously used in medical device applications, and no toxicology data exists in the literature, additional endpoints beyond those marked "E" in this table should be considered.

[i] Tissue includes tissue fluids and subcutaneous spaces. For gas pathway devices or components with only indirect tissue contact, see device specific standards for biocompatibility information relevant to these devices.

[j] For all devices used in extracorporeal circuits.

There is no difference in production technologies, content amounts, purpose of use and any other issue between Gentamicin-added OGM Antibiotic and non-added. In this sense, OGM Bone Cement with Gentamicin was subjected to biocompatibility tests because it has an extra content and is a more critical sample in biological and mechanical terms according to scientific data.

Test Name	Standard No	Report Date	Report No	Lab
Cytotoxicity	ISO 10993-5	18.03.2022	KBYU0005/2022-03/BYU/1565	Technical Universal Verification
Sensitization	ISO 10993-10	15.03.2022	KBYU0005/2022-03/BYU/1568	Technical Universal Verification
Intradermal Irritation	ISO 10993-10	01.02.2022	KBYU0005/2022-02/BYU/1557	Technical Universal Verification
Pyrogenicity	European Pharmacoope 9.0 (2.6.8)	04.04.2022	KBYU0005/2022-04/BYU/1575	Technical Universal Verification
Subacute Systemic Toxicity	ISO 10993-11	25.03.2022	KBYU0005/2022-03/BYU/1572	Technical Universal Verification
Acute Systemic Toxicity	ISO 10993-11	09.02.2022	KBYU0005/2022-02/BYU/1558	Technical Universal Verification
Genotoxicity	OECD/OCDE 487	24.03.2022	KBYU0005/2022-03/BYU/1570	Technical Universal Verification

In the Technical Universal Verification, our Gentamicin Added Bone Cement product is given the cytotoxicity test EN ISO 10993-5:2009-10, EN ISO 10993-10:2014 sensitization test, OECD/OCDE 487 genotoxicity test, EN ISO 10993-11:2009 Acute Systemic Toxicity and Subacute Systemic Toxicity tests applied. The evaluations of these tests were made according to EN ISO 10993-1:2018 and it was observed that no cytotoxic compounds were found in the material. The extract of the test material did not reduce cell viability compared to the negative control. According to the LDH (lactatehydrogenase) release test, which measures the integrity of the cell membrane, the material extract does not damage the cell membrane. No skin irritation or skin sensitization was observed after 24, 48 and 72 hours in the test performed on 10 volunteers according to the epicutaneous test. According to the applied Ames test, no genotoxic effect of the product was observed. Accordingly, the product is not expected to have any genotoxic effects.Gerçekleştirilen According to ISO 10993 tests, our products are biocompatible products. (Technical fileChapter 13 TD-13 Biological Assessment Report)

REVISION FOLLOWING PAGE

Revision Date	Revision No	Revision Explanation
07.03.2018	0	First Publishing
04.12.2018	1	Test reports were added.
14.09.2020	2	Informations which are related with Sales amounts, Position in Market and Shelf life were uptaded. Certificate No was added
18.08.2021	3	Sales amounts, purpose of product were uptaded
10.08.2022	4	Sales amounts of 2022 was attached.

PREPARED	APPROVED
	

MANUFACTURER NAME AND ITS ADRESS, THE ADRESS OF MANUFACTORY FIELD AND DESIGNING PLACE

MANUFACTURER:

Ormed Grup Medikal Tur. Sağ. Hiz. San. Ve Tic. Ltd. Şti.

THE ADRESS OF MANUFACTURER:

Macun Mahallesi 177.Cadde No:19 H/7 Yenimahalle/ANKARA

DESIGN, PRODUCTION AND CONTROL:

Macun Mahallesi 177.Cadde No:19 H/7 Yenimahalle/ANKARA

PACKING AND STORING

Macun Mahallesi 177.Cadde No:19 H/7 Yenimahalle/ANKARA

BOTTLE STERILIZATION (ASEPTIC FILLING)

Macun Mahallesi 177.Cadde No:19 H/7 Yenimahalle/ANKARA

PROCESS OF OUR SOURCES- THE LEGAL ENTITY AND ADRESS OF EO STERILIZATION:

AYA Validasyon Ambalaj Sterilizasyon A.Ş.

Fatih Mahallesi 3105 Cad. No:8 Kazan / ANKARA – TÜRKİYE

1) PRODUCT LIST AND GMDN EXPLANATIONS

PRODUCT NAME OGM Bone Cement With Antibiotic

BRANDS OGM

No	Product Name	Ref No	UBB	GMDN
1	OGM1A 20 Standard Viscosity Bone Cement – With Gentamisin	1506/SG	8682024000031	35217
2	OGM3A 20 Low Viscosity Bone Cement – With Gentamisin	1503/LG	8682024000048	35217
3	OGM1A 40 Standard Viscosity Bone Cement – With Gentamisin	1711/SG	8682024000079	35217
4	OGM3A 40 Low Viscosity Bone Cement – With Gentamisin	1810/LG	8682024000086	35217
5	OGM1A 60 Standard Viscosity Bone Cement – With Gentamisin	1071/SG	8682024000116	35217
6	OGM3A 60 Low Viscosity Bone Cement – With Gentamisin	1453/LG	86820240000123	35217

After sales of our products, any negative situation has occured such as; withdrawal of our products, reporting to authority. CE sertificate number: 21 95-M ED -1921 201

2) THE PURPOSE OF PRODUCTS AND THEIR INDICATION:

OGM bone cement with gentamicin is a bone cement which is used in orthopedic surgeries, based on polymethyl methacrylate radiopaque. After the mixing of powder and liquid components, a exothermic polymerization occured then the product become ready to use. It is aimed that the mix which is polymerized before the use should increase catching rate of implants to bone.

Surgical radiqopaque bone cement is indicated placing of prosthesis to living bone in orthopedic muscolosketal surgical procedures for severe joint fragmentation as a result of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, sickle cell anemia, collagen disease, trauma or other conditions and revision of past arthroplasty procedures

Cement is also indicated for fixing pathological fractures where loss of bone material or recalcitrance of the fracture renders more traditional procedures ineffective. Together with

adjecting antibiotic to bone cement, local oscillation is gained and it is recoverer in prosthesis surgeries which contains infection.The features of gentamicin which in bone cement with antibiotic;

(i) wide antibacterial spectrum,
(ii) (ii) well bactericidal effect in low concentration,
(iii) (iii) low resistence occurence,
(iv) (iv) low rate of bonding in proteins,
(v) (v) low allergic potential,
(vi) (vi) kemik çimentosu mekaniğine etkisiz olması ya da etkisinin önemsiz –being low effectiveness to bone cement or ineffectivenes,
(vii) vii being resistent to thermal or chemical factors,
(viii) (viii) solubility in water,
(ix) (ix)Good oscillation in bone cement

