



**WUHU RUIJIN MEDICAL INSTRUMENT  
& DEVICE CO.,LTD**

Address/Tel/Fax: No.33, EastWanchun Road, Wuhu Economic  
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***Medical electric saw -oscillating  
saw RJ-PS (NS-1511)***

***For application in cutting bone during articular  
(knee & hip Joint) surgery.***

## » Feature

- 01 *Lighter than common NI-MH battery, allowing for optimal manoeuvrability and minimizing wrist fatigue.*
- 02 *Imported motor*
- 03 *Main components are made of high strength stainless steel.*
- 04 *Can be autoclavable up to 135°C*
- 05 *3000mAh lithium battery ensure high power and longer working time*



## Composition »

*One handpiece  
One charger  
Two batteries  
Two battery aseptic transfer rings  
Five saw blades  
One instruction manual  
One Aluminum case*

## >> Main Technical Data

Hand Piece	Output Power	150W
	Unit rise in temperature	≤25℃
Charger	Input Voltage	AC 110-220V , 50-60Hz
Battery	Voltage	14.4V
	Battery capacity	3000mAh
	Battery feature	Lithium battery
	Charging time	Two hours

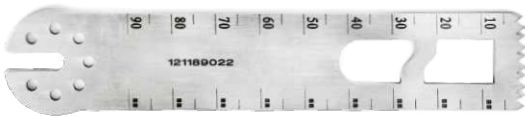
Non-loading frequency	0-18000cpm
Non-loading noise	≤75dB ( A )
Swing angle	4±0.5°

## >> Product details



## >> Accessories

Saw blades



Charger



Battery of 14. 4v



Aspetic battery transfer rings



Saw Blade :

Effective length : 90 mm

Length*Width ( mm )	Thickness ( mm )	Ruijin
90 X 24	0.8	
	1.0	118902410
	1.2	118902412
	1.27	
90 X 22	0.8	118902208
	1.0	118902210
	1.2	118902212
	1.27	1189022127
90 X 19	0.8	
	1.0	118901910
	1.2	118901912
	1.27	1189019127
90 X 13	0.8	118901308
	1.0	118901310
	1.2	118901312
	1.27	1189013127

Effective length : 70 mm

Length*Width ( mm )	Thickness ( mm )	Ruijin
70 X 24	0.8	
	1.0	98702410
	1.2	98702412
70 X 22	0.8	98702208
	1.0	
	1.2	
	1.27	987022127
70 X 13	1.0	98701310

Saw blades Effective length :  
special dimension

50*13	0.8	78501308
45*32	1.2	73453212
30*10	0.5	58301005
28*58	1.0	54285810
65*27		

Sterilization case is additional cost.



Aluminum case packing

Basic steps of sterilization, cleaning and maintenance of power tools.

1.Disaccessibly: All the consumable parts (saw blades, drill bits, etc) and battery should be removed before cleaning.

2.Cleaning: Please wash and rinse with flowing water. Note: use soft brush to clean, then wipe with soft dry cloth. All instruments are prohibited from soak cleaning.

3.Maintenance: Maintain by medical lubricant every time when cleaning and wiping instruments. Apply lubricant on every mobilizable part.

Note: Applying lubricant and rotate parts to lubricate to the full.

4.Assembly: Assembly and functional test. Note: After cleaning and applying lubricants, install all parts one by one and conduct function test and then check its intactness.

5.Sterilization: Forevacuum high temperature for 132 centigrade and high pressure within 20 minutes; natural cooling time is more than 40 minutes. Expoxymethane and formaldehyde are prohibited. Instruments must be kept dry before sterilization





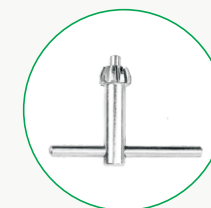
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***Medical electric drill -  
canulate drill RJ-PD (ND-2511) :***

***Holds K-wires or be used in  
intramedullary interlocking nail surgery  
or arthroscopic surgery.***

## » Feature

01 Variable speed, convenient for use

02 Imported motor

03 High coaxiality, low noise

04 Can be autoclavable up to 135°C



## Composition »

One handpiece  
One charger  
Two batteries  
Two battery aseptic transfer rings  
One drill chuck key  
One instruction manual  
One Aluminum case

