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"

Digitally signed by Kojevnikov Dmitrii
Date: 2025.06.27 15:52:18 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Executor : Mariana Guzun
Tel: 022 812 614

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

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

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

EC DECLARATION OF CONFORMITY

M - ZP - 07 - 01 R05

Manufacturer:	MEDIN, a.s.
Company address:	Vlachovická 619, 592 31 Nové Město na Moravě, Czech Republic
Product group:	**Intramedullary nails**
Product name:	**C-Nail**
Classification:	Medical Devices class IIb, Rule 8 according to annex IX of MDD 93/42/EEC as amended
Conformity assessment procedure:	Annex II (excluding section 4) of Council Directive 93/42/EEC as amended
Medical Device Nomenclature Code:	GMDN 67464

The undersigned declaration is issued under the sole responsibility of the manufacturer in order to display conformity of the product to the provisions of Medical Device Directive 93/42/EEC as amended.

The Notified Body:	DNV Product Assurance AS, Veritasveien 1, N-1363 Høvik, Norway
The Identification number of Notified Body:	2460

An overview of the product variants is given in the Annex.

Date of revision:	05. 05. 2025
Date of first issue:	03. 09. 2019
Place:	Nové Město na Moravě

Ing. Oldřich Pospíchal
Technical director

Used relevant harmonized standards:

EN ISO 10993-1:2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-15:2009	Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
EN ISO 11607-1:2020 EN ISO 11607-1:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020 EN ISO 11607-2:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016 EN ISO 13485:2016/AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects -- Good clinical practice
EN ISO 14602:2011	Non-active surgical implants. Implants for osteosynthesis. Particular requirement.
EN ISO 14630:2009	Non-active surgical implants - General requirements.
EN ISO 14971:2019 EN ISO 14971:2019/A11:2021	Medical devices. Application of risk management to medical devices
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
EN ISO 17665-1:2006	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN 62366-1:2015 EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 5832-1:2024	Implants for surgery - Metallic materials. Part 1: Wrought stainless steel

Place: Nové Město na Moravě
Date: 05. 05. 2025

Annex EC declaration of conformity

M-ZP-07-01 R05

Product name	REF	Variants
C-Nail	397 129 78 4160	8×65 mm, right
	397 129 78 4170	8×65 mm, left

Accessories:

Product name	REF	Variants
Locking screw with flat head	397 129 78 5651	3,5x22 mm
	397 129 78 5661	3,5x24 mm
	397 129 78 5671	3,5x26 mm
	397 129 78 5681	3,5x28 mm
	397 129 78 5691	3,5x30 mm
	397 129 78 5701	3,5x32 mm
	397 129 78 5711	3,5x34 mm
	397 129 78 5721	3,5x36 mm
	397 129 78 5731	3,5x38 mm
	397 129 78 5741	3,5x40 mm
	397 129 78 5751	3,5x42 mm
	397 129 78 5761	3,5x44 mm
	397 129 78 5771	3,5x46 mm
	397 129 78 5781	3,5x48 mm
	397 129 78 5791	3,5x50 mm
	397 129 78 5801	3,5x55 mm
	397 129 78 5811	3,5x60 mm
	397 129 78 5821	3,5x65 mm
	397 129 78 5831	3,5x70 mm

Product name	REF	Variants
Cancellous screw	397 129 79 6260	HB 4x22/9 mm
	397 129 79 6270	HB 4x24/10 mm
	397 129 79 6280	HB 4x26/12 mm
	397 129 79 6290	HB 4x28/14 mm
	397 129 79 6300	HB 4x30/14 mm
	397 129 79 6310	HB 4x32/14 mm
	397 129 77 4200	HB 4x34/14 mm
	397 129 77 4210	HB 4x36/14 mm
	397 129 77 4220	HB 4x38/14 mm
	397 129 79 6330	HB 4x40/14 mm
	397 129 77 4230	HB 4x42/15 mm
	397 129 77 4240	HB 4x44/15 mm
	397 129 77 4250	HB 4x46/15 mm
	397 129 77 4260	HB 4x48/15 mm
	397 129 79 6350	HB 4x50/15 mm

Annex EC declaration of conformity

M-ZP-07-01 R05

Product name	REF	Variants
End cap	397 129 77 2210	L0xM6 mm, 6HR 2,5
	397 129 77 2220	D8×L5×M6 mm, 6HR2,5
	397 129 77 2230	D8×L10×M6 mm, 6HR2,5
	397 129 78 8880	D8×L15×M6 mm, 6HR2,5
	397 129 78 8890	D8×L20×M6 mm, 6HR2,5

Product name	REF	Variants
Washer	397 129 99 0838	4,6 x 8,8 mm

Place: Nové Město na Moravě
Date: 05. 05. 2025

Digitally signed by Triboi Cătălina
Date: 2025.05.06 12:30:27 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

3EC®
International

SNAS
Reg. No. 305/Q-054

CERTIFICATE

This certifies that the Quality management system for medical devices of company

MEDIN, a.s.

