

Către Agenția Medicamentului  
și Dispozitivelor Medicale

**NOTIFICARE**

pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale  
**nr. \_\_\_\_\_ din 26 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](mailto:oxivit.medical@gmail.com),  
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor  
categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție  
pe piață a:

**1. Proteze pentru articulații de umar: suruburi - Bone Screw**

Se anexează următoarele acte:

- a) declarație pe proprie răspundere**
- b) declarația de conformitate CE emisă de producător;**
- c) certificatul de conformitate CE ;**
- d) Actul prin care producatorul isi desemneaza reprezentantul;**

Data 26.09.2023

Semnătura \_\_\_\_\_

**Tabelul de recepționare 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	

Către Agenția Medicamentului și Dispozitive Medicale

**DECLARAȚIE 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<sup>1</sup>, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. **Proteze pentru articulații de umăr: suruburi - Bone Screw**

**Sunt autentice și corespund realității.**

**Kojevnikov Dmitrii, Director**  
Numele, prenumele și funcția

Semnătura \_\_\_\_\_

Data 26.09.2023

We, **implantcast GmbH**, based in Germany, 21614 Buxtehude, Lüneburger Schanze 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



<b>Manufacturer:</b>	implantcast GmbH Lüneburger Schanze 26 21614 Buxtehude Germany
<b>Medical Device(s):</b>	<b>Bone Screw</b>
<b>Intended Use:</b>	Bone screws are intended to use for screwing into the bone for primary and/or permanent stable anchorage of an implant in case of inadequate primary stability.
<b>REF Number(s):</b>	REF-Numbers see Attachment I - IV
<b>Classification:</b>	Class IIb <i>(Council Directive 93/42/EEC, Annex IX, rule 8, in conjunction with commission directive 2005/50/EC)</i>
<b>Standard(s) applied:</b>	
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
<b>GMDN code(s) and term(s):</b>	
P 46646	Orthopaedic bone screw, non-bioabsorbable, sterile

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



Buxtehude, 03.12.2020  
Place, date

i.V. Juliane Höppner  
Head of Regulatory Affairs

# EU Declaration of Conformity

## Attachment I

Reference number	item description	size	GMDN	GTIN
57934026	cancellous screw	Ø 4,0 x 26mm	P 46646	4048844051051
57934028	cancellous screw	Ø 4,0 x 28mm	P 46646	4048844051068
57934030	cancellous screw	Ø 4,0 x 30mm	P 46646	4048844051075
57934032	cancellous screw	Ø 4,0 x 32mm	P 46646	4048844051082
57934034	cancellous screw	Ø 4,0 x 34mm	P 46646	4048844051099
57924525	cortical screw	Ø 4,5 x 25 mm	P 46646	4048844101961
57924530	cortical screw	Ø 4,5 x 30 mm	P 46646	4048844050955
57924535	cortical screw	Ø 4,5 x 35 mm	P 46646	4048844101978
57924540	cortical screw	Ø 4,5 x 40 mm	P 46646	4048844050962
57924545	cortical screw	Ø 4,5 x 45 mm	P 46646	4048844101985
57924550	cortical screw	Ø 4,5 x 50 mm	P 46646	4048844050986
57924555	cortical screw	Ø 4,5 x 55 mm	P 46646	4048844101992
57924560	cortical screw	Ø 4,5 x 60 mm	P 46646	4048844102005
57923510	cortical screw	Ø 3,5 x 10 mm	P 46646	4048844305703
57923512	cortical screw	Ø 3,5 x 12 mm	P 46646	4048844305710
57923514	cortical screw	Ø 3,5 x 14 mm	P 46646	4048844305727
57923516	cortical screw	Ø 3,5 x 16 mm	P 46646	4048844305734
57923518	cortical screw	Ø 3,5 x 18 mm	P 46646	4048844305741
57923520	cortical screw	Ø 3,5 x 20 mm	P 46646	4048844305758
57923522	cortical screw	Ø 3,5 x 22 mm	P 46646	4048844305765
57923526	cortical screw	Ø 3,5 x 26 mm	P 46646	4048844305772
57923528	cortical screw	Ø 3,5 x 28 mm	P 46646	4048844305789
57923532	cortical screw	Ø 3,5 x 32 mm	P 46646	4048844305796
57923534	cortical screw	Ø 3,5 x 34 mm	P 46646	4048844305802
57923536	cortical screw	Ø 3,5 x 36 mm	P 46646	4048844305819
57923538	cortical screw	Ø 3,5 x 38 mm	P 46646	4048844306281