3) PRODUCT FAMILY/CONTENT DEVICE SIZE AND CONTENT INFORMATION

Standard Viscosity With Gentamicin

Name of the product	Reference No	Barcode
OGM1A 20 Standard Viscosity Bone Cement With Gentamisin (1x20 g)	1506/SG	8682024000031
Powder Component Content	**Amount**	**raw material**
Polymethyl methacrylate	17,80 g	
Benzoyl Peroxide	0,2 g	
Barium Sulphate	2 g	Barium Sulfate
Gentamicin Sulfate	0,5 g	Gentamicin Sulfate Ph.Eur.9.0
Total Powder Amount	**20,5 g ± 1 g**	
Liquid Component Content	**Amount**	**raw material**
Methyl Methacrylate	9,8 ml	
N,N dimethyl p-toluidene	0,2 ml	
Hydroquinone	Trace amount (50 ppm)	
Total amount of liquid	**10 ml ± 0,5 ml**	

Name of the product	Reference No	Barcode
OGM1A 40 Standard Viscosity Bone Cement – With Gentamisin (1x40 g)	1711/SG	8682024000079
Powder Component Content	**Amount**	**raw material**
Polymethyl methacrylate	35,60 g	
Benzoyl Peroxide	0,4 g	
Barium Sulphate	4 g	Barium Sulfate
Gentamicin Sulfate	1 g	Gentamicin Sulfate Ph.Eur.9.0
Total Powder Amount	**41 g ± 2 g**	
Liquid Component Content	**Amount**	**raw material**
Methyl Methacrylate	19,6 ml	
N,N dimethyl p-toluidene	0,4 ml	
Hydroquinone	Trace amount (50 ppm)	
Total amount of liquid	**20 ml ± 1 ml**	

Name of the product	Reference No	Barcode
OGM1A 60 Standard Viscosity Bone Cement – With Gentamisin (1x60 g)	1071/SG	8682024000116
Powder Component Content	**Amount**	**raw material**
Polymethyl methacrylate	53,4 g	
Benzoyl Peroxide	0,6 g	
Barium Sulphate	6 g	Barium Sulfate
Gentamicin Sulfate	1,5 g	Gentamicin Sulfate Ph.Eur.9.0
Total Powder Amount	**61,5 g ± 3 g**	
Liquid Component Content	**Amount**	**raw material**
Methyl Methacrylate	29,4 ml	
N,N dimethyl p-toluidene	0,6 ml	
Hydroquinone	Trace amount (50 ppm)	
Total amount of liquid	**30 ml ± 1,5 ml**	

ORMED GRUP MEDİKAL TUR.SAĞ.HİZ.SAN.VE TİC.LTD.ŞTİ	**PRODUCTION DESCRIPTION** **Bone cement with antibiotic**	Document no: TD.02-03 Publishent Date: 07.03.2018 Revision No: 04 Revision Date: 10.08.2022

Low Viscosity With Gentamisin

Name of the product	Reference No	Barcode
OGM3A 20 Low Viscosity Bone Cement With Gentamisin (1x20 g)	1503/LG	8682024000048
Powder Component Content	**Amount**	**raw material**
Polymethyl methacrylate	17,80 g	
Benzoyl Peroxide	0,2 g	
Barium Sulphate	2 g	Barium Sulfate
Gentamicin Sulfate	0,5 g	Gentamisin Sülfat Ph.Eur.9.0
Toplam Toz Miktarı	**20,5 g ± 1 g**	
Liquid Component Content	**Amount**	**raw material**
Methyl Methacrylate	9,8 ml	
N,N dimethyl p-toluidene	0,2 ml	
Hydroquinone	Trace amount (50 ppm)	
Total amount of liquid	**10 ml ± 0,5 ml**	

Name of the product	Reference No	Barcode
OGM3A 40 Low Viscosity Bone Cement With Gentamisin Antibiyotikli (1x40 g)	1810/LG	8682024000086
Powder Component Content	**Amount**	**raw material**
Polymethyl methacrylate	35,60 g	
Benzoyl Peroxide	0,4 g	
Barium Sulphate	4 g	Barium Sulfate
Gentamicin Sulfate	1 g	Gentamisin Sülfat Ph.Eur.9.0
Toplam Toz Miktarı	**41 g ± 2 g**	
Liquid Component Content	**Amount**	**raw material**
Methyl Methacrylate	19,6 ml	
N,N dimethyl p-toluidene	0,4 ml	
Hydroquinone	Trace amount (50 ppm)	
Total amount of liquid	**20 ml ± 1 ml**	

Name of the product	Reference No	Barcode
OGM3A 60 Low Viscosity Bone Cement With Gentamisin (1x60 g)	1453/LG	86820240000123
Powder Component Content	**Amount**	**raw material**
Polymethyl methacrylate	53,4 g	
Benzoyl Peroxide	0,6 g	
Barium Sulphate	6 g	Barium Sulfate
Gentamicin Sulfate	1,5 g	Gentamisin Sülfat Ph.Eur.9.0
Toplam Toz Miktarı	**61,5 g ± 3 g**	
Liquid Component Content	**Amount**	**raw material**
Methyl Methacrylate	29,4 ml	
N,N dimethyl p-toluidene	0,6 ml	
Hydroquinone	Trace amount (50 ppm)	
Total amount of liquid	**30 ml ± 1,5 ml**	

Standards by raw materials:

Bone cement with antibiotic;

In the powder mixture; There are Polymethyl methacrylate, Barium sulfate, Benzoyl Peroxide and Gentamicin. There are polymethyl metacrylat, barium sulphate benzoyl peroxide and gentamicin in powder

In the liquid mixture; There are Methyl Methacrylate, N, N dimethyl p-toluidene, Hydoquinone.There are mehyl methacrylat, N N dimethyl p-tolyden, hydroquinone in liquid

The effect of powder to product

polymethyl metacrylat: It is main component of bone cement, after the reaction process, it become solid and it provides placing of implant to body

benzoyl peroxide: It provides inititation in reaction

barium sulphate: Ortopedik çimentoya radyo-opasite özelliği verir. (It provides feature of radio opacity to orthopedic bone cement

Gentamicin: Antibiotic

THE EFFECT OF LIQUID TO THE PRODUCT:

Methyl metacrylat: When react in polymethly metacrylat, polymerization occured

N,N dimetil p-toluiden : It make easier of bone cement's cold recovery

Hidrokinon : Under some conditions like exposing high temperature, it prevents early polymerization

4) PATIENT POPULATION

Bone cement with antibiotic can not be used in bone area and it can not ne used in patients who have strains which are insenstive to gentamicin and it can not be used in patients who have infection which is not recovered yet.

