

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. 3 din 7 iunie 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 pentru medicina: intrumente pentru implantarea tijei
necimentate, model EcoFit easy lock Container**
2. **Instrumente pentru medicina: intrumente pentru implantarea cupei
necimentate, model EcoFit EPORE Container**

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:

1. **Instrumente pentru medicina: intrumente pentru implantarea tijei necimentate, model EcoFit easy lock Container**
2. **Instrumente pentru medicina: intrumente pentru implantarea cupei necimentate, model EcoFit EPORE Container**

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.

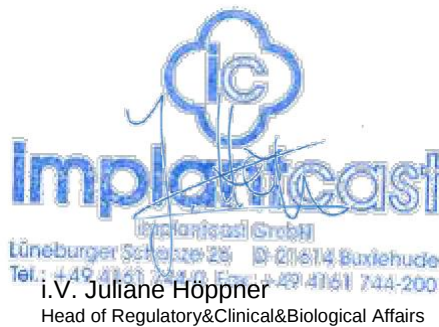
REF Number(s): REF-Numbers see Attachment I

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 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.

The implantcast logo is shown in blue ink, with a signature in blue ink over it. Below the logo, the following text is printed in blue ink:

implantcast GmbH
Lüneburger Schanze 25 D-21614 Buxtehude
Tel.: +49 4161 744-0 Fax: +49 4161 744-200

Buxtehude, 21.05.2021
Place, date

i.V. Juliane Höpner
Head of Regulatory&Clinical&Biological Affairs

EU Declaration of Conformity

Attachment I

Reference number	item description
7999-7043	EcoFit® easy lock Container
0220-0036	EcoFit EPORE Container

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



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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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

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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MEDCERT Identification Number: 0482



Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)		Denumire comercială (brand)*	Cod GMDN*
1	7999-7043	Instrumente pentru medicina: instrumente pentru implantarea tijei necimentate		EcoFit® easy lock Container	44758
2	0220-0036	Instrumente pentru medicina: instrumente pentru implantarea cupei necimentat		EcoFit EPORE Container	44758