# EU Declaration of Conformity

## Attachment II

Reference number	item description	size	GMDN	GTIN
57923545	cortical screw	Ø 3,5 x 45 mm	P 46646	4048844306304
57923555	cortical screw	Ø 3,5 x 55 mm	P 46646	4048844306311
57923560	cortical screw	Ø 3,5 x 60 mm	P 46646	4048844306328
57923565	cortical screw	Ø 3,5 x 65 mm	P 46646	4048844306335
57923570	cortical screw	Ø 3,5 x 70 mm	P 46646	4048844306342
57923575	cortical screw	Ø 3,5 x 75 mm	P 46646	4048844306359
57923580	cortical screw	Ø 3,5 x 80 mm	P 46646	4048844306366
57923585	cortical screw	Ø 3,5 x 85 mm	P 46646	4048844306373
57923590	cortical screw	Ø 3,5 x 90 mm	P 46646	4048844306380
57923595	cortical screw	Ø 3,5 x 95 mm	P 46646	4048844306397
579235100	cortical screw	Ø 3,5 x 100 mm	P 46646	4048844306403
579235105	cortical screw	Ø 3,5 x 105 mm	P 46646	4048844306410
579235110	cortical screw	Ø 3,5 x 110 mm	P 46646	4048844306427
579235115	cortical screw	Ø 3,5 x 115 mm	P 46646	4048844306434
579235120	cortical screw	Ø 3,5 x 120 mm	P 46646	4048844306441
02801015	spongiosa screw flat head	Ø 6,5 x 15 mm	P 46646	4048844006358
02801020	spongiosa screw flat head	Ø 6,5 x 20 mm	P 46646	4048844006365
02801025	spongiosa screw flat head	Ø 6,5 x 25 mm	P 46646	4048844006372
02801030	spongiosa screw flat head	Ø 6,5 x 30 mm	P 46646	4048844006389
02801035	spongiosa screw flat head	Ø 6,5 x 35 mm	P 46646	4048844006396
02801040	spongiosa screw flat head	Ø 6,5 x 40 mm	P 46646	4048844006402
02801045	spongiosa screw flat head	Ø 6,5 x 45 mm	P 46646	4048844006419
02801050	spongiosa screw flat head	Ø 6,5 x 50 mm	P 46646	4048844006426
02801055	spongiosa screw flat head	Ø 6,5 x 55 mm	P 46646	4048844006433
02801060	spongiosa screw flat head	Ø 6,5 x 60 mm	P 46646	4048844276430
02801065	spongiosa screw flat head	Ø 6,5 x 65 mm	P 46646	4048844248116
02801070	spongiosa screw flat head	Ø 6,5 x 70 mm	P 46646	4048844276751