» Main Technical Data

Hand Piece	Output Power	150W
	Unit rise in temperature	≤25℃
Charger	Input Voltage	AC 110-220V , 50-60Hz
Battery	Voltage	14.4V
	Battery capacity	3000mAh
	Battery feature	Lithium battery
	Charging time	Two hours
Non-loading speed	0-680/0-1000rpm	
Non-loading noise	≤65dB ( A )	
Axial run out	≤0.15mm	
Rated torque	5.5N.m/4N.m	
Impulsive torque	10.5N.m/8.5N.m	
Drill chuck clamping range	0.8-7.9mm	
Canulated diameter	≤4.2mm	

» Product details



» Accessories

Drill chuck & Key



Charger



Battery of 14. 4v

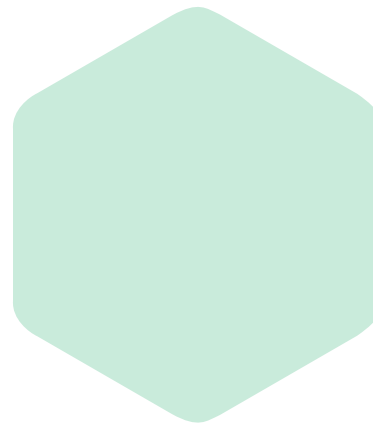


Aspetic battery transfer rings

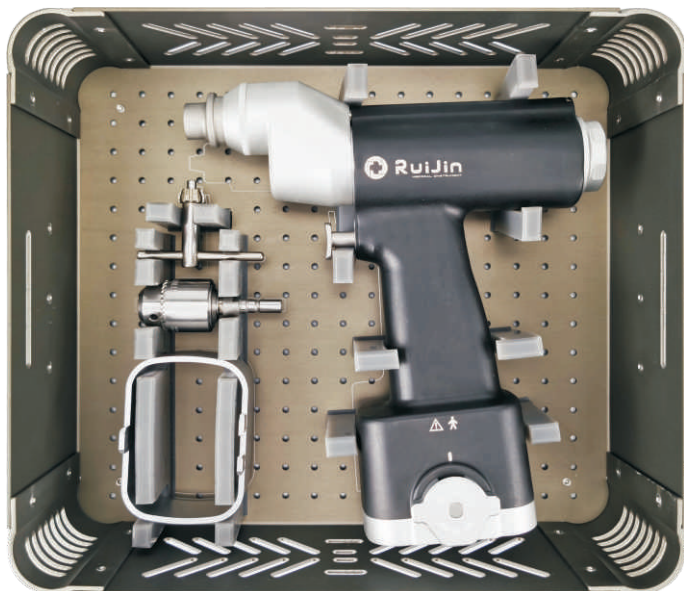




*Aluminum case packing*



*Sterilization case is additional cost.*



*Can connect various flexible reamer,  
k wire adapter and acetabular reamer,  
changable during the process of surgery.*

*Basic steps of sterilization, cleaning and  
maintenance of power tools.*

*1.Disaccessibly: All the consumable parts (saw blades, drill bits, etc) and battery should be  
removed before cleaning.*

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wipe with soft dry cloth. All instruments are prohibited from soak cleaning.*

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Apply lubricant on every mobilizable part.*

*Note: Applying lubricant and rotate parts to lubricate to the full.*

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install all parts one by one and conduct function test and then check its intactness.*

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minutes; natural cooling time is more than 40 minutes. Expoxymethane and formaldehyde are  
prohibited. Instruments must be kept dry before sterilization*



Revised date: Feb, 2022

Version/Times: B/3

# MEDICAL ELECTRIC SAW DRILL

## Operating Manual **N Series**

RJ-010001-Rev:03

Please read this manual carefully before  
use and keep it properly

# FOREWORD

## Dear user

Thank you for using this product! This manual contains important contents that must be understood for safe and proper use of the product.

The instruction manual is a part of the product. Therefore, this manual should be placed in a proper position for easy reference at any time for the whole lifetime. The product must be operated by trained personnel with relevant knowledge and experience. All personnel must read this instruction carefully before using this product.

