Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. __ din 28 septembrie 2023

Solicitantul **SRL "Oxivit-med"**, cu sediul **mun. Chisinau, MD-2020, str-la** (adresa)
Studentilor 6B, tel./fax: **079954795**, e-mail oxivit.medical@gmail.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1. **Ic-cerclage**

Se anexează următoarele acte:
a) declarația de conformitate CE emisă de producător;
b) certificatul de conformitate CE ;
c) Actul prin care producatorul isi desemneaza reprezentantul;

Data _____ Semnătura _____

Tabelul de recepţionare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Kojevnikov Dmitrii
Date: 2023.09.29 15:56:53 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **SRL "Oxivit-med"**, cu sediul **mun. Chisinau, MD-2020, str-la Studentilor 6B**, (adresa)

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. **Ic-cerclage**

Sunt autentice și corespund realității.

_____, Director
Numele, prenumele şi funcţia *Semnătura* _____

Data _____

implantcast GmbH · Lüneburger Schanze 26 · 21614 Buxtehude

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Tel.: +49 4161 744-0
Fax: +49 4161 744-200
E-Mail: info@implantcast.de
Internet: www.implantcast.de

We, **implantcast GmbH**, based in Germany, 21614 Buxtehude, Lüneburger Shanze 26,
(manufacturer) *(address)*

assign **OXIVIT-MED SRL**, based in Republic of Moldova, mun. Chisinau, MD-2020, str-la. Studentilor 6B,
(authorized representative) *(address)*

as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.

Vadim Lioubitski
Export Manager
C.I.S. countries

implantcast GmbH
Lüneburger Schanze 26 D-21614 Buxtehude
Tel.: +49 4161 744-0 Fax: +49 4161 744-200

MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

For the placing on the market of class III medical devices covered by this certificate, an additional EC design examination certificate according to Annex II, section 4 of Council Directive 93/42/EEC is required.

Effective date: **2020-12-01**
Expiry date: **2024-05-27**

Report No.: 7092FS12F
Process No.: QS – 7092
Certificate No.: 7092GB410201201A

Hamburg, 2020-12-01

MEDCERT Certification Body
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 7092
Certificate No.: 7092GB410201201A

List of locations included in the scope of certificate

Alter Postweg 10b
21614 Buxtehude
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

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Appendix of EC Certificate of Conformity

Process No.: QS – 7092
Certificate No.: 7092GB410201201A

List of products / product categories included in the scope of certificate

- **Primary endoprosthesis**
- **Tumor endoprosthesis**
- **Revision endoprosthesis**
- **Instruments (rasps, handles, reamer, drills, sawblades)**
- **Trial prostheses**
- **Metal augments**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

EU Declaration of Conformity

Manufacturer:	implantcast GmbH Lüneburger Schanze 26 21614 Buxtehude Germany
Medical Device(s):	**ic-Cerclagen**
Intended Use:	ic- Cerclages are intended for fixation and reduction of bone fragments (seamless and not absorbable) as well as for supplementary fixation and reduction with bone plate/screw systems.
REF Number(s):	REF-Numbers see Attachment I - I
Classification:	Class IIb *(Council Directive 93/42/EEC, Annex IX, rule 8, in conjunction with commission directive 2005/50/EC)*

Standard(s) applied:

EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Requirements for materials, sterile barrier systems and packaging systems
EN ISO 10993-1	Biological evaluation of medical devices – Part1: Evaluation and testing
EN ISO 14630	Non-active surgical implants - General requirements
EN ISO 21534	Non-active surgical implants - Joint replacement implants - Particular requirements

GMDN code(s) and term(s):

P 61690	Internal orthopaedic fixation system, cerclage wire/cable, sterile

EU Declaration of Conformity

We declare under our sole responsibility that the medical device specified above are in conformity with the essential requirements listed in Annex I of Council Directive 93/42/EEC and has been gone through the conformity assessment procedure according to Annex II of Council Directive 93/42/EEC.

Notified Body:	MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany
EC Certificate of Conformity	Council Directive 93/42/EEC Annex II excluding section 4 Certificate No.: 7092GB410201201A Validity: 01/12/2020 - 27/05/2024

Identification:

CE 0482

implantcast GmbH
Lüneburger Schanze 26 D-21614 Buxtehude
Tel.: +49 4161 744-0 Fax: +49 4161 744-200

Buxtehude, 04.12.2020
Place, date

i.V. Juliane Höppner
Head of Regulatory Affairs

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN
00601008	ic-cerclage for reconstruction	8 mm	P 40752	4048844004033
00601018	ic-cerclage band titanium 2R	/	P 40752	4048844254780
00602013	ic-titanium cerclage wire	Ø 1,4mm x 0,5m	P 40752	4048844127596
00602014	ic-titanium cerclage wire	Ø 1,4mm x 5m	P 40752	4048844004088

End of schedule. No additional information past this point.

Nr.	Numărul de catalog (referintă)*	Denumire generică (denumirea dispozitivului), Modelul	Denumire comercială (brand)*	Cod GMDN*
1	.00601008	ic-cerclage 8mm		P 40752
2	.00601018	ic-cerclage band titanum 2R		P 40752
3	.00602013	ic-titanium cerclage wire size Ø 1,4mm x 50cm		P 40752
4	.00602014	ic-titanium cerclage wire size Ø 1,4mm x 5m		P 40752