MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Digitally signed by Kojevnikov Dmitrii
Date: 2026.05.14 14:14:23 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
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Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

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BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531861** data **19.09.2023**

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**
Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1007600044280**
Data înregistrării de stat: **30.07.2007**
Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
2. Comerţul cu ridicata al parfumurilor şi produselor cosmetice
3. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă
4. Intermedieri pentru vînzarea unui asortiment larg de mărfuri
5. Alte tipuri de comerţ cu amănuntul în magazine nespecializate
6. Alte tipuri de comerţ cu ridicata
7. Închirierea altor maşini şi echipamente

Capitalul social: **5400** lei,

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociaţii:
1. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%
Beneficiar efectiv:
1.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **19.09.2023**.

Registrator în domeniul înregistrării de stat **Rusu Diana**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova

EB 0461498

Date cu caracter personal

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telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Date generale despre ofertant

S.C. OXIVIT-MED S.R.L
Administrator: Dmitrii Kojevnikov
Adresa poştală: mun. Chișinău, str. Decebal 82-90
Tel./Fax: 022 808 002, 022 808 003 **E-mail:** info@oxivit-med.com; oxivit.medical@gmail.com
Cod IBAN: MD09MO2224ASV23488147100
Banca: „Mobiasbanca OTP Group” S.A
Codul băncii: MOBBMD22
Cod fiscal: 1007600044280
Cod TVA: 0306300

Cu respect,

Dmitrii Kojevnikov

Administrator

Bioptimal™

INSTRUCTIONS FOR USE OF BIPOLAR PACING CATHETER

Read Instruction Manual Before Use

Keep Dry

STERILE EO Sterile And Non-Pyrogenic

Do Not Use If Package Is Damaged

For Single Use Only

Keep From Direct Sunlight

Do Not Re-sterilize

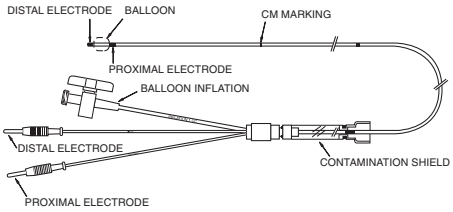
Non-Pyrogenic

READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY PRIOR TO USE.

DEVICE DESCRIPTION:

BIOPTIMAL Bipolar Pacing Catheters are constructed with a radiopaque polyurethane catheter tubing with 10 cm increments marked along its length that allow physician to determine depth of catheter insertion. Bipolar pacing catheter has an electrode lumen, which provides electrical conductor isolation from electrodes to the connector pins. Additional balloon inflation lumen on some model provides a means of inflating and deflating the latex balloon near the distal tip of the catheter to facilitate the catheter advancement to desired location.

Figure1. Drawing of Bipolar Pacing Catheter



Model	BPX2502-10	BP2502-10	BPX2502CS-10	BP2502CS-10
French Size	5Fr	5Fr	5Fr	5Fr
Usable Length	110cm	110cm	110cm	110cm
Balloon Inflation	-	1.0cc	-	1.0cc
Balloon diameter	(No balloon)	9mm	(No balloon)	9mm
Electrode spacing	10mm	10mm	10mm	10mm
Contamination Shield	-	-	110cm	110cm

INDICATIONS AND INTENDED USE

BIOPTIMAL Bipolar Pacing Catheters are designed for temporary transvenous cardiac pacing by transmitting a pacing electrical stimulus from a pulse generator to the heart. It can also be used for transmitting electrical signal of the heart to a recording device.

CAUTIONS

Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

PRECAUTIONS

- Do not use catheter after indicated expiration date on the packaging.
- This product is designed for single use only. Do not reuse or resterilize the catheter.
- Do not use catheter or components if package is opened or damaged as contents may lose sterility.
- Excessive kinking or bending of the catheter may cause damage to the internal conductive wires.
- To avoid damage to the catheter or balloon when cutdown is used, it is recommended that a vessel dilator or disposable vein guide be used. Never use forceps on the catheter.
- Never use liquid or contrast media to inflate the balloon. Liquid within the balloon inflation lumen may cause the balloon to stay inflated even after removal of the inflation syringe.
- To avoid balloon rupture during inflation, do not exceed the recommended balloon inflation volume.
- To minimize ventricular irritability, inflate the balloon before the catheter reaches the right ventricle.
- To minimize infection, it is generally recommended that the catheter should not be left in the patient for longer than three days.
- Always deflate the balloon prior to withdrawing the catheter.
- Used catheter must be properly disposed as biohazard material and processed according to facility protocol.
- The package is designed to prevent kinking to the catheter. A damaged catheter cannot be repaired. The catheter balloon is fragile; therefore, reasonable care should be employed when removing the catheter from the package.

WARNINGS

- Please use product with contamination shield.
- Use CO_2 for balloon inflation in any situation where balloon rupture may result in air embolism in the left heart of systemic circulation.
- Do not inflate the balloon exceeding the recommended inflation volume. Over inflating the balloon may cause balloon rupture.
- Catheterization must be performed by trained personnel well versed transvenous temporary pacing technique and potential complications.
- This device is intended for single patient use only.
- **DO NOT** resterilize and/ or reuse this device, as this can compromise its performance and can lead to device failure and procedure complications with severe injury or patient death. Reuse and resterilisation bear the risk of cross contamination and patient infection and may also cause transmission of infectious diseases from patient to patient.

