

Anexa 10 Fereastră electric chirurgical pentru amputații, reutilizabil

NS-1011, Wuhu Ruijin Medical Instruments & Device, China

Parametri solicitati	Parametri oferiti
Specificații 3 Destinație Aparatul destinat pentru tăiere țesuturilor osoase tubulare de diferite dimensiuni. Utilizat în intervențiile de amputație. 4 Specificație tehnica Dipozitivul de lucru (Fereastrăul) Votajul de lucru aproximativ 14,4 V. Putere de ieșire +/- 90 W Creterea temperaturii aparatului în timpul lucrului +/- 20 OC Viteza de lucru- 0-20 000 osc/min. Zgomot- ≤ 70 db. Dispozitiv de încărcare a bateriilor AC 220-240 V, 50HZ-60Hz Baterii Rezerva bateriei- 2 ore. Material, rezistent la dezinfectanți și la sterilizare, 135 OC 5 Dotatare Baterii de rezerva 2 piese Încarcator baterii 1 piese Lame de fereastră 2 piese	Specificații Destinație Aparatul destinat pentru tăiere țesuturilor osoase tubulare de diferite dimensiuni. Utilizat în intervențiile de amputație. Specificație tehnica Dipozitivul de lucru (Fereastrăul) Votajul de lucru aproximativ 14,4 V. Putere de ieșire = 130 W Creterea temperaturii aparatului în timpul lucrului ≤25°C Viteza de lucru- 0-18 000 osc/min. Zgomot- ≤ 75 db. Dispozitiv de încărcare a bateriilor AC 110-240 V, 50HZ-60Hz Baterii Rezerva bateriei- 2 ore. Material, rezistent la dezinfectanți și la sterilizare, 135°C Dotatare: Baterii de rezerva - 2 piese Încarcator baterii - 1 piese Lame de fereastră - 2 piese



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

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***Medical electric saw -oscillating
saw RJ-PS (NS-1011)***

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

» Feature

- 01 *Lightweight design, 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*



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	130W
	Unit rise in temperature	≤25℃
Charger	Input Voltage	AC 110-220V , 50-60Hz
Battery	Voltage	14.4V
	Battery capacity	1800mAh
	Battery feature	Environmental friendly nickel-metal hydrogen 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: Forevacum 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



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



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):

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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