5 CLASSIFICATION

No	Name	Rule	Class	Ref No	UBB	GMDN
Bone Cement						
1	OGM1A 20 Standard Viscosity Bone Cement – With Gentamisin	2017/745 MDR Added 8 Rule **8**	III	1506/SG	8682024000031	35217
2	OGM3A 20 Low Viscosity Bone Cement – With Gentamisin	2017/745 MDR Added 8 Rule **8**	III	1503/LG	8682024000048	
3	OGM1A 40 Standard Viscosity Bone Cement – With Gentamisin	2017/745 MDR Added 8 Rule **8**	III	1711/SG	8682024000079	
4	OGM3A 40 Low Viscosity Bone Cement – With Gentamisin	2017/745 MDR Added 8 Rule **8**	III	1810/LG	8682024000086	
5	OGM1A 60 Standard Viscosity Bone Cement – With Gentamisin	2017/745 MDR Added 8 Rule **8**	III	1071/SG	8682024000116	
6	OGM3A 60 Low Viscosity Bone Cement – With Gentamisin	2017/745 MDR Added 8 Rule **8**	III	1453/LG	86820240000123	

Applicable Description	All medical devices that, when used separately, contain a substance that is considered a medicinal product in accordance with the Regulation on the Registrar of Medicinal Products for Human Use and that supports the effect of the medical device on humans, are classified as Class III.
The Explanation of GMDN CODE	35217 - A substance made from methylmethacrylate, polymethylmethacrylate, methacrylic acid esters or copolymers containing polymethylmethacrylate (PMMA) and polystyrene, used in arthroplastic treatments of joints to fix polymer or metal prosthetic implants to living bone. It can also be used as a filler in case of bone pathologies. The tool may contain an antibiotic.
Convenience Evaluation (Bone cement with antibiotic)	2017/745 MDR Medical Device Regulation Attachment 8 Rule **8**

-USERS WHO ARE AIMED

It is designed for using of medical staf

-NUMBER OF USING

Single use.

6) CONTRADICTIONS OF PRODUCT

the use of the product is contraindicated in case of infectious arthritis and active infection of the joint or joints to be replaced, or in the presence of a history of such infection. The use of the product is also contraindicated where a lack of musculature or neuromuscular alignment in the affected limb would render the procedure inappropriate.

It can be not be used if there is active or undertreated infection which is stem from insensitive strains to gentamicin

7) WARNINGS AND PRECAUTIONS

Before the using of bone cement, user should be aware about its features, processing, implementation. It is recommended that user should completely practise mixing, processing and placing procedures before the first time using.

It should be cautious that while liquid and powder are mixing, the all componenets in bottle and bag ought to be used. Datas from in vitro studires shows that the loss of monomer firstly depend on frequency of mixing and secondly, it depends on the duration of mixing.

However, precaution should be taken; not to knead the product for too long to prevent the polymerization process from progressing to the point where the cement loses sufficient softness and flexibility to fill the bone cavities and fix it to the prosthesis. After the application, during the completion of the in polymerization of the product, the position of the prosthesis must be kept fixed without moving it to ensure correct fixation. situ In situ completion of polymerization operates in the patient and it is exothermic reaction which significant amount is released. It is reported that the temperature reached to 110 cantigrat during polymerization. The long term effects of the generated and the resulting tissue damage are not known. Special precautions should be taken to detect and recover the temporary decrease in blood pressure that may occur when the product is implanted in the bone.

The sufficient air conditioning should be provided to annihilate maximum monomer steam in operating rooms because liquid monomer has a high volatility and flammability feature. Precaution should be taken when mixing the two compnenets to avoid excessive exposure to concentrated monomer vapors which may may cause irritation to the respiratory tract, eyes and possbily the liver. The liquid component is a strong lipid solvent. It caused contact dermatitis in susceptible individuals. Wearing a second pair of surgical gloves and following strict mixing instructions can reduce the possibility of hypersensitivity reactions. The compound should not be allowed to come into direct contact with sensitive tissues or be absorbed by the body. Soft contact lens manufacturers recommend removing such lenses "in environments where hazardous and irritating vapors are present.". Soft contact lenses are highly permeable and should not be used in the operating room while mixing Methyl methacrylate. Due to the lack of sufficient information, the use of the product in young patients is not recommended. Use in pregnancy: Although the results of teratology studies in animals are negative, the benefits need to be considered compareatively against the potential hazards to the mother or foetus for use by women who are pregnant or likely to become pregnant. Data from clinical trials have shown that strict adherence to effective surgical principles and techniques is an absolute necessity. Deep wound infection is a serious post-operative complication and it may require complete removal of the prosthesis and placed cement. Deep wound infection may be hiden and it may not be show itself for several years after surgery.

INFORMATIONS FOR PATIENTS

- Surgeons should inform patients about the limitations of reconstruction and the need to protect the implant from full weight carrying until adequate healing is achieved.
- Surgeons should inform patients that the product has a limited service life and it may need to be replaced in the future.
- Surgeons should warn the patient of surgical risks and potential adverse effects.
- • Dental procedures, endoscopic examinations, and other minor surgical procedures have been associated with transient bacteremia. Instruct the patient to inform their doctor that they are carrying an artificial hip replacement so that their doctor can decide whether to use antibiotic prophylaxis for such procedures.

8) SIDE EFFECTS

Transient blood pressure decreasing are infrequently seen following prosthetic operationing preparation or immediately after implantation of endoprostheses with PMMA bone cements. In individual cases, serious complications such as severe allergic reactions such as cardiac arrest, anaphylactic shock or even sudden death may occur. In order to avoid pulmonary and cardiovascular complications such as pulmonary embolism and cardiac

arrest, it is recommended to thoroughly wash the implantation site with isotonic solution (pulse lavage application) before placing the bone cement. In the case of pulmonary or cardiovascular occurence, the blood volume should be followed and if increasing blood volume requires, enhancement in blood volume should be operated. Anesthesiological measures should be taken in cases of acute respiratory failure.

The following adverse effects have been observed with the use of polymethyl methacrylate bone cements: thrombophlebitis, hemorrhage, trochanteric bursitis.

Other side effects observed: myocardial infarction, short-term cardiac arrhythmia, cerebrovascular situation. Beyond that, complications are possible during any surgical procedure.

The requirements of modern cementing technology must be taken into account in order to limit undesirable side effects and to ensure a firm and long-term anchorage of the bone cement in the vertebral body.

9) SIGNIFICANT INFORMATIONS FOR DOCTORS

Adverse reactions affecting the cardiovascular system have been attributed to leakage of unpolymerized liquid monomer into the circulatory system. Recent data show that the monomer is converted to methacrylic acid by rapid hydrolysis, and a significant portion of the circulating methacrylate is in the form of free acid rather than methyl ester.

No link has yet been established between varying circulating methyl methacrylate/methacrylic acid concentrations and changes in blood pressure. Reported hypotensive episodes occur primarily in patients with high or high normal blood pressure, hypovolemia, and pre-existing cardiovascular abnormalities. If a hypotensive reaction occurs, this may begin 10-165 seconds after bone cement operation This can take from 30 seconds to 56 minutes.

Although the etiology of cardiac arrest is unclear, it may be due to direct embolic effects or hypoxia induced by a pulmonary embolic event. Clinical experience has shown that meticulous cleaning of the medullary cavity prior to cement placement can significantly reduce fat, bone marrow and air embolism. Placement of liquid cement under pressure into a clean medullary canal has been shown to significantly improve the filling of bone cavities by contributing significantly to the safety of the bone cement interface. Precaution must be taken during continuous application of cement from the distal to the proximal position to prevent lamination in the cement.10)

PREPARATION AND OPERATION

After mixing the cement powder with the monomer liquid, a fast-setting, formable paste is formed and placed in bone cavities for fixation and/or filling purposes. A dose is prepared

when all the cement powder contained in a sachet is mixed with all the monomer liquid in an ampoule. The amount of cement paste required depends on the specific surgical operation and it also depends on performed technique which is used. Before starting the operation, at least one more dose of bone cement should be available as a backup.

