

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

Către Agenția Medicamentului
și 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 și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție
pe piață a:

- 1. Instrumente medicale pentru proteze pentru articulații, model**
MUTARS®

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 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. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Instrumente medicale pentru proteze pentru articulații, model MUTARS®

Sunt autentice și corespund realității.

_____, **Director**
Numele, prenumele și funcția

Semnătura _____

Data _____

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



Manufacturer: implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s): **Instruments**

Intended Use: Reusable surgical instruments used for implantation an orthopaedic prosthesis.

REF Number(s): REF-Numbers see Attachment I - I

Classification: Class I
(Council Directive 93/42/EEC, Annex IX, rule 6)

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 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 16061	Instrumentation for use in association with non-active surgical implants - General requirements
EN ISO 17664	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
EN 62366	Medical devices – Application of usability engineering to medical devices

We declare under our sole responsibility that the medical devices listed in the attachment(s) are in conformity with the essential requirements of Annex I of Council Directive 93/42/EEC and have undergone the conformity assessment procedure according to Annex VII of Council Directive 93/42/EEC.

Identification:



Buxtehude, 25.09.2023
Place, date

i.V. Juliane Höppner
Head of Regulatory Affairs

REF	Name	GMDN
79996715	MUTARS® RS ES container 2	44742
79996716	MUTARS® RS ES container 3	44742
79996721	MUTARS® RS broach container	44742
79996722	MUTARS® RS broach container 150mm	44742
79996723	MUTARS® RS broach container 200mm	44742
79996724	MUTARS® RS trial stem container	44742
79996725	MUTARS® RS trial stem cemented container*	44742
79996726	MUTARS® RS trial stem 120mm cemented container*	44742
79996727	MUTARS® RS trial stem container 150mm + 200mm	44742
79996731	MUTARS® RS trial stem container 250mm	44742
79997000	flexible reamer nitinol container	44742
79609999	ic-bipolar head container	44742
.02201081	EcoFit® 2M container I	44742
.02201082	EcoFit® 2M container II	44742
79990060	ic-cerclage container	44742
79995712	MUTARS® basic container	44742
79997701	MUTARS® trial container	44742
79997744	MUTARS® prox. femur RS trial container	44742
79997745	MUTARS® Prox. Femur trial container	44742
7999-5723	MUTARS® GenuX® femur container	44742
7999-5722	MUTARS® Genux® femur container	44742
7999-5734	MUTARS® proximal tibia container	44742
7999-5735	MUTARS® rigid drills container	44742
79995150	MUTARS® distal humerus container	44742
79995151	MUTARS® distal humerus left container	44742
79995152	MUTARS® distal humerus right container	44742
79995200	MUTARS® humerus container	44742
79995201	MUTARS® humerus invers container	44742
79995202	MUTARS® humerus trial container	44742
79995203	MUTARS® distal humerus 30mm for M6 long fit container	44742
79995204	MUTARS® distal humerus 30mm container	44742
79995205	MUTARS® proximal ulna container	44742
79995208	MUTARS® distal humerus 30mm for M6 container	44742
79995210	MUTARS® humerus container 14-16mm	44742

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.

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
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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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 –

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ZLG-BS-237.10.15

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului), Modelul	Denumire comercială (brand)*	Cod GMDN*
1	79996715	MUTARS® RS ES container 2	MUTARS®	44742
2	79996716	MUTARS® RS ES container 3	MUTARS®	44742
3	79996721	MUTARS® RS broach container	MUTARS®	44742
4	79996722	MUTARS® RS broach container 150mm	MUTARS®	44742
5	79996723	MUTARS® RS broach container 200mm	MUTARS®	44742
6	79996724	MUTARS® RS trial stem container	MUTARS®	44742
7	79996725	MUTARS® RS trial stem cemented container	MUTARS®	44742
8	79996726	MUTARS® RS trial stem 120mm cemented container	MUTARS®	44742
9	79996727	MUTARS® RS trial stem container 150mm + 200mm	MUTARS®	44742
10	79996731	MUTARS® RS trial stem container 250mm	MUTARS®	44742
11	79997000	flexible reamer nitinol container		44742
12	79609999	ic-bipolar head container		44742
13	02201081	EcoFit® 2M container	EcoFit®	44742
14	02201082	EcoFit® 2M container I	EcoFit®	44742
15	79990060	ic-cerclage container		44742
16	79995712	MUTARS® basic container	MUTARS®	44742
17	79997701	MUTARS® trial container	MUTARS®	44742
18	79997744	MUTARS® prox. femur RS trial container	MUTARS®	44742
19	79997745	MUTARS® Prox. Femur trial container	MUTARS®	44742
20	7999-5723	MUTARS® GenuX® femur container	MUTARS®	44742
21	7999-5722	MUTARS® Genux® femur container	MUTARS®	44742
22	7999-5734	MUTARS® proximal tibia container	MUTARS®	44742
23	7999-5735	MUTARS® rigid drills container	MUTARS®	44742
24	79995150	MUTARS® distal humerus container	MUTARS®	44742
25	79995151	MUTARS® distal humerus left container	MUTARS®	44742
26	79995152	MUTARS® distal humerus right container	MUTARS®	44742
27	79995200	MUTARS® humerus container	MUTARS®	44742
28	79995201	MUTARS® humerus invers container	MUTARS®	44742
29	79995202	MUTARS® humerus trial container	MUTARS®	44742
30	79995203	MUTARS® distal humerus 30mm for M6 long fit container	MUTARS®	44742
31	79995204	MUTARS® distal humerus 30mm container	MUTARS®	44742
32	79995205	MUTARS® proximal ulna container	MUTARS®	44742
33	79995208	MUTARS® distal humerus 30mm for M6 container	MUTARS®	44742
34	79995210	MUTARS® humerus container 14-16mm	MUTARS®	44742