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

Către Agenţia Medicamentului
şi 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,
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. **Instrumente pentru implantarea Protezelor pentru articulații de umar, model AGILON®**

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;

Digitally signed by Kojevnikov Dmitrii
Date: 2023.09.28 09:44:41 EEST
Reason: MoldSign Signature
Location: Moldova

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	

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:

Instrumente pentru implantarea Protezelor pentru articulatii de umar, model AGILON®

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

EU Declaration of Conformity

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

EU Declaration of Conformity

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:

CE

Buxtehude, 01.09.2023
Place, date

i.V. Juliane Höppner
Head of Regulatory Affairs

EU Declaration of Conformity

Attachment I

REF	Item description	GMDN
79993831	AGILON® basic container	44742
79993832	AGILON® drill container	
79993833	AGILON® trial stem container	
79993834	AGILON® omarthrosis container	
79993816	AGILON® retractor container	
79993819	AGILON® CTA trial cap container	
79993822	AGILON® retentive inverse trial cap container	
79993836	AGILON® glenoid cemented sz. 2-4 container	
79993837	AGILON® glenoid cementless sz. 2-4 container	
79993838	AGILON® glenoid cementless inverse sz. 2-4 container	

End of schedule. No additional information past this point.

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
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ZLG-BS-237.10.15

MED CERT®

Certification. Medical Only.

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

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
		Instrumente pentru medicina:			
1	79993831	AGILON® basic container		AGILON®	44742
2	79993832	AGILON® drill container		AGILON®	44742
3	79993833	AGILON® trial stem container		AGILON®	44742
4	79993834	AGILON® omarthrosis container		AGILON®	44742
5	79993816	AGILON® retractor container		AGILON®	44742
6	79993819	AGILON® CTA trial cap container		AGILON®	44742
7	79993822	AGILON® retentive inverse trial cap container		AGILON®	44742
8	79993836	AGILON® glenoid cemented sz. 2-4 container		AGILON®	44742
9	79993837	AGILON® glenoid cementless sz. 2-4 container		AGILON®	44742
10	79993838	AGILON® glenoid cementless inverse sz. 2-4 container		AGILON®	44742