

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. Ic-Lavage

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. Ic-cerclage

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





Certificate

No. Q5 107765 0001 Rev. 01

Holder of Certificate: **Guangzhou Clean Medical Products Manufacturing Corp.**
No.163 Meidu Road, Chengjiao
Conghua District
510900 Guangzhou, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Disposable Electronically Pulsed Lavage Suction Apparatus and Bone Cement Mixing System**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 107765 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_107765_0001_Rev.01)

Report No.: GZ2101502

Valid from: 2022-01-01

Valid until: 2024-12-31

Date, 2021-12-02

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



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Declaration of Conformity

To Council Directive 93/42/EEC Concerning Medical Devices

**Manufacturer:**

Name: Guangzhou Clean Medical Products Manufacturing Corp.
Address: No.163 Meidu Road, Chengjiao, Conghua District, Guangzhou, Guangdong, China.
Zip code: 510900
SRN: CN-MF-000008926

Medical Device:

Name: Disposable Electronically Pulsed Lavage Suction Apparatus
Model No.: W-203 **UMDNS code:** 12306
Basic UDI-DI (GS1, GMN) code: 69512337W203U1CH
Classification- Annex IX: Class IIa, Rule 11 **MD code:** MD1104_1, MDS7006_1
Conformity Assessment Route: Annex V

We, Guangzhou Clean Medical Products Manufacturing Corp., herewith declare that the stated
medical devices meet the transposition into national law,
the provisions of Council Directive
93/42/EEC concerning medical devices;
All supporting documentation is retained at the premises of the manufacturer.
The manufacturer is exclusively responsible for the Declaration of Conformity.

Standards applied:

EN 556-1:2001/AC:2006, EN ISO 10993-1:2009/AC:2010 (ISO 10993-1:2009/Cor 1:2010), EN ISO 10993-5:2009 (ISO 10993-5:2009), EN ISO 10993-7:2008/AC:2009 (ISO 10993-7:2008/ A1:2019), EN ISO 10993-10:2010 (ISO 10993-10:2010), EN ISO 11135:2014 (ISO 11135:2014), EN ISO 11138-1:2017 (ISO 11138-1:2017), EN ISO 11138-2:2017 (ISO 11138-2:2017), EN ISO 11607-1:2019 (ISO 11607-1:2019), EN ISO 11607-2:2019 (ISO 11607-2:2019), EN ISO 11737-1:2018 (ISO 11737-1:2018), EN ISO 11737-2:2020 (ISO 11737-2:2019), EN ISO 13485:2016 (ISO 13485:2016), EN ISO 14971:2019 (ISO 14971:2019), EN ISO 15223-1:2021 (ISO 15223-1:2021), EN ISO 20417:2021 (ISO 20417:2021), EN 15986:2011, EN 60601-1:2006 /AC:2010 /A1:2013 (IEC 60601-1:2005 /A1:2012), EN 60601-1-2:2015 (IEC 60601-1-2:2014), EN 62366-1:2015 (IEC 62366-1:2015)

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65 • 80339 Munich • Germany.

Identification Number: 0123
EC Certificate No.: G2 107765 0002, Rev.00

EC

REP

European Representative:

Name: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands.

Start of CE-marking: 2013-11-08

Place, Date of Declaration: Guangzhou, China., 2023-03-02

Signature:**Name:** Margin Yu (余裕富)**Position:** Management Representative

Declaration of Equivalence

Product	REF	GTIN
implantcast: ic-Lavage set with nozzles and splash shield	implantcast: 00678000 Clean: W-203-B(EC)	4048844211417 1 box = 10 piece
Clean: Disposable Pulse Lavage System	implantcast: 00678001 Clean: W-203-B(EC)	4048844211448 1 piece
implantcast: ic-Lavage femoral brush with suction	implantcast: 00678002 Clean: W-203-P3(EC)	4048844211424 1 box = 5 piece
Clean: Femoral Brush Nozzle	implantcast: 00678003 Clean: W-202-P3(EC)	4048844211431 1 piece