This manual shall be transmitted to subsequent owners or users of the product. Any duplication, photogrammetry, digital post-processing or duplication is prohibited without consent of Wuhu Ruijin Medical Instrument & Device Co., Ltd.

This product is safe and reliable to use, except for the risk arising from special factors like operated by non-professionals or used for other purposes, etc. Therefore, please follow strictly the following rules to avoid accidental use. The product must be operated by professionals.

Product maintenance must be carried out by professional technicians or skilled users of Wuhu Ruijin Medical Instrument & Device Co., Ltd and the authorized person.

If there are any operation problems not mentioned, please contact Wuhu Ruijin Medical Instrument & Device Co., Ltd.

Instructions are subject to change without prior notice. Please put the manual in a proper position for reference.

## Product introduction

Product information	01	Installation and dis-assembly	07
Corporate information	01	Operating instructions	12
Main performance parameters	01		
The structural composition	02		
The scope of application	05		
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## Instructions

## Maintenance and cleaning

## Service Guide

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# Product introduction

## I. Product information

Product Name: Medical Electric Saw Drill

Product Model No.: RJ-MP RJ-PD RJ-PS

Product technical requirement No.: W.X.Z.Z No.: 20162040284

## II. Corporate information

Registrant/manufacturer name: Wuhu Ruijin Medical Instrument & Device Co., Ltd.

Registrant's Residence/ Production Address: 33rd, East Wanchun Road, Wuhu Economic and Technological Development Zone, Wuhu, Anhui Province, P.R.C.

After-sales service unit: Wuhu Ruijin Medical Instrument & Device Co., Ltd

TEL: 0553-2673688 FAX: 0553-2672513 Zip Code: 241000

Production License: W.X.Z.Z.XU NO.: 20160013

Medical Device Registration Certificate: W.X.Z.Z. No.: 20162040284

## III. Main performance parameters

Sequence	Model No.:	Performance parameters
1	RJ-MP	Main performance parameters: Non-loading rotation speed or frequency of electric saw and drill: i. Drill rotating speed 120rpm ii. Saw frequency: ≥6000 times/min iii. Output power: ≥50W
2	RJ-MP	iv. Temperature rise: the temperature rise of the shell is no more than 50°C after 5min of non-loading operation; v. Non-loading noise: drill saw non-loading noise ≤75dB(A);
3	RJ-PS	vi. Electric saw & drill saw blades shall be heat treated and its hardness shall be no less than 30 HRC.

## IV.The structural composition

This product is mainly composed of handpiece, drill components, saw components, accessories, battery and charger.

### i.RJ—MP

#### (i).NM-100/NM-101

##### Note

All instructions in this manual are for the purpose of explanation only. If the appearance and function are inconsistent with the real object, the real object shall prevail.



#### (ii).NM-300



#### (iii).NM-500



## ii.RJ—PD

### Note

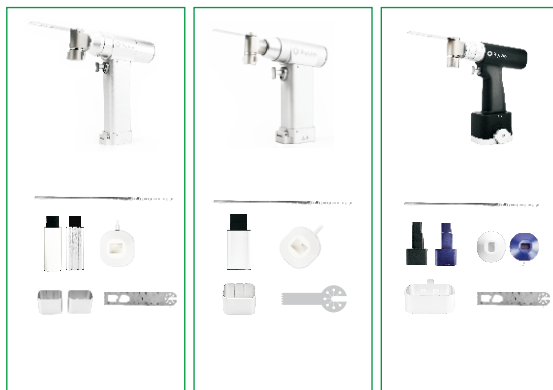
All instructions in this manual are for the purpose of explanation only. If the appearance and function are inconsistent with the real object, the real object shall prevail.



## iii.RJ—PS

### Note

All instructions in this manual are for the purpose of explanation only. If the appearance and function are inconsistent with the real object, the real object shall prevail.



## V.The scope of application

Applied in bone drilling and cutting in orthopedic surgeries for medical organization.