CONTRAINDICATIONS

- Catheter with natural latex balloon is contraindicated for patient with known or suspected allergy to natural rubber latex.
- Patients with recurrent sepsis or with a hypercoagulant state should not be considered as candidates for transvenous catheter since the catheter could serve as a focal point for septic or bland thrombus formation.
- Patients with a tricuspid valve prosthesis should not be considered for ventricular pacing.

COMPLICATIONS

All invasive procedures inherently involve some patient risks. The physician is advised to weigh the potential benefits and risks associated with the use of the catheter against alternative procedures before deciding to use the catheter. Perforations, arteriovenous flatula formation and other vascular trauma have been reported in the scientific literature and should be considered before inserting the catheter [1,2,3,4,5,6].

Possible side effects include, but not limited to:

- arrhythmias,
- thrombocytopenia,
- pneumothorax,
- encocardial perforation
- cardiac tamponade
- air embolism
- diaphragmatic stimulation
- arteriovenous fistula formation
- damage to vessels or valve structure
- endocarditis
- knotting of the catheter
- sepsis/infection
- thrombophlebitis
- thrombosis

INSTRUCTIONS FOR USE

CATHETER INSPECTION AND TESTING:

1. Catheter is supplied in sterile packages. Inspect the package

to ensure that it has not already been opened or damaged. The catheter will lose its sterility and become pyrogenic if the package is opened or damaged.

2. Test each electrodes and appropriate connector for continuity with ohmmeter.

CAUTION: Do not use ohmmeter or a standard continuity checker when the catheter is in the vascular system. The relatively high current in the meter can cause electrical shock to the patient in the event of insulation breakdown.

3. Test the balloon for leakage by inflating it with the recommended inflation volume of either bacteria-filtered CO_2 or air under sterile solution. If there is any evidence of balloon leakage, do not use the catheter.

CAUTION: Remove the balloon cover before conducting the balloon inflation test. Never inflate the balloon with liquid. Never inflate the balloon in ice water for testing.

4. Read carefully the instruction manual of your instruments for additional information.

RECOMMENDED INSERTION PROCEDURE:
The following instructions are a general guide intended for informational purposes only; the physician should add to or alter procedural details with respect to his clinical experiences.

CAUTION: Follow aseptic technique and employ Universal Precautions and procedures per institutional protocols.

1. Insert the catheter into the vein either by cutdown or percutaneous technique.
2. Under the aid of ECG or fluoroscopy, gently advance the catheter to the desired intracardiac position.
3. Air may be used for inflating the balloon only if there is no possibility of an air embolus entering the arterial circulation in case the balloon should rupture, CO_2 should be used if this possibility cannot be excluded.

CAUTION: Over inflating the balloon may cause balloon rupture. Do not exceed recommended inflation volume.

CAUTION: Possibility of catheter knot or loop exists if a redundant length of catheter is inserted. If a loop is suspected, withdraw the catheter to the right atrium and advance again. If a knot is suspected, deflate the balloon and gently withdraw the catheter. Withdrawal of a knotted catheter may be facilitated in some cases by anaesthetization of the patient to minimize possible venous spasm and pain.

4. Once a satisfactory pacing location had been achieved, firmly secure the catheter at the insertion site. This helps prevent accidental displacement of the electrodes.
5. For temporary pacing, the distal electrode connector (negative) must be connected to the negative terminal of the external pulse generator. This proximal electrode connector (positive) must be connected to the positive terminal of the external pulse generator.
6. For intracardiac ECG monitoring, the distal electrode connector (negative) is connected to the V lead of the ECG. The proximal electrode connector (positive) is connected to the positive terminal of the external pacemaker.

CATHETER REMOVAL:

1. To prevent air embolism after removal of the catheter, cover wound with dressing impermeable to air.
2. Inspect the catheter upon removal to make sure that the entire catheter length has been removed.

CAUTION: Always deflate the balloon prior to withdrawing the catheter.

CAUTION: Do not reuse or resterilize the catheter.

PACKAGING AND STERILITY
Product is supplied sterile and non-pyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Catheters are for single use only. Do not clean or resterilized a used catheter.

STORAGE
Bioptimal Bipolar Pacing Catheters should be stored unopened in its original packaging in dark, cool dry places to avoid exposure to fluorescent or sunlight, which will prematurely deteriorate the latex balloon.

SHELF-LIFE
The recommended shelf-life is indicated on each package.

WARRANTY
BIOPTIMAL warrants all its products free from defect in workmanship and materials under proper use and handling. This warranty is in lieu of all other warranties, whether expressed or implied, including any warranty of merchantability, suitability or fitness for a particular purpose since handling, storage as well as factors relating to the patient, his diagnosis, treatment, surgical procedures, and other matters beyond BIOPTIMAL'S control, directly affect BIOPTIMAL'S products and the results obtained from their use. BIOPTIMAL shall not be liable for any incidental or consequential loss, damage, or expense directly arising from the use of its products. BIOPTIMAL neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with its products.

PRODUCT INFORMATION
For further information or assistance relating to the BIOPTIMAL products, please contact:

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REFERENCES:

1. Chang, T.O., "Percutaneous Transfemoral Venous Cardiac Pacing." CHEST, 60: 73-78, 1971.
2. K. Chatlerjee, M.D., MRCP, H. Swan, M.D., W. Ganz., *et al.* "Use of a Balloon-Tipped Floatation Electrode Catheter for Cardiac Monitoring." American Journal of Cardiology, July 1975 vol. 36, pp. 56-61.
3. Lipp, H., *et al.* "Intra-cardiac Knotting of a Flow-Directed Balloon Catheter." N. Engl. J. Med., 284:220, 1971.
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