OPENING UNDER STERILE CONDITIONS

It must be opened to the outer blister pack from the designated opening under sterile conditions so that the powder pack and the glass ampoule remain sterile when removed. Before opening the powder package, collect the contents by shaking or tapping it lightly, so you will prevent powder lossTo facilitate the opening of the glass ampoule, a predetermined breaking point was created in the neck region between the body and the head of the ampoule. Do not open the ampoule on the mixing device to avoid mixing cullet into the cement.

MIXING OF COMPONENTS:

The relative ratios of both components, i.e. powder and monomer, are exactly matched. Therefore, the sachet and ampoule must be completely emptied in order to obtain the optimum mixture. Cement components should only be filled into the mixing bowl just before mixing. Filling and mixing processes should be done under sterile conditions. The entire ampoule is poured into the Pet container with the powder and the mixing process is conducted here. The time of mixing is 30 seconds. During this time, the two components are mixed with each other by mixing them properly. The result is a composition in the form of a homogeneous paste. This composition is ready to be processed as soon as it becomes non-sticky to the rubber glove. Always mix the entire contents of one sachet with the entire contents of one ampoule of monomer liquid.

Working and freezing times are dependent on temperature, mixing process and humidity, and particularly the direct ambient temperature, i.e. the temperature of the cement powder, the temperature of mixing syste and temperature of table and hands are important. High temperature shortens standby, working and freezing times.

11) MECHANISM OF EFFECT

Bone cement is a space-filling substance formed as a result of polymerization of methyl methacrylate triggered by the combination of prepolymerized solid particles and liquid monomers. Before each application, the user manual of the manufacturer should be read and the paste and freezing times of the cement should be observed. Since cement does not form a chemical bond with the bone and becaue of it is not an adhesive with its physical properties, it only serves to fill the gaps between the bone and the implant. Among the bone-cement-implant interfaces, cement is the weakest bone interface. The most important

feature of cement is that it immediately stabilizes the implant. It provides a definite primary stabilization to the prosthesis; but it does not increase secondary biological detection. As it is a viscoelastic polymer, it provides the transfer of loads reaching the prosthesis to the bone with its elastic modulus close to the bone. It causes less stress shielding on the proximal femur than cementless prostheses. In order for the cement to adhere well to the bone, the bone surface should be clean and its relationship with the cortex should be in a large area. The thickness of the metaphysis and medulla should be as equal as possible, Cement needs to be applied with low viscosity and pressure. [13].

In the powder part of the cement, there are PMMA or MMA copolymers containing dibenzoyl peroxide (BPO), which is a reaction initiator. The powder also contains the radiopacifiers zirconium dioxide or barium sulfate. In addition to the powder, antibiotics or dyes can be added to powder. Neither dyestuff, antibiotic, nor radiopacifier play a role in chemical reactions. The initial reaction and free radicals are formed following the interaction of BPO, which is the initiator, in the powder and the activator DMpT in the liquid. By mixing the powder with the liquid, the powder absorbs the liquid and becomes a sticky, viscous liquid. This pasty structure is formed as a result of a chemical reaction called radical polymerization, and liquid monomers turn into polymers. When two of the increasing polymer chains meet, they combine with each other to form the non-reactive polymer molecule. Therefore, there are no free radicals in the environment. During this exothermic reaction, heat is released. For one hundred grams of MMA, 52 kJ (kilo joules) of heat is generated. Maximum heat generation is between about 60 and 120 °C, although it is affected by the chemical content of the cement, the powder-liquid ratio and the radiopacifier. high heat; necrosis not only causes local circulation disruption and fibrous tissue formation but also incomplete polymerization can lead to chemical necrosis. As shown in in vitro studies, if the cement structure is thick, the room temperature is high, and the monomer/polymer ratio is increased, more heat is produced while the cement hardens (freezes). Collagen is known to be denatured above 56 °C. However, in vivo studies have emphasized that the temperature does not usually rise above 50 °C. The reasons for this include the cooling effect of the local blood flow, the metal handle of the prosthesis spreads heat, being relatively wide bone-cement interface, and the poor heat conduction of the cement. [14].

Gentamicin, which is in the class of aminoglycosides, is a fast bactericidal drug that passes through the bacterial cell membrane with active transport. They are ineffective on anaerobic bacteria as they use active transport. Because active transport requires oxygen. The aminoglycoside entering the bacterial cell causes the genetic code to be misread and disrupts protein synthesis. Concomitant use with cell wall synthesis inhibitor antibiotics (such as beta-lactams, vancomycin) increases their effects. [3].

12) STORING

It should be stored in a dark environment below 25 °C.

It is flamable. It should keep away from sources that may cause ignition.

13) SHELF LİFE/STERILITY

Shelf life is determined as 36 months for sterile products.

Shelf life is printed on the folding box, protective aluminum sleeve and inner bag. If the specified date has passed, do not use the product.

The monomer is filled with aseptic filling, after which the final product (liquid and powder together) is sterilized by the ethylene oxide method.

The monomer is filled with aseptic filling, after which the final product (liquid and powder together) is sterilized by the ethylene oxide methodIf the cement powder turns yellow, do not use the cement.

14) IFU

It can be found in the box of product

13) RAW MATERIAL INFORMATION

<u>Standards as raw materials:</u>

Bone cement with antibiotic;

In the powder mixture; There are Polymethyl methacrylate, Barium sulfate and Benzoyl Peroxide and Gentemicin.

In the liquid mixture; Contains Methyl Methacrylate, N, N dimethyl p-toluidene, Hydoquinone.

Raw materials for all products are specified in the "3) Product Family/Content, Product Size and Content Information" section of this document.

14) PRODUCT LABEL AND PACKAGING INFORMATION

The product consists of 2 components, powder and liquid. The powder part is placed in a pet bagThe liquid component is presented in a bottle (ampoule). The bottle is packed in blister. Liquid and solid components should package with together by using blister. Finally, another packaging is made outside the blister packaging. Thus, each component is packaged 3 times.

- **Label information**

Ormed sends the antibiotic bone cement product to the current user as sterile. It is only for single use only before expiration date. The product should not be used if the packaging has been compromised or previously opened. All information and warnings about the product are on the product label.

Informations which is included in label ;

-Production description

-Referans number

-Lot number

-Production date

-Expiry date

-Manufacturer name

-Manufacturer adress

-The number of approved institution

-Barcode

17) Content Knowledge

DRUG INFORMATION

It includes bone cement with antibiotic.

ANIMAL TISSUE CONTENT

Bone cement with antibiotic does not include animal tissue.

CONTENT OF HUMAN BLOOD AND DERIVATIVES

Bone cement with antibiotic does not include content of human blood and derivatives

18) PERFORMANCE AND SECURITY

Product Performance Criteria

Our product performance criteria are determined by market and user requirements. Requirement checks are in the 93/42/EEC Medical Device Directive Annex I Essential Requirements section and Described under the heading Harmonized Standards.