## VI. Contraindications, precautions, warnings and explanatory notes

### i. Contraindications

NO

### ii. Precautions

(i) Check whether the radial run-out of the bit is intact before use. The bit with large radial run-out cannot be used. Check the sharpness of the drill bit. The drill body should be fixed during drilling without loosening according to conventional surgical methods.

(ii) The drill bit must be firmly fixed well with drill chuck key to avoid accidents. Products and accessories should be placed in a dry place to prevent corrosion after use.

(iii) The battery shall not be disinfected by high temperature, high pressure or stay in the machine for a long time, take out battery after the operation. If power is cut off during the operation (the handpiece does not work), the backup battery should be replaced immediately.

(iv) If there is abnormal sound when using, stop using it immediately. Please contact with the manufacturer or distributor immediately and return the machine to the manufacturer for repairing.

(v) Charge the battery immediately after use. If the battery is not used, charge it every three months to prevent battery loss.

### iii. Warning and suggestive notes

The medical electric drill saw is classified according to the protection of electronic equipment from shock and vibration. The motor belongs to B-type equipment of internal power supply, and the charger belongs to class II B-type ordinary equipment; The equipment shall not be used with a mixture of flammable anesthetic gas or carbon oxide; Sterilization must be carried out before use.

Supplementary external mark:  Working schedule: Short time operation  
Each startup time shall not exceed 5min.

Marking pattern description:  B-type equipment

Rotation mark: **F**: Forward **R**: Reverse **S**: Stop  Operation

Battery cover marking:  Unlock  Lock

Recycling marks for electronic products at the end of their life: 

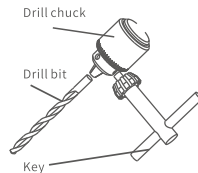
# Instructions

## VII. Installation and dis-assembly

This product is professional medical device, the installation and dis-assembly must be performed by medical personnel with appropriate technology or with appropriate professional training.

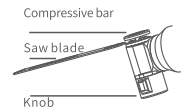
### i. Installation and dis-assembly of drill bits

- (i). Loosen the chuck by turning counterclockwise with the drill chuck key;
- (ii). Insert the prepared bit into the three-jaw hole
- (iii). Turn the drill chuck key clockwise and tighten it vigorously.
- (vi). Conversely, the drill bit can be removed



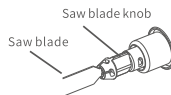
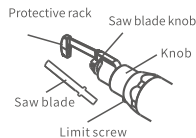
### ii. Installation and removal of oscillating saw blade

- (i). Turn the knob counterclockwise to lift the pressure bar;
- (ii). Insert the blade into the interface along the guide direction. Align the seven holes of the blade with the seven lugs of the product. Press down gently to make the lugs pass through the saw blades holes.
- (iii). Turn the knob clockwise and pull down the pressure bar Locking saw blade;
- (vi). Conversely, the saw blade can be removed.



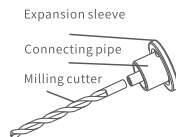
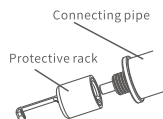
### iii. Installation and removal of sternal saw/reciprocating saw blade

- (i). Hold the knob with one hand, apply force to the limit screw, and rotate the knob;
- (ii). Pull the protective rack with the other hand, and the protective rack can be removed;
- (iii). Rotate the saw blade knob;
- (iv). Aim the saw blade at the installation slot, loosen the saw blade knob, and then saw blades is installed well.
- (v). Repeat the operation with serial number 1, insert the protection frame into the slot;
- (vi). Release the knob, the protection frame is fixed, and the installation is completed;
- (vii). Conversely, the saw blade can be removed.



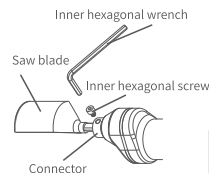
### iv. Installation and removal of cranial milling cutter

- (i). Rotate the protective frame clockwise to lower the protective frame;
- (ii). Pull back the expansion sleeve;
- (iii). Insert the milling cutter into the jack and loosen the expansion sleeve to make the milling cutter stuck in the card slot;
- (iv). Tighten the protection rack counterclockwise and the installation is completed;
- (v). Conversely, the cranial milling cutter can be removed.



