

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. _____ din 07 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:**
- **Alezor (reamer), model RJ-PD**
 - **Motor oscilant, model RJ-PS**
 - **Lame pentru Motor oscilant, RJ-5050**

Se anexează următoarele acte:

- a) declarația de conformitate CE emisă de producător**;
b) certificatul de conformitate CE ;
c) actul prin care producătorul își desemnează 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,**

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:

- **Alezor (reamer), model RJ-PD**
- **Motor oscilant, model RJ-PS**
- **Lame pentru Motor oscilant, RJ-5050**

Sunt autentice și corespund realității.

Dmitrii Kojevnicov, Director
Numele, prenumele și funcția

Semnătura _____

Data _____

We, WUHU RUIJIN MEDICAL INSTRUMENT & DEVICE CO.,LTD,
(manufacturer)

based in 33 Wanchun Rd, Wuhu economic & technology development zone, Wuhu, Anhui, China,
(address)

assign **SRL "Oxivit-med"**, 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.

Place: WUHU, CHINA

Date: 2023-5-28

Signed: _____



Declaration of conformity

Manufacturer name: **Wuhu Ruijin Medical Instrument & Device Co., Ltd.**

Address: No.33, Wanchun Road, Economic and Technological Development Zone, Wuhu City, Anhui Province, P.R.China

European Representative name: **Shanghai International Holding Corp. GmbH (Europe)**

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Tel : 0049-40-2513175 Fax: 0049-40-255726

Dimdi No.:DE/0000040627 E-mail: shholding@hotmail.com

Product: **Medical electrical saw drill, saw blades**

Please refer to the appendix.

Classification (MDD, Annex IX): **IIa**

According to the ANNEX IX of MDD93/42/EEC, Rules 9,

Conformity Routes: MDD93/42/EEC Annex V (Production quality assurance)

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr.65, 80339, Munich, Germany.

NB identification number: 0123

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.

DIRECTIVES

Address/Tel/Fax: No.33, East Wanchun Road, Economic & Technological Development Zone, Wuhu City, Anhui Province, PEOPLE'S REPUBLIC OF CHINA

Tel: 86-553-2672510- Fax: 86-553-2672511

Website: **www.ruijinmedical.com**

General applicable directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC +amendment 2007/47/EC).

Standards:

All applicable harmonized Standards (see standards list in the CE technical file)

Certificate No.: G2 095446 0005 Rev.00

Valid from: 2020-01-08

Valid until: 2024-05-26

Date CE mark was affixed: CE0123

Place, date of issue: Wuhu, China

Signature: 

Name/Position: Yang shangbing / GM 2020-01-15



Appendix

No.	Model	Code:
1	RJ-MP	NM100
2		NM101
3		NM300
4		NM500
5	RJ-MP	EM100
6		EM300
7	RJ-MP	SM100
8		SM300
9	RJ-PD	ND-1001
10		ND-2011
11		ND-3011
12		ND-5001
13		ND-5002
14		ND-1501
15		ND-2511
16		ND-3511
17	RJ-PS	NS-1011
18		NS-3031
19		NS-3032
20		NS-2011
21		NS-4031

22		NS-1511
23		NS-3531
24		NS-3532
25	RJ-PS	ES-1011
26		ES-3031
27		ES-3032
28		ES-2011
29		ES-4031
30	RJ-PS	SS-1011
31		SS-3031
32		SS-3032
33		SS-2011
34		SS-4031
35	RJ-5050	RJ-5050



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 095446 0005 Rev. 00

Manufacturer:

**Wuhu Ruijin Medical Instrument & Device
Co., Ltd.**

No.33, Wanchun Road
Economic and Technological Development Zone
241000 Wuhu City, Anhui Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Wuhu Ruijin Medical Instrument & Device Co., Ltd.
No.33, Wanchun Road, Economic and Technological
Development Zone, 241000 Wuhu City, Anhui Province,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Medical Electric Saw Drill,
Medical Electric Drill,
Medical Electric Saw**

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.:

SH19104901

Valid from:

2020-01-08

Valid until:

2024-05-26

Date,

2020-01-08

Christoph Dicks
Head of Certification/Notified Body



Certificate

No. Q6 095446 0004 Rev. 01

Holder of Certificate: **Wuhu Ruijin Medical Instrument & Device Co., Ltd.**

No.33, Wanchun Road
Economic and Technological Development Zone
241000 Wuhu City, Anhui Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Wuhu Ruijin Medical Instrument & Device Co., Ltd.
No.33, Wanchun Road, Economic and Technological
Development Zone, 241000 Wuhu City, Anhui Province,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:



Scope of Certificate:

**Production and Distribution of
Medical Electric Saw Drill,
Medical Electric Drill, Medical Electric Saw,
Saw Blade, Drill Bit, Autoclavable Box, Flexible Reamer**

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), 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:Q6_095446_0004_Rev.01

Report No.: SH22104901

Valid from: 2022-11-08

Valid until: 2025-11-07

Date, 2022-10-24

Christoph Dicks
Head of Certification/Notified Body

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	ND-3511	Alezor (motor reamer)	RUIJIN	RJ-PD	44987
2	NS-1511	Motor oscilant	RUIJIN	RJ-PS	44987
3	RJ-5050	Lama pentru motor ocilant	RUIJIN	RJ-5050	44984