Performance tests in the annexes of TS ISO 5833:2014 were applied to the Antibiotic Bone Cement product. Tests were made on sterile and aged product. Because the aged product is more challenging than the unaged product. Requires tests to be performed on aged products, with the possibility of some chemical and physical changes in the product or its packaging during the aging period. In addition, since gentamicin-added bone cement is a more biologically critical product, the tests were applied to gentamicin-added sterile and aged bone cement. The tests performed are given below. Test reports are given in the appendices.

The performance criteria determined accordingly are as follows:

Determination of the stability of the liquid component: The flow time (viscosity) of the liquid component is determined before and after accelerated aging by heating.

Determination of the pulping time of the bone cement liquid-powder mixture intended to be used in paste form: The bone cement is mixed and the time taken from the start of mixing until the mixture becomes non-glove sticky is recorded.

Determination of the maximum temperature and setting time for the liquid-powder mixture edilmesi: When the powder and liquid ingredients are mixed, the exothermic reaction is monitored and the maximum temperature reached by the batch is recorded. The hardening time is defined as the time it takes to reach the temperature between room temperature and maximum temperature.

Determination of intrusion of liquid-powder mixture of bone cement intended for use in paste form: The bone cement is compacted into a container with a perforated bottom surface. After the bone cement has hardened, the length of penetration into the holes is measured.

Determination of flexural modulus and flexural strength of polymerized bone cement

Standard Viscosity Gentamicin Bone Cement Test Results						
Test Name	**Standard No**	**Report No**	**Report Date**	**Acceptance criteria**	**Laboratory**	**Conclusion-Evaluation**
Liquid Component Fluidity Time	ISO 5833-EkA	131118-10	27.11.2018	<%10	Aya Validasyon	%6,9 Appropriate.
Pasting Time	ISO 5833-EkB	131118-10	27.11.2018	< 5min	Aya Validasyon	3min Appropriate.
Hardening Time	ISO 5833-EkC	131118-10	27.11.2018	3-15 min	Aya Validasyon	4min Apprpriate.

Maximum Temperature	ISO 5833-EkC	131118-10	27.11.2018	85-95℃	Aya Validasyon	90,6℃ Appropriate.
Intrusion Determination	ISO 5833-EkD	131118-10	27.11.2018	> 2mm	Aya Validasyon	3,8mm Appropriate.
Compression Strenght	ISO 5833-EkE	131118-10	27.11.2018	> 70MPa	Aya Validasyon	143 MPa Appropriate.
Bending strength and Bending module	ISO 5833-EkF	131118-10	27.11.2018	Strength > 50 Module> 1800	Aya Validasyon	Strength:55,78 MPa Module: 4091 MPa Appropriate.

Low Viscosity Gentamicin Bone Cement Test Results

Test Name	Standard No	Report No	Report Date	Acceptance criteria	Laboratory	Conclusion-Evaluation
Liquid Component Fluidity Time	ISO 5833-EkA	131118-13	27.11.2018	<%10	Aya Validasyon	%9,6 Appropriate.
Pasting Time	ISO 5833-EkB	131118-13	27.11.2018	< 5dk	Aya Validasyon	3min Appropriate.
Hardening Time	ISO 5833-EkC	131118-13	27.11.2018	3-15 dk	Aya Validasyon	4min Appropriate
Maximum Temperature	ISO 5833-EkC	131118-13	27.11.2018	85-95℃	Aya Validasyon	92,9℃ Appropriate.
Intrusion Determination	ISO 5833-EkD	131118-13	27.11.2018	> 2mm	Aya Validasyon	4,0 mm Appropriate.
Compression Strenght	ISO 5833-EkE	131118-13	27.11.2018	> 70MPa	Aya Validasyon	143 MPa Appropriate.
Bending strength and Bending module	ISO 5833-EkF	131118-13	27.11.2018	Strength > 50 Module> 1800	Aya Validasyon	Stregth:66,11 MPa Module: 4937 MPa Appropriate.

Product Safety Criteria

The safety criteria of our product are determined by the market and user requirements. Requirement checks are described in Annex I Basic Requirements of the 93/42/EEC Medical Device Directive and under the heading Harmonized Standards. The performance criteria determined accordingly are listed below.

Criteria	Declaration
Biocompatibility	The product will be biocompatible.
Clean Room Validation	Products must be produced in a clean room.
Sterilization Validation	Products must be sterilized with ethyleneoxide and remain sterile for the life of the product.
Packaging Validation	The products in the package must be sterile and show the required performance.
Flushing Validation	Washing validation of the bottle in which the liquid is placed should be done.
Aseptic Filling	Filling of the liquid should be carried out aseptically.
Powder Mixing Validation	It should be verified that the powder is homogeneously mixed.
Bulb Flushing Validation	Flushing of bulbs must be validated.
Aseptic Filling Validation	Aseptic filling must be validated. Process in which the liquid raw material is filled into the bottle and capped must be validated.

The table below is prepared which is based on ISO 10993-1 and Evaluation and Testing version 2009The E markings (E) indicate the testing requirements for biological safety assessment according to ISO 10993-1 There is no difference in production technologies, content amounts, purpose of use and any other issue between Gentamicin-added OGM

Table A.1 — Endpoints to be addressed in a biological risk assessment

Medical device categorization by			Endpoints of biological evaluation														
Nature of Body Contact		Contact Duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (> 30 d)	Physical and/or chemical information	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Material mediated pyrogenicity [a]	Acute systemic toxicity [b]	Subacute toxicity [b]	Subchronic toxicity [b]	Chronic toxicity [b]	Implantation effects [b,c]	Hemocompatibility	Genotoxicity [d]	Carcinogenicity [d]	Reproductive/ developmental toxicity [d,e]	Degradation [f]
Surface device	Intact skin	A	X [g]	E [h]	E	E											
		B	X	E	E	E											
		C	X	E	E	E											
	Mucosal membrane	A	X	E	E	E											
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E			
	Breached or compromised surface	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E	E		
External communicating device	Blood path, indirect	A	X	E	E	E	E	E					E				
		B	X	E	E	E	E	E	E				E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
	Tissue/ bone/ dentin [i]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Circulating blood	A	X	E	E	E	E	E					E	E [j]			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

Table A.1 *(continued)*

Medical device categorization by			Endpoints of biological evaluation														
Nature of Body Contact		Contact Duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (> 30 d)	Physical and/or chemical information	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Material mediated pyrogenicity [a]	Acute systemic toxicity [b]	Subacute toxicity [b]	Subchronic toxicity [b]	Chronic toxicity [b]	Implantation effects [b,c]	Hemocompatibility	Genotoxicity [d]	Carcinogenicity [d]	Reproductive/ developmental toxicity [d,e]	Degradation [f]
Implant device	Tissue/ bone	A	X	E	E	E	E	E				E		E			
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	X	E	E	E	E	E				E	E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

[a] Refer to ISO 10993-11, Annex F.

[b] Information obtained from implantation assessments can be appropriate to address acute systemic toxicity, subacute toxicity, subchronic toxicity and chronic toxicity.

[c] Relevant implantation routes should be considered. For instance devices in contact with intact mucosal membranes should ideally be studied/ considered in contact with intact mucosal membranes.

[d] If the device can contain substances known to be carcinogenic, mutagenic and/or toxic to reproduction, this should be considered in the risk assessment.