# EU Declaration of Conformity

## Attachment III

Reference number	item description	size	GMDN	GTIN
02801075	spongiosa screw flat head	Ø 6,5 x 75 mm	P 46646	4048844248130
02801080	spongiosa screw flat head	Ø 6,5 x 80 mm	P 46646	4048844248147
57936525	cancellous screw	Ø 6,5 x 25 mm	P 46646	4048844051105
57936530	cancellous screw	Ø 6,5 x 30 mm	P 46646	4048844051112
57936535	cancellous screw	Ø 6,5 x 35 mm	P 46646	4048844051129
57936540	cancellous screw	Ø 6,5 x 40 mm	P 46646	4048844051136
57936545	cancellous screw	Ø 6,5 x 45 mm	P 46646	4048844051143
57936550	cancellous screw	Ø 6,5 x 50 mm	P 46646	4048844051150
57936555	cancellous screw	Ø 6,5 x 55 mm	P 46646	4048844051167
57936560	cancellous screw	Ø 6,5 x 60 mm	P 46646	4048844051174
57944210	cancellous screw angle stable	Ø 4,2 x 10mm	P 46646	4048844104900
57944212	cancellous screw angle stable	Ø 4,2 x 12mm	P 46646	4048844104917
57944214	cancellous screw angle stable	Ø 4,2 x 14mm	P 46646	4048844104924
57944216	cancellous screw angle stable	Ø 4,2 x 16mm	P 46646	4048844104931
57944218	cancellous screw angle stable	Ø 4,2 x 18mm	P 46646	4048844104948
57944220	cancellous screw angle stable	Ø 4,2 x 20mm	P 46646	4048844104955
57944222	cancellous screw angle stable	Ø 4,2 x 22mm	P 46646	4048844104962
57944224	cancellous screw angle stable	Ø 4,2 x 24mm	P 46646	4048844104979
57944226	cancellous screw angle stable	Ø 4,2 x 26mm	P 46646	4048844104986
57944228	cancellous screw angle stable	Ø 4,2 x 28mm	P 46646	4048844104993
57944230	cancellous screw angle stable	Ø 4,2 x 30mm	P 46646	4048844105006
57944232	cancellous screw angle stable	Ø 4,2 x 32mm	P 46646	4048844105013
57944234	cancellous screw angle stable	Ø 4,2 x 34mm	P 46646	4048844105020
57944236	cancellous screw angle stable	Ø 4,2 x 36mm	P 46646	4048844105037
57944238	cancellous screw angle stable	Ø 4,2 x 38mm	P 46646	4048844105044
57944240	cancellous screw angle stable	Ø 4,2 x 40mm	P 46646	4048844105051



# EU Declaration of Conformity

## Attachment IV

Reference number	item description	size	GMDN	GTIN
02870070	cancellous screw	Ø 8 x 70mm	P 46646	4048844009182
02870080	cancellous screw	Ø 8 x 80mm	P 46646	4048844009199
02870090	cancellous screw	Ø 8 x 90mm	P 46646	4048844009205
02870100	cancellous screw	Ø 8 x 100mm	P 46646	4048844009212

*End of schedule. No additional information past this point.*

# 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](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

**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.  
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ZLG-BS-237.10.15

**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.  
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ZLG-BS-237.10.15

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	57944220	cancellous screw angle stable Ø4.2 /20mm	cancellous screw angle stable Ø4.2 /20mm	Ø 4,2 x 20mm	P 46646
2	57944222	cancellous screw angle stable Ø4.2 /22mm	cancellous screw angle stable Ø4.2 /22mm	Ø 4,2 x 22mm	P 46646
3	57944224	cancellous screw angle stable Ø4.2 /24mm	cancellous screw angle stable Ø4.2 /24mm	Ø 4,2 x 24mm	P 46646
4	57944226	cancellous screw angle stable Ø4.2 /26mm	cancellous screw angle stable Ø4.2 /26mm	Ø 4,2 x 26mm	P 46646
5	57944228	cancellous screw angle stable Ø4.2 /28mm	cancellous screw angle stable Ø4.2 /28mm	Ø 4,2 x 28mm	P 46646
6	57944230	cancellous screw angle stable Ø4.2 /30mm	cancellous screw angle stable Ø4.2 /30mm	Ø 4,2 x 30mm	P 46646
7	57944232	cancellous screw angle stable Ø4.2 /32mm	cancellous screw angle stable Ø4.2 /32mm	Ø 4,2 x 32mm	P 46646
8	57944234	cancellous screw angle stable Ø4.2 /34mm	cancellous screw angle stable Ø4.2 /34mm	Ø 4,2 x 34mm	P 46646
9	57944236	cancellous screw angle stable Ø4.2 /36mm	cancellous screw angle stable Ø4.2 /36mm	Ø 4,2 x 36mm	P 46646
10	57944238	cancellous screw angle stable Ø4.2 /38mm	cancellous screw angle stable Ø4.2 /38mm	Ø 4,2 x 38mm	P 46646
11	57944240	cancellous screw angle stable Ø4.2 /40mm	cancellous screw angle stable Ø4.2 /40mm	Ø 4,2 x 40mm	P 46646