Vlachovická 619, 592 31 Nové Město na Moravě, Czech Republic

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

DESIGN, DEVELOPMENT, PRODUCTION, SERVICE AND PLACING ON THE MARKET OF STERILE AND NON-STERILE NON-ACTIVE MEDICAL DEVICES FOR TRAUMATOLOGY, SURGERY AND DENTISTRY

DISTRIBUTION AND IMPORT OF MEDICAL DEVICES

Certificate No.: M-0541/23 **Date of issuance: April 27th, 2023** **Original date of approval: June 12th, 2018**

This certificate is valid from **June 12th, 2023** to **June 11th, 2026** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarina Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 077608 0079 Rev. 00

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

Product Category(ies):

Medical Instruments, Surgical Products and Hemostatic Materials:
- **Surgical Suture Products, Pledgets and Retention Tapes**
- **Endoscopy Instruments and Accessories including Lubricant**
- **Surgical Staple, Clip Products and Accessories**
- **Manual Surgical Instruments**
- **Implantable Wound Dressing Materials**
- **Ultrasonic Surgical Devices and Accessories**
- **Suction / Irrigation Devices and Accessories**
- **Arthroscopy Implants, Instruments and Accessories**
- **Bone Wax**
- **Temporary Cardiac Pacing Lead**
- **Powered Stapling Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713164286

Valid from: 2019-09-13
Valid until: 2024-05-26

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 077608 0079 Rev. 00

Facility(ies):

Covidien llc
15 Hampshire Street,
Mansfield, MA 02048, USA

./.

OXIVIT-MED
00760004428

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Covidien llc
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

Holds Certificate Number: FM 71825

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development and manufacture of electrosurgical generator systems and associated sterile and nonsterile accessories; radiofrequency ablation and lesioning generators and associated sterile and nonsterile accessories; ultrasonic surgical systems and associated sterile and nonsterile accessories; Argon gas delivery surgical systems and associated sterile accessories; surgical smoke evacuation systems and associated sterile and nonsterile accessories; microwave generators and associated sterile and nonsterile accessories, sterile and nonsterile electromagnetic navigation accessories; procedure planning software; electrosurgical vessel sealing systems and associated sterile and nonsterile accessories; radiofrequency detection consoles and associated sterile and nonsterile accessories; sterile and nonsterile woven disposables.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-12-30
Latest Revision Date: 2023-10-03

Effective Date: 2023-10-26
Expiry Date: 2026-10-25

...making excellence a habit.™

Certificate No: FM 71825

Location	Registered Activities
Covidien llc 6044 Longbow Court Boulder Colorado 80301 USA	The manufacturing of electrosurgical generator systems and associated sterile and nonsterile accessories; radiofrequency ablation and lesioning generators and associated sterile and nonsterile accessories; ultrasonic surgical systems and associated sterile and nonsterile accessories; electrosurgical vessel sealing systems and associated sterile and nonsterile accessories.
Covidien llc 15 Hampshire Street Mansfield Massachusetts 02048 USA	Administrative Activities.
Covidien llc 200 Medtronic Drive Lafayette Colorado 80026 USA	The design and development of electrosurgical generator systems and associated sterile and nonsterile accessories; radiofrequency ablation and lesioning generators and associated sterile and nonsterile accessories; ultrasonic surgical systems and associated sterile and nonsterile accessories; Argon gas delivery surgical systems and associated sterile accessories; surgical smoke evacuation systems and associated sterile and nonsterile accessories; microwave generators and associated sterile and nonsterile accessories, sterile and nonsterile electromagnetic navigation accessories; procedure planning software; electrosurgical vessel sealing systems and associated sterile and nonsterile accessories; radiofrequency detection consoles and associated sterile and nonsterile accessories; sterile and nonsterile woven disposables.
Covidien llc 6027 Longbow Court Boulder Colorado 80301 USA	The manufacturing of electrosurgical generator systems and associated sterile and nonsterile accessories; radiofrequency ablation and lesioning generators and associated sterile and nonsterile accessories; ultrasonic surgical systems and associated sterile and nonsterile accessories; electrosurgical vessel sealing systems and associated sterile and nonsterile accessories.
Covidien llc 6042 Longbow Court Boulder Colorado 80301 USA	The manufacturing of electrosurgical generator systems and associated sterile and nonsterile accessories; radiofrequency ablation and lesioning generators and associated sterile and nonsterile accessories; ultrasonic surgical systems and associated sterile and nonsterile accessories; electrosurgical vessel sealing systems and associated sterile and nonsterile accessories.

Original Registration Date: 2002-12-30

Effective Date: 2023-10-26

Latest Revision Date: 2023-10-03

Expiry Date: 2026-10-25