

Anexă
Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. din

Solicitantul **IM Vivamed International SRL**, cu sediul or. Chisinau, str. Mircea cel
Batrin, 16 (adresa)
tel./fax: 022926801, e-mail info@vivamed-int.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:

- Concentrator de oxigen 5 litri;

Se anexează următoarele acte:

CE, Autorizații

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 dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **IM Vivamed International SRL**, cu sediul în mun. Chisinau, Bd. Mircea cel Batrin, 16,

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:

Concentrator de oxigen, 5 litri;

Sunt autentice și corespund realității.

Numele, prenumele și funcția
Director Beregoi Valeriu

Semnătura _____



Data _____

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Concentrator de oxigen 5 litri	Zhengzhou Olive Electroni Technology Co.,Ltd	OX-5	



Director IM Vivamed International SRL
Beregoi Valeriu

REF N.183 /2023

Date 08/06/2023

MESSERS:

COMPANY: TO WHOM IT MAY CONCERN

ADDRESS:

CITY:

AREA CODE:

COUNTRY:..

FAX:

TEL.:

att: TO WHOM IT MAY CONCERN

Registration of Medical Devices

We FAZZINI SRL, who are official Manufacturers and Suppliers of MEDICAL EQUIPMENT, having premises at S.S. Padana Superiore 317 20055 Vimodrone (MI) Italy,

Assign IM VIVAMED INTERNATIONAL SL Rep. Of Moldova, Str Bogdan Voievod 7 MD-2068 Chisinau City as authorized representative in correspondence with the conditions of directive 93/42/EEC

We declare that the Company mentioned above is authorized to register, notify, renew or modify the registration of medical devices we supplied in the territory of Republic of Moldova

IM VIVAMED INTERNATIONAL SL is also authorized to promote, sell and distribute our Products (Medical Equipment) in the territory of Republic of Moldova, as well as quote them in Public Tenders.

IM VIVAMED INTERNATIONAL SL is also authorized to install, train, commission and maintain our product, as well as taking care of the After-Sale Service.

This Authorization is valid for 1 year period, with the possibility of mutual extension.

**BEST REGARDS
GIANLUCA MALETTI
GENERAL MANAGER**

**FAZZINI SRL
S.S. PADANA SUPERIORE 317
20055 VIMODRONE (MI)
TEL. 02/2651521 FAX. 02/26515221
VAT: IT11626520156**



Visit our New Internet Site: www.fazzini.it



Zhengzhou Olive Electronic Technology Co.Ltd.
Add: 5th Floor, Block D, Building 18, Henan International University
Science Park (East District), 450001 Zhengzhou, Henan, China
Web: www.zzolive.com E-mail: info@zzolive.com
Tel: 0086 371 8609 7307 Fax: 0086 371 6906 7368

LETTER OF AUTHORIZATION

Date: 30/06/2023

To whom it may concern

We, Zhengzhou Olive Electronic Technology Co., Ltd., with Registered Address: 5th Floor, Block D, Building 18, Henan International University Science Park (East District), 450001 Zhengzhou, Henan, China are established manufacturers of Oxygen Concentrator.

We hereby authorized FAZZINI SRL with Registered Address: S.S. Padana Superiore, 317 - 20055 - Vimodrone (MI) Italy as our authorized distributor to implement marketing, sales, after-sales service, maintenance and participate tenders for our products.

This appointment shall remain effective for 5 years from 30th June 2023 until 30th June 2028.

Name: Grace Zhang

In the capacity of: Sales Manager

Signed: Duly authorized to sign the Authorization for and on behalf of:
Zhengzhou Olive Electronic Technology Co.Ltd





Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 103099 0002 Rev. 00

Manufacturer:

**Zhengzhou Olive Electronic
Technology Co., Ltd.**

11th Floor, Block B, Building 18
Henan International University
Science Park (East District)
450001 Zhengzhou, Henan
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 München, GERMANY

Product
Category(ies):

Oxygen Concentrator

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

SH19144201

Valid from:

2019-04-25

Valid until:

2024-04-24

Date,

2019-04-25

Stefan Preiß



Declaration of Conformity

Manufacturer: Zhengzhou Olive Electronic Technology Co.,Ltd
11th floor, Block B, Building 18 , Henan International University Scie
(East District) 450001 ZhengZhou, Henan, P.R. China

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 München, GERMANY

Product Name: Oxygen Concentrator

Models:
OLV-3,OLV-3W,OLV-5,OLV-5W,OLV-5A,OLV-5AW,OLV-B1,OLV-C1,OLV-8,OLV-1

UMDNS Code: 12-873

Classification (MDD, Annex IX):IIb, rule 11
Conformity Assessment Route: Annex V.3

We herewith declare in sole responsibility that the above mentioned products meet transposition into national law, the provisions of the following EC Council Directives Standards. All supporting documentations are retained under the premises of manufacturer. We are exclusively responsible for the declaration of conformity

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339, München, Germany
Identification number: CE0123
(EC) Certificate(s): G2 103099 0002
Expire date of the Certificate: 2024-04-24
Start of CE Marking: 2019-04-25
Place of Issue: Zhengzhou, CHINA
Date of Issue: 2019-04-25

Signature:

Name:

Position:



EC Declaration of Conformity
OLIVE/CE-01 Ver.: B/0

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