### v. Installation and removal of TPLO saw blade

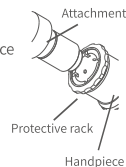
- (i). Loosen the inner hexagon screw with the hexagon wrench;
- (ii). Insert the triangular flat position of the saw blade into the triangular hole of the interface of the handpiece;
- (iii). Tighten the hexagon screw with the hexagon wrench and complete the installation;
- (iv). Detachable on the contrary.



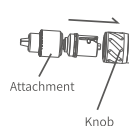
### vi. Installation and removal of drill saw adapters.

- (i). Press down the expansion sleeve on the handpiece;
- (ii). Align the assembly installation position with the handpiece interface, and pay attention to the phase position;
- (iii). After insertion, loosen the expansion sleeve, jam the drill or saw adapter and complete installation;
- (iv). Converse to detach components.

Type A






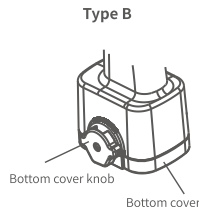
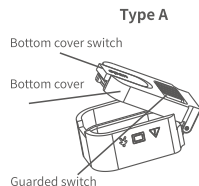
Type B





- (i). Align the assembly installation position with the handpiece, and pay attention to the phase position;
- (ii). Turn the knob on the handpiece;
- (iii). Release the knob after insertion, jam the drill or saw adapter and complete installation;
- (iv). Converse to detach components.

## vii. Opening and closing of the bottom cover

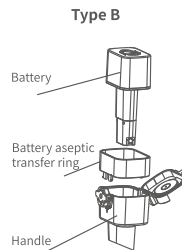
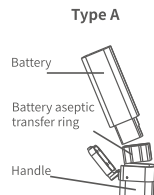
- (i). Push the guided switch to  when opening the bottom cover;
- (ii). Push and press the bottom cover switch to  open the bottom cover;
- (iii). Push the safety switch to  when closing the bottom cover;
- (iv). Press the bottom cover to the handle cover and hear the "click" sound;



- (i). When opening the bottom cover, select the knob to the position  to open the bottom cover;
- (ii). When closing the bottom cover, close the bottom cover and turn the knob to the position .

## viii. Battery installation

- (i). The battery should not be in direct contact with the handpiece to prevent pollution;
- (ii). To install the battery, first install the battery aseptic transfer ring on the handle, install the battery into the battery bin through the battery aseptic transfer ring, press into position, close the bottom cover, and move the dial block to lock the bottom cover.



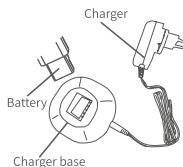
- (i). The battery should not be in direct contact with the handpiece to prevent pollution;
- (ii). To install the battery, first install the battery aseptic transfer ring on the handle, install the battery into the battery bin through the battery aseptic transfer ring, press into position, close the bottom cover, and move the dial block to lock the bottom cover.

## VIII. Operating instructions

This product must be disinfected before use and tested before use after disinfection. The method is: insert the corresponding battery for the handpiece, press the trigger gently, the motor shall rotate, switch forward and reverse, the motor work, or else, the handpiece has a problem, then please stop using immediately, contact the manufacturer or distributor to send product back to the manufacturer for maintenance.

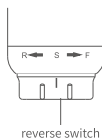
### i. Battery charging

- Plug the charger into the power supply, and the blue green light flashes alternately to indicate that the self-test is qualified and the charger enters the standby state;
- Insert the battery into the charger base. The blue light is always on to indicate charging, the green light indicates full, and the blue light flashes to indicate an error.



### ii. Forward and reverse operation

- When you need forward rotation, please adjust the knob mark to the corresponding F mark.
- When you need reverse rotation, please adjust the knob mark to the corresponding R mark.
- Turn the mark to position S to show stop.



### iii. Trigger operation

The adjustment of the speed is linear and depends on the extent of pressing the trigger. When turning on the trigger for the first time, you should lightly touch the trigger until it starts, and then press it slowly until it reaches the maximum speed. Quick release of trigger triggers the emergency stop function. This



## IX. Maintenance

This product is maintenance-free. It contains no parts that require maintenance by the user or manufacturer. However, the manufacturer recommends that the function and safety of the product be checked regularly by a professional or hospital technician. It must be checked once before each operation, and be recorded, analyzed and evaluated in time to ensure that the product is in good condition and guarantee the use quality.