[e] Reproductive and developmental toxicity should be addressed for novel materials, materials with a known reproductive or developmental toxicity, devices with relevant target populations (e.g., pregnant women), and/or devices where there is the potential for local presence of device materials in the reproductive organs.

[f] Degradation information should be provided for any devices, device components or materials remaining within the patient, that have the potential for degradation.

[g] X means prerequisite information needed for a risk assessment.

[h] E means endpoints to be evaluated in the risk assessment (either through the use of existing data, additional endpoint-specific testing, or a rationale for why assessment of the endpoint does not require an additional data set). If a device is manufactured from novel materials, not previously used in medical device applications, and no toxicology data exists in the literature, additional endpoints beyond those marked "E" in this table should be considered.

[i] Tissue includes tissue fluids and subcutaneous spaces. For gas pathway devices or components with only indirect tissue contact, see device specific standards for biocompatibility information relevant to these devices.

[j] For all devices used in extracorporeal circuits.

Antibiotic and non-added. In this sense, OGM Bone Cement with Gentamicin was subjected

to biocompatibility tests because it has an extra content and is a more critical sample in biological and mechanical terms according to scientific data.

In the Technical Universal Verification, our Gentamicin Added Bone Cement product is given the cytotoxicity test EN ISO 10993-5:2009-10, EN ISO 10993-10:2014 sensitization test, OECD/OCDE 487 genotoxicity test, EN ISO 10993-11:2009 Acute Systemic Toxicity and

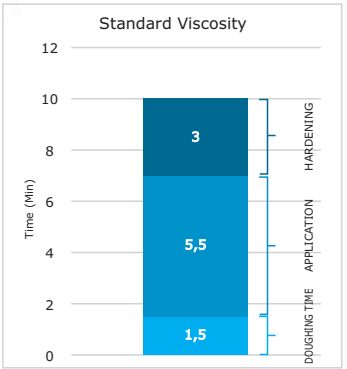
Test Name	Standard No	Report Date	Report No	laboratory
Cytotoxicity	ISO 10993-5	18.03.2022	KBYU0005/2022-03/BYU/1565	Technical Universal Verification
Sensitization	ISO 10993-10	15.03.2022	KBYU0005/2022-03/BYU/1568	Technical Universal Verification
Intradermal Irritation	ISO 10993-10	01.02.2022	KBYU0005/2022-02/BYU/1557	Technical Universal Verification
Pyrogenicity	European Pharmacoope 9.0 (2.6.8)	04.04.2022	KBYU0005/2022-04/BYU/1575	Technical Universal Verification
Subacute Systemic Toxicity	ISO 10993-11	25.03.2022	KBYU0005/2022-03/BYU/1572	Technical Universal Verification
Acute Systemic Toxicity	ISO 10993-11	09.02.2022	KBYU0005/2022-02/BYU/1558	Technical Universal Verification
Genotoxicity	OECD/OCDE 487	24.03.2022	KBYU0005/2022-03/BYU/1570	Technical Universal Verification

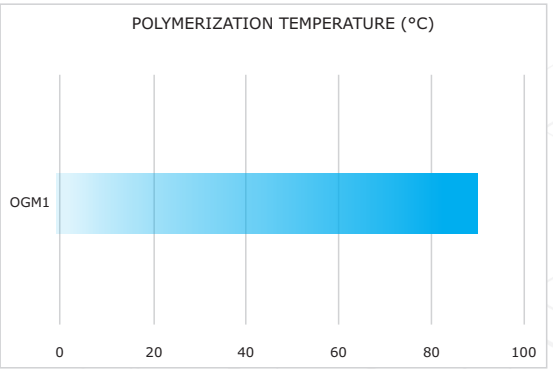
Subacute Systemic toxicity tests were applied. The evaluations of these tests were made according to EN ISO 10993-1:2018 and it was observed that no cytotoxic compounds were found in the material. Extract of test material did not reduce cell viability relative to negative control. According to the LDH (lactatehydrogenase) release test, which measures the integrity of the cell membrane, the material extract does not damage the cell membrane. According to the epicutaneous test, no skin irritation or skin sensitization was observed after 24, 48 and 72 hours in the test performed on 10 volunteers. According to the applied Ames test, no genotoxic effect of the product was observed. Accordingly, the product is not expected to have any genotoxic effects. Our products are biocompatible according to the ISO 10993 tests carried out. (Technical document Chapter 13 TD03-13 Biological Assessment Report)

OGM1 BONE CEMENT
Standard Viscosity

OGM Bone cement is a polymethylmethacrylate based radiopaque acrylic bone cement used in orthopedic surgeries. Surgical Radiopaque Bone Cement is indicated for anchoring the prosthesis to living bone in orthopedic musculoskeletal surgical procedures for osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, sickle cell anemia, collagen disease, severe joint disruption resulting from trauma or other conditions, and revision of past arthroplasty procedures. OGM Bone Cement has two types of viscosity: low and standard. OGM1 Bone Cement has standard viscosity.

REF NO	PRODUCT	QUANTITY
1012/S	OGM1 20 Standard Viscosity Bone Cement	20 gr
1201/S	OGM1 40 Standard Viscosity Bone Cement	40 gr
1881/S	OGM1 60 Standard Viscosity Bone Cement	60 gr



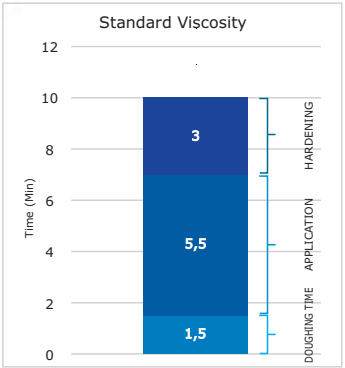


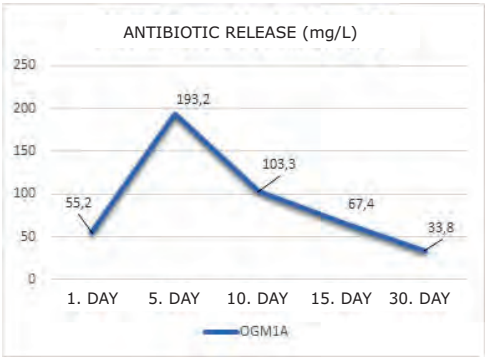
ISO 13485:2016 CE 2195 FDA ISO 5833

OGM1A BONE CEMENT WITH ANTIBIOTIC
Standard Viscosity

By adding antibiotics to bone cement, local release of antibiotics is achieved and is a recoverer, especially in prosthetic surgeries with infections. Properties of Gentamicin in OGM Antibiotic Bone Cement; Broad antibacterial spectrum, good bactericidal effect at low concentrations, low resistance development, low protein binding rate, low allergic potential, ineffective or insignificant effect on bone cement-water mechanics, resistant to chemical and thermal factors, good water solubility, bone It has good release from cement.

REF NO	PRODUCT	QUANTITY
1506/SG	OGM1A 20 Bone Cement Standard Viscosity With Antibiotics	20 gr
1711/SG	OGM1A 40 Bone Cement Standard Viscosity With Antibiotics	40 gr
1071/SG	OGM1A 60 Bone Cement Standard Viscosity With Antibiotics	60 gr





ISO 13485:2016 CE 2195 FDA ISO 5833

Specificații de preț

[Acest tabel va fi completat de către ofertant în coloanele 5,6,7,8, iar de către autoritatea contractantă – în coloanele 1,2,3,4,9]

Numărul licitației:	LP nr. ocds-b3wdp1-MD-1737734481286	Data: „07" 02 2025	Alternativa nr.: _____
Denumirea licitației:	În scopul atribuirii contractelor subsecvente ca urmare a acordului-cadru (nr. ocds...30646 din 14.01.2025) încheiat prin procedura de achiziție publică ocds-b3wdp1-MD-1718205130646 din 12.06.2024 privind încheierea acordului-cadru - Achiziționarea endoprotezelor pentru anii 2025-2027	Lot: _____	Pagina: __din __

Cod CPV	Nr. Lot	Denumire Lot	Denumirea poziției	Unitatea de măsură	cantitatea	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare/prestare	Valoarea estimativă fără TVA
1	2			3	4	5	6	7	8	9	
33100000-1	8	Ciment ortopedic fără antibiotic	Ciment ortopedic fără antibiotic	bucată	15	403,36	435,6288	6050,40	6534,43	DDP - Franco destinație vămuit, Incoterms 2020, în termen de până la 30 de zile de la comanda scrisă a beneficiarului	8100
33100000-1	9	Ciment ortopedic cu antibiotic	Ciment ortopedic cu antibiotic	bucată	2510	381,25	411,75	956937,50	1033492,50	DDP - Franco destinație vămuit, Incoterms 2020, în termen de până la 30 de zile de la comanda scrisă a beneficiarului	1635452,748
							Suma total:	**962987,90**	**1040026,93**		

Semnat:_____ Numele, Prenumele: Chitic Vlad În calitate de Director executiv

Ofertantul: Lismedfarm S.R.L. Adresa: 167/B, sos. Muncesti, MD-2002 Chisinau, Republica Moldova

		Specificaţii tehnice							
			[Acest tabel va fi completat de către ofertant în coloanele 3, 4, 5, 7, iar de către autoritatea contractantă – în coloanele 1, 2, 6, 8]						
		Numărul licitaţiei:	LP nr. ocds-b3wdp1-MD-1737734481286				Data: „07” 02 2025		Alternativa nr.: _____
		Denumirea licitaţiei:	În scopul atribuirii contractelor subsecvente ca urmare a acordului-cadru (nr. ocds...30646 din 14.01.2025) încheiat prin procedura de achiziție publică ocds-b3wdp1-MD-1718205130646 din 12.06.2024 privind încheierea acordului-cadru - Achiziționarea endoprotezelor pentru anii 2025-2027						Pagina: __din __
Cod CPV	**Nr. Lot**	**Denumire Lot**	**Denumirea poziției**	**Modelul articolului**	**Țara de origine**	**Produ-cătorul**	**Specificarea tehnică deplină solicitată de către autoritatea contractantă**	**Specificarea tehnică deplină propusă de către ofertant**	**Standarde de referinţă**
1	**2**			**3**	**4**	**5**	**6**		**8**
33100 000-1	8	Ciment ortopedic fără antibiotic	Ciment ortopedic fără antibiotic	OGM1 REF: 1201/S	Turcia	Ormed Grup Medikal Tur. Sağ. Hiz. San. Ve Tic.Ltd.Şti.	Ciment ortopedic fără antibiotic Cimentul sa contina minim 40 g Ambalat steril - Sa aiba 2 componente – o fiola cu lichid si o punga pudra polimer - Radioopac - Viscozitate medie - Termen restant al sterilizării nu mai mic de 2 ani la momentul livrării	Ciment ortopedic fără antibiotic. Cimentul contine 40 g. **-conform catalogului pentru modelul OGM1 codul 1201/S pag.4** Ambalat steril. Sunt 2 componente – o fiola cu lichid si o punga pudra polimer -Radioopac - Viscozitate medie - Termen restant al sterilizării nu mai mic de 2 ani la momentul livrării. **-conform descrierea produsului pentru modelul OGM1 codul 1201/S**	CE DM000322468
33100 000-1	9	Ciment ortopedic cu antibiotic	Ciment ortopedic cu antibiotic	OGM1A REF: 1711/SG	Turcia	Ormed Grup Medikal Tur. Sağ. Hiz. San. Ve Tic.Ltd.Şti.	Disponibil în pachete ce conțin minim 40 grame de pudră ce va conține polimer și monomer sub formă lichidă. - Să prezinte viscozitate medie, indicat pentru artroplastii de șold și genunchi si alte articulații. - Să conțină oxidul de zirconiu sau sulfatul de bariu în pudra de ciment ca agent radioopac. -Să conțină Gentamicină. - Să prezinte o toxicitate redusă și să posede proprietăți hipoalergene. - să corespundă standardului ISO 5833. - Termen restant al sterilizării nu mai mic de 2 ani la momentul livrării.	Disponibil în pachete ce conțin 40 grame de pudră. **-conform catalogului pentru modelul OGM1A codul 1711/SG pag.5** -Pudra conține polimer și monomer sub formă lichidă. -Prezintă viscozitate medie, indicat pentru artroplastii de șold și genunchi si alte articulații. -Contine oxidul de zirconiu sau sulfatul de bariu în pudra de ciment ca agent radioopac. -Conține Gentamicină. -Prezintă o toxicitate redusă și posedă proprietăți hipoalergene. -Corespunde standardului ISO 5833. -Termen restant al sterilizării nu mai mic de 2 ani la momentul livrării. **-conform descrierea produsului pentru modelul OGM1A codul 1711/SG**	CE DM000322462

Semnat:_____ Numele, Prenumele: Chitic Vlad În calitate de Director executiv

Ofertantul: Lismedfarm S.R.L. Adresa: 167/B, sos. Muncesti, MD-2002 Chisinau, Republica Moldova

LISMEDFARM S.R.L.
Șos. Munceşti, 167/B, MD – 2002, mun. Chișinău, Republica Moldova
tel.: 022-80-47-98, 022-55-64-38, 022-56-94-91, e-mail: oficiu@lismedfarm.md,
web: https://lismedfarm.md, c/f: 1003600113573, TVA: 0304618, director – Ecaterina Chitic

PROCURĂ nr. 18 din 03.11.2023

Subsemnata, Chitic Ecaterina, în calitate de fondator unic şi administrator al S.R.L. „Lismedfarm", IDNO **1003600113573**, cu sediul în Republica Moldova, mun. Chișinău, șos. Munceşti, 167/B, MD-2002, împuternicească pe d-nul **Chitic Vlad**, directorul executiv al companiei S.R.L. „Lismedfarm", cetățeanul al Republicii Moldova, având IDNP **2007042030196**, posesor al buletinului de identitate seria **B** nr. **01232897** eliberat la data de **23.10.2023**, pentru a reprezenta interesele companiei S.R.L. „Lismedfarm". în faţa tuturor persoanelor competente, inclusiv in fata instanţelor de judecată, organelor de stat / autorităţilor publice (de toate nivelurile), instituţii (asociaţii, uniuni, etc.) publice, bancare, instituţii obştești, şi/sau profesionale, persoanele fizice şi/sau juridice în orice procedură judiciară, civilă, penală, administrativă sau contravenţionala.