## X. Cleaning and sterilization

A. Cleaning: the protection of cleaning after use is same as sterilization, and the handpiece can be wiped clean with gauze soaked in water or alcohol and then store.

B. Disinfection: Product can be used only when passing inspection after disinfection and sterilization according to the hospital standards.

**Note: Do not soak any part of the medical electric saw drill in liquid.**

## Recommended handpiece disinfection method

Disinfection method	Operating conditions and environment	Scope of application	Limitation
Moist heat sterilization	Sterilization conditions are generally are: 121°C*15min, 121°C*30min or 116°C*40min	High temperature and humid product sterilization	1. High temperature 2. High humidity 3. It is easy to breed bacteria again when the product is wet

## Commitment

i: This instrument has no parts that can be disassembled and repaired by non-professionals. If it fails, please contact the company's after-sales service department.

ii: If you need technical information about this medical electric drill, please write to us.



# Service Guide

## XI.Transport and storage conditions

### ⚠ Attention

Parameters in this table are for reference only. In case of any conflict between this table and the information on the nameplate of the machine, the nameplate prevails.

Transport and storage conditions	Ambient temperature range	-10°C~+40°C
	Relatively moderate range	≤90%
	Atmospheric pressure range	500hPa~1060hPa
Equipment operating conditions	Ambient temperature range	5°C~40°C
	Relatively moderate range	≤70%
	Atmospheric pressure range	860hPa~1060hPa
	Charger power	100-240V±10%;50/60Hz±1Hz
	Main power supply (DC)	14.8V±10%

Note: According to YY0904-2013 battery-powered bone tissue surgery equipment

Production date: Refer to product certificate  
Service life: two years short-time running 1000 times

## XII.Accessories list

Prepare standard configuration and accessories according to product model number and product customer need, such as saw blade, drill bits, battery aseptic transfer ring, drill chuck keys, etc.

Parts List				
No.	Name	Model No.	Quantity	Note
1	Handpiece	XXXX	1pcs	According to customer needs
2	Battery	XXXX	2pcs	According to the handpiece model
3	Charger	XXXX	1pcs	According to the handpiece model
4	Charger base		1pcs	According to the handpiece model
5	Manual		1pcs	
6	Certificate of conformity		1pcs	
7	Three certificates		1pcs	

## XIII.Electromagnetic compatibility

### ⚠ Attention

Parameters in this table are for reference only. In case of any conflict between this table and the information on the nameplate of the machine, the nameplate prevails.

### Guidance and manufacturer's declaration – electromagnetic emission

The RJ-MP(RJ-PS;RJ-PD) is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions GB4842	Group 1	The RJ-MP(RJ-PS;RJ-PD) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions GB4842	Class A	The RJ-MP(RJ-PS;RJ-PD) is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions GB17625.1	Not applicable	
Voltage fluctuations flicker emissions GB17625.1	Not applicable	

### Guidance and manufacturer's declaration – electromagnetic immunity

The RJ-MP(RJ-PS;RJ-PD) is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge GB/T 17626.2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst GB/T 17626.4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	± 1 kV wire to wire	± 1 kV wire to wire	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines GB/T 17626.11	0 % UT; 0.5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RJ-MP(RJ-PS;RJ-PD) requires continued operation during power mains interruptions, it is recommended that the RJ-MP(RJ-PS;RJ-PD) be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

### ⚠ Attention

Parameters in this table are for reference only. In case of any conflict between this table and the information on the nameplate of the machine, the nameplate prevails.

### Guidance and manufacturer's declaration – electromagnetic immunity

The RJ-MP(RJ-PS;RJ-PD) is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF GB/T 17626.6	3 V(Effective value) 150 kHz to 80 MHz	3 V (Effective value)	Portable and mobile radio frequency communication equipment should not be used in any part of RJ-MP (RJ-PS, RJ-PD), including cables, than the recommended isolation distance. The distance should be calculated by the formula corresponding to the transmitter frequency.  Recommended isolation distance $d=1.2$ $d=1.2 \sqrt{P}$ 800MHz~800MHz $d=2.3 \sqrt{P}$ 800MHz~2.5GHz Where: $P$ ---According to the maximum output power of the transmitter provided by the transmitter manufacturer, in watts (w); $d$ ---Recommended isolation distance, in meters (m)  The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field a, and in each frequency range b should be lower than the compliance level. Interference may occur near equipment marked with symbols as beside. 
Radiated RF GB/T 17626.3	3 V(Effective value) 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

b Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RJ-MP(RJ-PS;RJ-PD) is used exceeds the applicable RF compliance level above, the RJ-MP (RJ-PS;RJ-PD) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RJ-MP(RJ-PS;RJ-PD).


c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

### ⚠ Attention

Parameters in this table are for reference only. In case of any conflict between this table and the information on the nameplate of the machine, the nameplate prevails.

### Recommended isolation distance between portable and mobile video communication equipment and RJ-MP (RJ-PS, RJ-PD)

RJ-MP (RJ-PS, RJ-PD) is expected to be used in an electromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum rated output power of communication equipment, the purchaser or user can prevent electro magnetic waves by maintaining the minimum distance between portable and mobile radio frequency communication equipment (transmitter) and RJ-MP (RJ-PS, RJ-PD) as recommended below interference.

Interference test	IEC60601 test level	Coincidence level	Electromagnetic
Maximum rated output power of the transmitter	Corresponding to the isolation distance of the transmitter at different frequencies/m		
	150kHz~80MHz $d=1, 2$	80MHz~800MHz $d=1. 2$	800MHz~2.5GHz $d=2.3$
0. 01	0. 12	0. 12	0. 23
0. 1	0. 38	0. 38	0. 73
1	1. 2	1. 2	2. 3
10	3. 8	3. 8	7. 3 
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance  $d$ , in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where  $P$  is the emission provided by the transmitter manufacturer The maximum rated output power of the machine, in watts (w).

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and from structures, objects and people.



Product Service

# Certificate

No. Q6 095446 0004 Rev. 00

**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

**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). See also notes overleaf.

**Report No.:** SH19104904

**Valid from:** 2019-11-12

**Valid until:** 2022-11-07

**Date,** 2019-11-12

Christoph Dicks  
Head of Certification/Notified Body



# 认证证书

证书号. Q6 095446 0004 Rev. 01

证书持有者：

芜湖锐进医疗设备有限公司

中华人民共和国安徽芜湖市芜湖经济技术开发区万春路33号  
241000

生产场地：

芜湖锐进医疗设备有限公司

中华人民共和国安徽芜湖市芜湖经济技术开发区万春路33号  
241000

认证标志：

见证书认证范围



认证范围：

生产和分销：医用电动锯钻、医用电动钻、  
医用电动锯、锯片、钻头、高压灭菌盒、软杆铰刀

认证标准：

EN ISO 13485:2016

医疗器械 - 质量管理体系 - 用于法规的要求  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系  
(删除第7.3条款)。TÜV 南德集团检测及认证规则所有适用要求也须得到遵守。详情及证书有效期请见

[www.tuvsud.com/ps-cert?q=cert:Q6 095446 0004 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q6_095446_0004_Rev_01)

报告号：

SH22104901

生效期：

2022-11-08

有效期：

2025-11-07

发证日期, 2022-10-24

Christoph Dicks

Head of Certification/Notified Body





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 16 06 95446 002

**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

**EC-Representative:**

**Wellkang Ltd**

Suite B, 29 Harley Street  
LONDON  
W1G 9QR  
UNITED KINGDOM

**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.:**

SH16104901

**Valid from:**

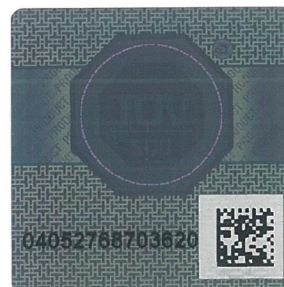
2016-11-08

**Valid until:**

2021-11-07

Date, 2016-11-08

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



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 16 06 95446 002****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

## **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**

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**

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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](http://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 shangping / 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