D-ul Chitic Vlad se autorizează pentru orice act de administrare şi dispoziţie pentru buna desfăşurare a activităţii S.R.L. „Lismedfarm".

Pentru utilizarea scopului menționat, mandatarului i se oferă:

- dreptul de a îndeplini din numele companiei toate actele procedurale inclusiv va prezenta la orice bancă şi va putea efectua orice operaţiuni financiar-bancare pe conturile deschise pe numele S.R.L .„Lismedfarm", necesare desfăşurării activităţii societăţii, inclusiv deschideri, derijerii şi lichidări conturilor, va perfecta şi va inainta cereri şi declaraţi necesare, va prezenta documentaţia solicitată, va efectua plăţi, încasări, viramente, depuneri etc. din şi în aceste conturi, va achita orice taxe, va ridica extrasele de cont, îndeplinind toate formalităţile necesare, cu dreptul de a semna din numele companiei, în limita prezentului mandat;
- este împuternicit cu toate drepturile procesual penale și procesual civile, inclusiv de a achita taxa de stat și a înainta cererea prealabilă/somația; a semna și depune acțiunea, cererea introductiva, cererea de admitere a creanței, cerere de validare a popririi, referința, cererea de apel, cererea de recurs, cererea de revizuire; a recurge la arbitraj; a renunța total/parțial la pretențiile din acțiune; a majora/reduce cuantumul pretențiilor din acțiune; a prezenta probe; a modifica temeiul sau obiectul acțiunii; a recunoaște acțiunea; a recurge și participa la mediere, a negocia și semna tranzacții de împăcare; a intenta acțiunea reconvențională; a transmite împuternicirile unei alte persoane; a ataca hotărîrea judecătorească cu apel, recurs sau revizuire și a-i schimba modul de executare; a reclama probe; a da explicații și a pleda în dezbaterile judiciare; a strămuta pricina;; a depune cereri și plîngeri în adresa organelor abilitate, inclusiv privind intentarea cauzei penale; a solicita si primi informatii/acte de la organele de stat și persoane; a depune cereri de intervenție în proces;
- dreptul de a duce tratativele şi de a încheia contracte cu persoane fizice sau juridice, în vederea desfăşurării activităţii societăţii şi a unei bune administrări a acesteia, fiind nelimitat de suma tranzacției, va putea achiziționa în numele societăţii documentația de evidența contabilă-financiară de strictă evidență (chitanţiere şi facturi fiscale şi alte) și alte acte cu sau fără regim special, de a depune toate raporturile financiare /bilanţurile şi de a supraveghea şi verifica evidenţa contabilă a societăţii, cu dreptul de a perfecta, semna și inainta orice contestaţii şi plângeri la actele organelor financiare, fiscale sau a altor organe de control, cu dreptul de a semna procese verbale de constatare, declaraţii fiscale, declaraţii unice, facturi fiscale va obţine semnături electronice în numele societăţii, fiind direct răspunzător pentru acţiunile sale proprie;
- de a duce tratativele, încheia şi semna în numele societăţii şi pentru aceasta contracte de prestări servicii, de vinzarea mărfii, contracte de închiriere/comodat, contracte individuale de

- muncă, stabilind condiţiile acestor contracte, va efectua operaţiunile ce se impun cu casa(ele) de marcat, va putea semna contracte de asociere, colaborare, participaţiune, contracte comerciale, cu privire la activitatea societăţii. Va efectua operaţiuni comerciale, va achiziţiona şi distribui marfă, se va ocupa de derularea corespunzătoare a contractelor comerciale/muncă, va angaja/ concedia /disponibiliza personal, va efectua aprovizionarea societăţii, va achiziţiona marfă şi va ocupa inclusiv de buna administrare şi funcţionare a punctului/punctelor de lucru ale societăţii (dacă este cazul);
- dreptul de a îndeplini din numele companiei toate actele procedurale în faţa instanţelor de judecată în orice acţiuni judiciare, având toate drepturile părţii în proces, cu dreptul de a semna şi a depune în judecată cereri de chemare în judecată, cereri de eliberare a ordonanţelor judecătoreşti şi alte acte procesuale necesare, de a strămuta pricina în altă judecată, de a renunţa total sau parţial la pretenţiile din acţiune, de a majora sau reduce cuantumul acestor pretenţii, de a modifica temeiul sau obiectul acţiunii, de a încheia tranzacţii, inclusiv tranzacţii de împăcare, de a intenta acţiune reconvenţională, de a ataca hotărârea judecătorească cu apel şi/sau recurs sau revizuire, de a cere şi de a primi hotărârile, încheierile şi ordonanţele instanţei de judecată şi documentele executorii.
- de a înregistra din numele companiei cereri și demersuri la Agenția Serviciilor Publice (inclusiv la toate Departamentele structurale - Departamentul Cadastru, Departamentul înregistrare și licențiere a unităților de drept, Departamentul înmatriculare a mijloacelor de transport și calificare a conducătorilor auto, Departamentul înregistrare și evidență a populației și alte), și la alte instituții de înregistrare a bunurilor sau a drepturilor, de a semna cereri, contracte și alte acte necesare, de a susține în aceste organe drepturile șu interesele companiei, de a depune, de a solicita, de a primi actele necesare pentru realizarea scopului menționat;
- de a efectua toate actele legate de procedura de executare, inclusiv de prezentare sau retragere a documentului executoriu, de încheiere a tranzacţiei, de contestare a actelor executorului judecătoresc, de schimbare a modului de executare, de amânare sau eşalonare a executării, de depunere a cererilor, va semna şi va îndeplini toate acţiunile şi formalităţile, necesare pentru atingerea scopului executării silite;
- de a efectua toate acțiunile legate de procedura de insolvabilitate, să participe la toate adunările creditorilor și ședințele comitetului creditorilor si să voteze cu toate voturile pe toate chestiunile de pe ordinea de zi, inclusiv cu drept de vot asupra planului de restructurare, de a fi desemnat în calitate de membru al comitetului creditorilor precum și reprezentant al debitorului;
- are dreptul de a efectua toate acte legate de procedura de executare, inclusiv de primire, prezentare sau de retragere a documentului executoriu, de transmitere a împuternicirilor către o alta persoana (substituire), de încheiere a tranzacției, a reprezenta societatea în procedura de executare cu dreptul de a contesta actele executorului judecătoresc, a semna și depune cerere de calculare și încasare a a dobînzilor, a participa la acțiunile de executare de schimbare a modului de executare, de amanare sau de eșalonare a executarii;
- de a autentifica din numele companiei corespunderea copiei documentului originalului;

Procura este valabilă în decurs de 3 (trei) ani calendaristice de la data eliberării.

Specimenul semnăturii

Digitally signed by Chitic Vlad
Date: 2024.01.18 14:28:39 EET
Reason: MoldSign Signature
Location: Moldova

Administratorul S.R.L. „Lismedfarm” Ecaterina Chitic

Digitally signed by Chitic Ecaterina
Date: 2024.01.18 14:06:28 EET
Reason: MoldSign Signature
Location: Moldova